

QAS Terminology db - List of Terms and related guidelines

<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Abuse of scheme		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See sections 4.9 and 5.2 of the guidelines.
Accelerated stability testing		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	Studies designed to increase the rate of chemical degradation and physical change of a drug by using exaggerated storage conditions as part of the formal stability testing programme. The data thus obtained, in addition to those derived from real-time stability studies, may be used to assess longer-term chemical effects under non-accelerated conditions and to evaluate the impact of short-term excursions outside the label storage conditions, as might occur during shipping. The results of accelerated testing studies are not always predictive of physical changes.
Acceptance criteria		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Measurable terms under which a test result will be considered acceptable.
Accountability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The obligation to account for one's conduct and actions, usually to an individual or group, but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and transparency (see below).
Action limit		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The action limit is reached when the acceptance criteria of a critical parameter have been exceeded. Results outside these limits will require specified action and investigation
Active ingredients (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See sections 1.5, 4.4 and 4.5 of the guidelines.
Active ingredients (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	The herbal material(s) or the herbal preparation(s) will be considered to be active ingredient(s) of a herbal medicine(s). However, if constituents with known therapeutic activities are known, the active ingredients should be standardized to contain a defined amount of this/ these constituent(s). (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Active moiety		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	The term used for the therapeutically active entity in the final formulation of therapeutic goods, irrespective of the form of the API. The active is alternative terminology with the same meaning. For example, if the API is propranolol hydrochloride, the active moiety (the active) is propranolol.
Active pharmaceutical ingredient (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).
Active pharmaceutical ingredient (API) (2)	Fall	
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Active pharmaceutical ingredient (API) (3)		
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used in the production of a drug, becomes an active ingredient of that drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Active pharmaceutical ingredient (API) (4)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form. When so used the API becomes the active moiety as defined below, often termed simply the active. The API may be a salt, hydrate or other form of the active moiety, or may be the active moiety itself. Active moieties are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Active pharmaceutical ingredient (API) (5)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A substance or compound intended to be used in the manufacture of a pharmaceutical product as therapeutically active compound (ingredient).
Addresses of competent authorities		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	See sections 2.2 and 3.3 of the guidelines.
Adverse event		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Any untoward medical occurrence in a clinical trial subject administered a pharmaceutical product; it does not necessarily have a causal relationship with the treatment.
Affordability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The extent to which pharmaceutical products are available to the people who need them at a price they can pay.
Agreement (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Arrangement undertaken by and legally binding on parties.
Agreement (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Arrangement undertaken by and legally binding on parties.

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Air-handling unit (AHU)	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	The air-handling unit serves to condition the air and provide the required air movement within a facility.
Airlock (1)	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g., of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for and used by either people or goods.
Airlock (2)	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.
Airlock (3)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for and used by either people or goods (PAL, personnel airlock; MAL, material airlock)
Alert limit	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The alert limit is reached when the normal operating range of a critical parameter has been exceeded, indicating that corrective measures may need to be taken to prevent the action limit being reached.
Ampoule	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container sealed by fusion and to be opened exclusively by breaking. The contents are intended for use on one occasion only.
Analytical worksheet	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A printed form for recording information about the sample, test procedure and results of testing (see Part Three, section 15).
Applicant (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The party applying for a Product Certificate. This is normally the product-licence holder. Because certain data are confidential for commercial reasons, the competent authority in the exporting country must always obtain permission to release these data from the product-licence holder or, in the absence of a product licence, from the manufacturer.

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Applicant (2)	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	The party applying for a certificate for a pharmaceutical starting material.
Applicant (3)	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	The person or company who submits an application for marketing authorization of a new pharmaceutical product, an update to an existing marketing authorization or a variation to an existing market authorization.
Application	Guidelines on pre-approval inspections. (36th report, 2002)	A marketing authorization for a new drug application.
As-built	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
At-rest	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
Audit or trial	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A systematic examination, carried out independently of those directly involved in the trial, to determine whether the conduct of a trial complies with the agreed protocol and whether the data reported are consistent with the records on site, e.g. whether data reported or recorded in the case-report forms (CRFs) are consonant with those found in hospital files and other original records.
Auditing	Good distribution practices for pharmaceutical products. (40th report, 2006)	An independent and objective activity designed to add value and improve an organization's operations by helping an organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Authentication of certificates	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 4.9 of the guidelines.

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Authorized person (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A person responsible for the release of batches of finished product for sale. In certain countries the batch documentation of a batch of finished product must be signed by an authorized person from the production department and the batch test results by an authorized person from the quality control department for batch release.
Authorized person (2)		
	Quality systems requirements for national good manufacturing practice inspectorates. (36th report, 2002)	A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale. (Good manufacturing practices: authorized person — role, functions and training. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report. Geneva, World Health Organization, 1999, Annex 4 (WHO Technical Report Series, No. 885)).
Authorized person (3)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.
Authorized person (4)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A person (among key personnel of a manufacturing establishment) responsible for the release of batches of finished products for sale. In some good manufacturing practice (GMP) guides and legal texts, the term qualified person is used to describe analogous functions.
Available sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Whatever total quantity of sample materials is available.
Bag		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container consisting of surfaces, whether or not with a flat bottom, made of flexible material, closed at the bottom and at the sides by sealing; the top may be closed by fusion of the material, depending on the intended use.
Batch (1)		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	A defined quantity of product processed in a single process or series of processes and therefore expected to be homogeneous. In continuous manufacture, the batch must correspond to a defined fraction of production, characterized by its intended homogeneity.
Batch (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	A defined quantity of any drug processed in a single process or series of processes such that it is reasonably expected to be uniform in character and quality.

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Batch (3)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	A defined quantity of any drug product processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality.
Batch (4)		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	A quantity of any drug produced during a given cycle of manufacture. If the manufacturing process is continuous, the batch originates in a defined period of time during which the manufacturing conditions are stable and have not been modified.
Batch (9)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous. (adapted from GMP)
Batch (or lot) (5)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch.
Batch (or lot) (6)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A defined quantity of a starting material, packaging material, or product processed in a single process or series of processes so that it can be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. (Reference to (should conform with) "Good manufacturing practices for pharmaceutical products")

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Batch (or lot) (7)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Batch (or lot) (8)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced during a fixed time interval.
Batch certificate (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A document containing information, as set out in Appendix 3 of the guidelines, will normally be issued for each batch by the manufacturer. Furthermore, a batch certificate may exceptionally be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate accompanies every major consignment (see also section 3.14 of the guidelines).
Batch certificate (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	A document containing information, as set out in Appendix 3 of the Guidelines for Use of the WHO Certification Scheme (Guidelines on the WHO certification scheme on the quality of pharmaceutical products moving in international commerce. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-fourth report. Geneva, World Health Organization, 1996, Annex 10 (WHO Technical Report Series No. 863)), will normally be issued for each batch by the manufacturer. Furthermore, a batch certificate may be exceptionally validated or issued by the competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate accompanies every major consignment.
Batch number (4)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.

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Batch number (or lot number) (1)

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.
Guidelines for inspection of drug distribution channels. (35th report, 1999)	A distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, etc.

Batch number (or lot number) (2)

Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
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Batch number (or lot number) (3)

Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, the batch records, the certificates of analysis, etc.
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Batch numbering system

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Standard operating procedure describing the details of the batch numbering.
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Batch records

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.
Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

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Definition

Bioavailability (1)

Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)

The rate and extent of availability of an active drug ingredient from a dosage form as determined by its concentration-time curve in the systemic circulation or by its excretion in urine.

Bioavailability (2)

A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)

The rate and extent at which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action.

Bioavailability (3)

Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)

The rate and extent to which the active moiety is absorbed from a pharmaceutical dosage form and becomes available at the site(s) of action. Reliable measurements of drug concentrations at the site(s) of action are usually not possible. The substance in the general circulation, however, is considered to be in equilibrium with the substance at the site(s) of action. Bioavailability can be therefore defined as the rate and extent to which the active pharmaceutical ingredient or active moiety is absorbed from a pharmaceutical dosage form and becomes available in the general circulation. Based on pharmacokinetic and clinical considerations it is generally accepted that in the same subject an essentially similar plasma concentration time course will result in an essentially similar concentration time course at the site(s) of action.

Bioequivalence (1)

Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.

Bioequivalence (2)

A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (C_{max} and T_{max}) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.

Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities, in terms of peak (C_{max} and T_{max}) and total exposure (area under the curve (AUC)), after administration in the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same.

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Bioequivalence test		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.
Biopharmaceutics Classification System (BCS)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	The BCS is a scientific framework for classifying active pharmaceutical ingredients based upon their aqueous solubility and intestinal permeability. When combined with the dissolution of the pharmaceutical product, the BCS takes into account three major factors that govern the rate and extent of drug absorption (exposure) from immediate-release oral solid dosage forms: dissolution, solubility, and intestinal permeability.
Biowaiver		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	The term biowaiver is applied to a regulatory drug approval process when the dossier (application) is approved based on evidence of equivalence other than through in vivo equivalence testing.
Blending		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Blending is the process of combining materials or different batches to produce a homogenous intermediate or finished product.
Blister		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A multi-dose container consisting of two layers, of which one is shaped to contain the individual doses. Strips are excluded.
Bottle		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container with a more or less pronounced neck and usually a flat bottom.
Bulk harvest		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A homogeneous pool of individual harvests or lysates processed in a single manufacturing run.
Bulk product (1)		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	The product following purification, but before final formulation. It is obtained from a bulk harvest, and is kept in a single container and used in the preparation of the final dosage form.

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Bulk product (2)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Any product that has completed all processing stages up to, but not including, final packaging.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Any product that has completed all processing stages up to, but not including, final packaging.
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	Any product that has completed all processing stages up to, but not including, final packaging.
Bulk product (3)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A product that has completed all processing stages up to, but not including, final packaging. (Reference to (should conform with) "Good manufacturing practices for pharmaceutical products")
Calibration (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

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Calibration (2)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	The performance of tests and retests to ensure that measuring equipment (e.g. for temperature, weight, pH) used in a manufacturing process or analytical procedure (in production or quality control) gives measurements that are correct within established limits.
Calibration (3)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (for example, weight, temperature and pH), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.
Calibration of equipment		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	The documented act of proving that the equipment is performing to predefined tolerances or criteria.
Cartridge		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container, usually cylindrical, suitable for liquid or solid pharmaceutical dosage forms; generally for use in a specially designed apparatus (e.g. a prefilled syringe).
Case-report form (CRF)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A document that is used to record data on each trial subject during the course of the trial, as defined by the protocol. The data should be collected by procedures which guarantee preservation, retention and retrieval of information and allow easy access for verification, audit and inspection.
Central air-conditioning unit		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	See Air-handling unit.
Certificate of a pharmaceutical starting material		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	A document containing the information (as set out in Appendix 1 of these Guidelines) that is validated and issued for a specific starting material by the competent authority of the exporting country and intended for use by the competent authority in the importing country or in the absence of such an authority by, for example, the manufacturer of the finished product when exporting.

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Certificate of analysis (1)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	Report of the results obtained, including the final conclusion of the examination of a sample issued by the manufacturer and repacker/trader (see Model certificate of analysis. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report. Geneva, World Health Organization, 2002, Annex 10 (WHO Technical Report Series 902)).
Certificate of analysis (COA) (2)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A document listing the results of testing a representative sample drawn from the batch to be delivered. A COA should be equivalent to the WHO Model COA (Model certificate of analysis. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report. Geneva, World Health Organization, 2002, Annex 10 (WHO Technical Report Series 902)).
Certificate of pharmaceutical product		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A WHO-type certificate of the form described in Guidelines for implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva, World Health Organization, 1998.
Certification		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	The final review and formal approval of a validation or revalidation, followed by approval of a process for routine use.
Certifying authority		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The competent authority that issues product certificates. It must ensure that it possesses the capacities listed in section 2.4 of the guidelines.
Challenge tests/ worst case		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	A condition or set of conditions encompassing upper and lower processing limits and circumstances, within standard operating procedures, that pose the greatest chance of process or product failure when compared with ideal conditions.
Change control		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The intent is to determine the need for action that would ensure that the system is maintained in a validated state.

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Term

Related reference(s)

Definition

Charges for product certificates

Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.11 of the guidelines.
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Clean area

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
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Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.
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Clean area (clean room)*

Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	An area (or room) with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area. *Note: Clean area standards, such as ISO 14644-1 provide details on how to classify air cleanliness by means of particle concentrations, whereas the GMP standards provide a grading for air cleanliness in terms of the condition (at-rest or operational), the permissible microbial concentrations, as well as other factors such as gowning requirements. GMP and clean area standards should be used in conjunction with each other in order to define and classify the different manufacturing environments.
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Cleaning validation

Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented evidence to establish that cleaning procedures are removing residues to predetermined levels of acceptability, taking into consideration factors such as batch size, dosing, toxicology and equipment size.
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Climatic zones

Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The four zones into which the world is divided based on the prevailing annual climatic conditions. (see section 2)
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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Clinical trial		
Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)		<p>Any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. Clinical trials are generally divided into Phases I-IV. It is not possible to draw clear distinctions between these phases, and different opinions about details and methodology do exist. However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows:</p> <p>Phase I. These are the first trials of a new active ingredient or new formulations in humans, often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, and an initial pharmacokinetic/ pharmacodynamic profile of the active ingredient.</p> <p>Phase II. The purpose of these therapeutic pilot studies is to determine activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which it is intended. The trials are performed in a limited number of subjects and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. This phase is also concerned with the determination of appropriate dose ranges/ regimens and (if possible) the clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.</p> <p>Phase III. This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety-efficacy balance of formulation(s) of the active ingredient, and assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated, and special features of the product must be explored (e.g. clinically relevant drug interactions, factors leading to differences in effect, such as age). The trials should preferably be randomized double-blind, but other designs may be acceptable, e.g. long-term safety studies. In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use.</p> <p>Phase IV. In this phase studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance, and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to Phase IV studies as are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally regarded as trials of new pharmaceutical products.</p>
Combined sample		
WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)		Sample resulting from combining all or parts of two or more samples of the material.
Commingling		
Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (35th report, 1999)		The blending of carry-over material from one grade of an excipient with another, usually due to a continuous process.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Commissioning (1)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Commissioning is the documented process of verifying that the equipment and systems are installed according to specifications, placing the equipment into active service and verifying its proper action. Commissioning takes place at the conclusion of project construction but prior to validation.
Commissioning (2)	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	The setting up, adjustment and testing of equipment or a system to ensure that it meets all the requirements, as specified in the user requirement specification, and capacities as specified by the designer or developer. Commissioning is carried out before qualification and validation.
Comparator	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	The finished pharmaceutical product with which an FDC-FPP is to be compared. The comparison may be by means of bioequivalence studies or clinical studies of safety and/or effectiveness. A single study may use more than one comparator, for example several single entity FPPs. A comparator may be a placebo.
Comparator product (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	The comparator product is a pharmaceutical product with which the multisource product is intended to be interchangeable in clinical practice. The comparator product will normally be the innovator product for which efficacy, safety and quality have been established. The selection of the comparator product is usually made at the national level by the drug regulatory authority. (see section 6.5.2).
Comparator product (2)	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A pharmaceutical or other product (which may be a placebo) used as as reference in a clinical trial.
Competence and evaluation of national authority	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See sections 2.4, 2.5 and 4.2 of the guidelines.
Competent authority (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The national authority as identified in the formal letter of acceptance in which each Member State informs WHO of its intention to participate in the Scheme. The extent of its participation should be indicated in the letter of acceptance (see section 2.1 of the guidelines). The competent authority can issue or receive certificates. WHO makes available on request a continuously updated list of addresses of competent authorities and, when applicable, the specific conditions for participation.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Competent authority (2)	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	The national regulatory authority in the Member State. The competent authority can issue or receive certificates.
Competitive tender	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A procedure for procuring pharmaceutical products which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by the suppliers in response to a public notice.
Computer validation	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented evidence which provides a high degree of assurance that a computerized system analyses, controls and records data correctly and that data processing complies with predetermined specifications.
Concurrent validation	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Validation carried out during routine production of products intended for sale.
Consignment (1)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The quantity of a pharmaceutical starting material made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (2)	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	The quantity of a bulk starting material, or of a drug product, made by one manufacturer or supplied by an agent, and supplied at one time in response to a particular request or order. A consignment may comprise one or more lot-identified packages or containers and may include material belonging to more than one lot-identified batch.
Consignment (or delivery) (3)	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The quantity of starting material, or of a drug product, made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.
Consignment (or delivery) (4)	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Consignment (or delivery) (5)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch (adapted from GMP).
Constituents with known therapeutic activity (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	Substances or groups of substances which are chemically defined and known to contribute to the therapeutic activity of a plant material or of a preparation.
Constituents with known therapeutic activity (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Constituents with known therapeutic activity are substances or group of substances which are chemically defined and known to contribute to the therapeutic activity of a herbal material or of a preparation. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Container		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

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<u>Term</u>	<u>Definition</u>
Containers	
Guidelines on packaging for pharmaceutical products. (36th report, 2002)	<p>A container for pharmaceutical use is an article which holds or is intended to contain and protect a drug and is or may be in direct contact with it. The closure is a part of the container. The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers (see the reference below):</p> <ul style="list-style-type: none">• Well-closed containers must protect the contents from extraneous matter or from loss of the substance under normal conditions of handling, shipment or storage.• Tightly closed containers must protect the contents from extraneous matter, from loss of the substance, and from efflorescence, deliquescence or evaporation under normal conditions of handling, shipment or storage. If the container is intended to be opened on several occasions, it must be designed to be airtight after reclosure.• Hermetically closed containers must protect the contents from extraneous matter and from loss of the substance, and be impervious to air or any other gas under normal conditions of handling, shipment or storage. <p>Substances and dosage forms requiring protection from light should be maintained in a light-resistant container that — either by reason of the inherent properties of the material of which it is composed, or because a special coating has been applied to it — shields the contents from the effects of light. Alternatively, the container may be placed inside a suitable light-resistant (opaque) covering and/or stored in a dark place.</p> <p>(The international pharmacopoeia, 3rd ed. Vol. 4. Tests, methods, and general requirements. Quality specifications for pharmaceutical substances, excipients, and dosage forms. Geneva, World Health Organization, 1994).</p>
Containment	
Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A process or device to contain product, dust or contaminants in one zone, preventing it from escaping to another zone.
Contamination (1)	
Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.
Contamination (2)	
Guide to good storage practices for pharmaceuticals. (37th report, 2003)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, or intermediate or finished product during production, sampling, packaging or repackaging, storage or transport.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Contamination (3)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The undesired introduction of impurities of a chemical or microbial nature, or of foreign matter, into or on to a starting material or intermediate, during production, sampling, packaging or repackaging, storage or transport.
Contamination (4)	Good distribution practices for pharmaceutical products. (40th report, 2006)	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transport.
Continuous culture production	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A system in which the number of passages or population doublings after production has been started is not restricted. Strict criteria for terminating production must be specified by the manufacturer.
Contract (1)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Business agreement for supply of goods or performance of work at a specified price.
Contract (2)	Good distribution practices for pharmaceutical products. (40th report, 2006)	Business agreement for the supply of goods or performance of work at a specified price.
Contract (3)	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A document, dated and signed by the investigator, institution and sponsor, that sets out any agreements on financial matters and delegation/distribution of responsibilities. The protocol may also serve as a contract when it contains such information and is signed.
Contract research organization	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A scientific organization (commercial, academic or other) to which a sponsor may transfer some of its tasks and obligations. Any such transfer should be defined in writing.
Control (noun)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The state wherein correct procedures are being followed and criteria are being met.
Control (verb)	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The taking of all necessary actions to ensure and maintain compliance with the criteria established in the HACCP plan.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Control measure		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	Any action and activity that can be used to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.
Controlled drugs		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	Narcotic drugs and psychotropic substances regulated by provisions of national drug laws.
Co-packaged product		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A product consisting of two or more separate pharmaceutical products in their final dosage form that are packaged together for distribution to patients in the co-packaging.
Corrective action		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	Any action to be taken when the results of monitoring at the CCP (critical control point) indicate a loss of control.
Counterfeit		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
Counterfeit pharmaceutical product		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	A pharmaceutical product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an insufficient quantity of active ingredient or with fake packaging.
Counterfeit product		
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	A pharmaceutical product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.
Critical control point (CCP)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	A step at which control can be applied and is essential to prevent or eliminate a pharmaceutical quality hazard or reduce it to an acceptable level.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Critical limit		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	A criterion which separates acceptability from unacceptability.
Critical operation		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	An operation in the manufacturing process that may cause variation in the quality of the pharmaceutical product.
Critical parameter or component		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A processing parameter (such as temperature or humidity) that affects the quality of a product, or a component may have a direct impact on the quality of the product.
Critical process		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A process that may cause variation in the quality of the pharmaceutical product.
Cross-contamination (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.
Cross-contamination (2)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Contamination of a starting material, intermediate product or finished product with another starting material or material during production.
Cross-contamination (3)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Design condition	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Design condition relates to the specified range or accuracy of a controlled variable used by the designer as a basis to determine the performance requirements of an engineered system.
Design qualification (DQ) (1)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	DQ is the documented check of planning documents and technical specifications for design conformity with the process, manufacturing, GMP and regulatory requirements.
Design qualification (DQ) (2)	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented evidence that the premises, supporting systems, utilities, equipment and processes have been designed in accordance with the requirements of GMP.
Deviation	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	Failure to meet a critical limit.
Direct impact system	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A system that is expected to have a direct impact on product quality. These systems are designed and commissioned in line with good engineering practice (GEP) and, in addition, are subject to qualification practices.
Distribution	Good distribution practices for pharmaceutical products. (40th report, 2006)	The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.
Dosage form (1)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir, injection, suppository.
Dosage form (2)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The form of the completed pharmaceutical preparation, e.g. tablet, capsule, elixir, suppository.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Dosage form (3)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	The form of the completed pharmaceutical product, e.g. tablet, capsule, elixir or suppository.
Drug (1)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	An active pharmaceutical ingredient or a pharmaceutical product (see also pharmaceutical excipient and pharmaceutical product).
Drug (2)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Any substance or product for human or veterinary use that is intended to modify or explore physiological states for the benefit of the recipient.
Drug (5)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the term drug, medicine and pharmaceutical product (see below) are used interchangeably.
Drug (medicine, pharmaceutical product, pharmaceutical) (3)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	Any substance or mixture of substances that is manufactured for sale or distribution, offered for sale, sold, supplied or presented for use in: (i) the treatment, mitigation, cure, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof in humans or animals (ii) normal physiological conditions in humans or animals; or (iii) the restoration, correction or modification of organic functions in humans or animals, or any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.
Drug (pharmaceutical product) (4)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	Any substance or mixture of substances that is manufactured for sale or distribution, sold, supplied, offered for sale or presented for use in: (i) the treatment, mitigation, cure, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in human or animal; or (ii) the restoration, correction or modification of organic functions in human or animal.
Drug legislation		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The legal conditions under which pharmaceutical activities should be organized. (See also legislation below.)

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Drug master file		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (35th report, 1999)	Detailed information concerning a specific facility, process or product submitted to the drug regulatory authority, intended for the incorporation into the application for marketing authorization.
Drug regulatory authority (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	An authority appointed by the government of a Member State to administer the granting of marketing authorizations for pharmaceutical products in that country.
Drug regulatory authority (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	The national agency responsible for the registration of and other regulatory activities concerning pharmaceutical products.
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	The national agency responsible for the registration of and other regulatory activities concerning pharmaceutical products.
Drug regulatory authority (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A national body that administers the full spectrum of drug regulatory activities, including at least all of the following functions in conformity with national drug legislation: <ul style="list-style-type: none">•marketing authorization of new products and variation of existing products;•quality control laboratory testing;•adverse drug reaction monitoring;•provision of drug information and promotion of rational drug use;•good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;•enforcement operations;•monitoring of drug utilization.
Earliest expiry/first out principle concept (EEFO)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A distribution procedure to ensure that the stock with the earliest expiry date is distributed and/or utilized before an identical stock item with a later expiry date is distributed and/or utilized.
Effectiveness		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	An expression of the degree to which activities have produced the effects planned.

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Efficiency		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The relationship between the results of activities and the corresponding effort expended in terms of money, resources and time.
Equivalence requirements		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	In vivo and/or in vitro testing requirements for approval of a multisource pharmaceutical product and marketing authorization.
Equivalence test		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	A test that determines the equivalence between the multisource product and the comparator product using in vivo and/or in vitro approaches.
Essential pharmaceutical products		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Those pharmaceutical products that satisfy the health care needs of the majority of the population. WHO's Expert Committee on the Selection and Use of Essential Medicines updates the WHO Model List of Essential Medicines at two-year intervals. Each country may use this model to generate its own list of essential pharmaceutical products.
Ethics committee		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	An independent body (a review board or a committee, institutional, regional or national), constituted of medical professionals and non medical members, whose responsibility is to verify that the safety, integrity and human rights of the subjects participating in a particular trial are protected and to consider the general ethics of the trial, thereby providing public reassurance. Ethics committees should be constituted and operated so that their tasks can be executed free from bias and from any influence of those who are conducting the trial.
Excipient (1)		
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to: <ul style="list-style-type: none">— aid in the processing of the drug delivery system during its manufacture;— protect, support or enhance stability, bioavailability, or patient acceptability;— assist in product identification; or— enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Excipient (2)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a pharmaceutical product.
Excipient (3)	Good distribution practices for pharmaceutical products. (40th report, 2006)	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a pharmaceutical product.
Expiry date (1)	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The date given on the individual container (usually on the label) of a drug product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life period to the date of manufacture.
Expiry date (2)	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	The date given on the individual container (usually on the label) of a drug product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Expiry date (3)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The expiry date displayed on the container of a pharmaceutical starting material is the date up to and including which the pharmaceutical starting material is expected to remain within specification if stored correctly. It is established for every batch by adding the shelf-life to the date of manufacture.
Expiry date (4)	Good distribution practices for pharmaceutical products. (40th report, 2006)	The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Facility	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The built environment within which the clean area installation and associated controlled environments operate together with their supporting infrastructure.
Final dosage form	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	The finished formulated product; it may be freeze-dried and contain excipients, which should have been shown not to affect stability adversely.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Final report		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A comprehensive description of the trial after its completion including a description of experimental methods (including statistical methods) and materials, a presentation and evaluation of the results, statistical analysis and a critical, ethical, statistical and clinical appraisal.
Final sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample ready for the application of the test procedure.
Finished herbal products		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term "mixture herbal product" can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished herbal products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Finished pharmaceutical product (1)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	A pharmaceutical product that has undergone all stages of production and quality control, including being packaged in its final container and labelled.
Finished pharmaceutical product (FPP) (2)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more actives.
Finished product (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A product that has undergone all stages of production, including packaging in its final container and labelling.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A product that has undergone all stages of production, including packaging in its final container and labelling.
Finished product (2)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.
First expiry/first out (FEFO)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used; earliest expiry/first out (EEFO) has a similar meaning.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
First in/first out (FIFO)	Good distribution practices for pharmaceutical products. (40th report, 2006)	A distribution procedure to ensure that the oldest stock is distributed and/or used before a newer and identical stock item is distributed and/or used.
First in/first out principle concept (FIFO)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A distribution procedure to ensure that the oldest stock is distributed and/or utilized before a newer and identical stock item is distributed and/or utilized.
Fixed-dose combination (FDC) (1)	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A combination of two or more actives in a fixed ratio of doses. This term is used generically to mean a particular combination of actives irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product.
Fixed-dose combination (FDC) (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	A combination of two or more active pharmaceutical ingredients in a fixed ratio of doses. This term is used generically to mean a particular combination of active pharmaceutical ingredients irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product.
Fixed-dose combination finished pharmaceutical product (FDC-FPP) (1)	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A finished pharmaceutical product that contains two or more actives.
Fixed-dose combination finished pharmaceutical product (FDC-FPP) (2)	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	A finished pharmaceutical product that contains two or more active pharmaceutical ingredients.
Flow diagram	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	A systematic representation of the sequence of steps or operations used in the production, control and distribution of a particular pharmaceutical.
Free sale certificate	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.2 of the guidelines.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Gas cylinder		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container, usually cylindrical, suitable for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.
Generic product (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	The term "generic product" has somewhat different meanings in different jurisdictions. In this document, therefore, use of this term is avoided as much as possible, and the term "multisource pharmaceutical product" (see definition below) is used instead. Generic products may be marketed either under the nonproprietary approved name or under a new brand (proprietary) name. They may sometimes be marketed in dosage forms and/or strengths different from those of the innovator products. However, where the term "generic product" has had to be used in this document, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights.
Generic product (4)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	See multisource pharmaceutical products.
Generic products (2)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	The term generic product has somewhat different meanings in different jurisdictions. Use of this term has therefore been avoided as far as possible, and the term multisource pharmaceutical product is used instead (see the definition below). Multisource products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different to those of the innovator products. Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.
Generic products (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The term generic product has somewhat different meanings in different jurisdictions. The use of this term is therefore avoided as much as possible, and the term multisource pharmaceutical product (see below) is used instead. Generic products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products (see below). Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Generic substitution		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Practice of substituting a product, whether marketed under a trade name or generic name, with an equivalent product, usually a cheaper one, containing the same active ingredient(s).
GMP certificate		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.2 of the guidelines.
Good clinical practice (GCP)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analysis, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented.
Good distribution practices (GDP)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Good distribution practices are that part of quality assurance that ensures that the quality of a pharmaceutical products is maintained by means of adequate control of the numerous activities which occur throughout the distribution process.
Good engineering practice (GEP)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.
Good engineering practices (GEP) (2)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Established engineering methods and standards that are applied throughout the project life-cycle to deliver appropriate, cost-effective solutions.
Good laboratory practice (GLP)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

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Term

Related reference(s)

Definition

Good manufacturing practice (GMP) (1)

A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Guidelines for inspection of drug distribution channels. (35th report, 1999)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good manufacturing practice(s) (GMP) (2)

Good practices for national pharmaceutical control laboratories. (36th report, 2002)

That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.
(Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2. Good manufacturing practices and inspection. Geneva, World Health Organization, 1999.).

Good manufacturing practices (3)

Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)

That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization/product licence.

Good manufacturing practices (GMP) (4)

Good distribution practices for pharmaceutical products. (40th report, 2006)

That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Good pharmacy practice		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.
Good storage practices (GSP)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Good storage practices are that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.
Good trade and distribution practices (GTDP) (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Good trade and distribution practices are that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process.
GTDP		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	Good Trade and Distribution Practices (Annex 2, WHO Technical Report Series, No. 917).
HACCP plan		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	A document prepared in accordance with the principles of HACCP to ensure the control of hazards which are significant for pharmaceutical quality in the production and supply chain.
Hazard		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	Any circumstance in the production, control and distribution of a pharmaceutical which can cause an adverse health effect.
Hazard analysis		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The process of collecting and evaluating information on hazards which should be addressed in the HACCP plan.
Health establishment		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A health establishment is the whole or part of a public or private facility, building or place, whether operated for profit or not, that is operated or designed to provide health care services including the supply of pharmaceutical products to the end user.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Herbal materials		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Herbal medicinal product		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	Medicinal product containing, as active ingredients, exclusively plant material and/or preparations. This term is generally applied to a finished product. If it refers to an unfinished product, this should be indicated.
Herbal preparations		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Herbal preparations are the basis for finished herbal products and may include comminuted or cut herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Herbs		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Herbs include crude materials which could be derived from lichen, algae, fungi and higher plants, such as leaves, flowers, fruit, fruiting bodies, seeds, stems, wood, bark, roots, rhizomes or other parts, which may be entire, fragmented or powdered. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Homogeneity		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	A material is regarded as homogeneous when it is all of the same origin (e.g. from the same batch) and as non-homogeneous when it is of differing origins.
Homogeneous material		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Material of uniform consistency and composition throughout a batch.
Import authority		
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	The national agency responsible for authorizing imports (e.g. the ministry or department of trade or of imports and exports).
Importation		
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Importation (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
Importer		
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	An individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A "licensed" or "registered" importer is one who has been granted a licence or registration status for the purpose. In addition to a general licence or permit as an importer, some countries require an additional licence to be issued by the national drug regulatory authority if pharmaceutical products are to be imported.
Importing agents, guidelines for		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.4 of the guidelines.
In vitro equivalence test		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	An in vitro equivalence test is a dissolution test that includes comparison of the dissolution profile between the multisource product and the comparator product in three media: pH1.2, pH 4.5 and pH 6.8.
In vitro quality control dissolution test		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	A dissolution test procedure identified in the pharmacopoeia, generally a one time point dissolution test for immediate-release products and a three or more time points dissolution test for modified release products.
Indicator		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Criterion used to measure changes, directly or indirectly, and to assess the extent to which the targets or objectives of a programme or project are being attained. Indicators should meet the criteria of clarity, usefulness, measurability, reliability, validity (see below) and acceptance by key stakeholders.
Indirect impact system		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	This is a system that is not expected to have a direct impact on product quality, but typically will support a direct impact system. These system are designed and commissioned according to GEP only.
Infiltration		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Infiltration is the ingress of contaminated air from an external zone into a clean area.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Informed consent		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A subject's voluntary confirmation of willingness to participate in a particular trial, and the documentation thereof. This consent should be sought only after all appropriate information has been given about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconveniences, alternative treatment that may be available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.
Injection needle		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A hollow needle with a locking device intended for the administration of liquid pharmaceutical dosage forms.
Injection syringe		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A cylindrical device with a cannula-like nozzle, with or without a fixed needle and a movable piston, used for the administration, usually parenteral, of an accurately measured quantity of a liquid pharmaceutical form. The syringe may be prefilled, and can be for single-dose or multi-dose use.
Innovator pharmaceutical product (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	Generally, the innovator pharmaceutical product is that which was first authorized for marketing (normally as a patented drug) on the basis of documentation of efficacy, safety and quality (according to contemporary requirements). When drugs have been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Innovator pharmaceutical product (2)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Generally the pharmaceutical product which was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorization. When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Innovator pharmaceutical product (3)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	Generally, the innovator pharmaceutical product is that which was first authorized for marketing, on the basis of documentation of quality, safety and efficacy.
In-process control (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
In-process control (2)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the material conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.
Inspection		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	An officially conducted examination (i.e. review of the conduct of the trial, including quality assurance, personnel involved, any delegation of authority and audit) by relevant authorities at the site of investigation and/or at the site of the sponsor in order to verify adherence to GCP and GLP as set out in this document.
Installation qualification (1)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities, manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.
Installation qualification (IQ) (2)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	IQ is documented verification that the premises, HVAC system, supporting utilities and equipment have been built and installed in compliance with their approved design specification.
Installation qualification (IQ) (3)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	The performance of tests to ensure that the installations (such as machines, measuring devices, utilities and manufacturing areas) used in a manufacturing process are appropriately selected and correctly installed and operate in accordance with established specifications.
Interchangeability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	An interchangeable pharmaceutical product is one that is therapeutically equivalent to a comparator (reference) product.
Interchangeable pharmaceutical product (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	An interchangeable pharmaceutical product is one which is therapeutically equivalent to a reference product.
Interchangeable pharmaceutical product (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	An interchangeable pharmaceutical product is one which is therapeutically equivalent to a comparator product and can be interchanged with the comparator in clinical practice.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Intermediate		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Partly processed material that must undergo further manufacturing steps before it becomes a bulk product.
Intermediate product (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Partly processed material that must undergo further manufacturing steps before it becomes a bulk product.
Intermediate product (2)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
Intermediate product (3)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.
International Nonproprietary Name		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances.
Investigational labelling		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Labelling developed specifically for products involved in a clinical trial.
Investigational product (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	Any pharmaceutical product (new product or reference product) or placebo being tested or used as a reference in a clinical trial.
Investigational product (synonym: study product) (2)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Any pharmaceutical product (see definition) or placebo being tested or used as a reference in a clinical trial.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Investigator (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	The person responsible for the trial and for protecting the rights, health and welfare of the subjects in the trial. The investigator must be an appropriately qualified person legally allowed to practice medicine/dentistry.
Investigator (2)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and the provision of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practise medicine or dentistry.
Labelling (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The action involving the selection of the correct label, with the required information, followed by line-clearance and application of the label.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	The action involving the selection of the correct label, with the required information, followed by line-clearance and application of the label.
Labelling (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Process of identifying a pharmaceutical product including the following information, as appropriate: name, active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier. (adapted from GMP)
Labels		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	All finished drug products should be identified by labelling, as required by the national legislation, bearing at least the following information: (a) the name of the drug product; (b) a list of the active ingredients (if applicable, with the International Nonproprietary Names (INNs)), showing the amount of each present, and a statement of the net contents, e.g. number of dosage units, mass or volume; (c) the batch number assigned by the manufacturer; (d) the expiry date in an unencoded form; (e) any special storage conditions or handling precautions that may be necessary; (f) the directions for use, and any warnings and precautions that may be necessary; (g) the name and address of the manufacturer or the company or person responsible for placing the product on the market.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Language of product certificate		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.10 of the guidelines.
Large-volume parenterals		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Sterile solutions intended for parenteral application with a volume of 100ml or more in one container of the finished dosage form.
Legislation		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The first state of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter, e.g. control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also regulations below).
Licence holder		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	An individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.
Licensee		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	An individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable, for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.
Licensing system		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	National legal provisions on who should manufacture, import or supply pharmaceutical products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.
Limits of certification by competent authority		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See sections 3.12 and 4.8 of the guidelines.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Manufacture (1)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and the related controls.
Manufacture (2)		
	Guidelines on pre-approval inspections. (36th report, 2002)	All operations concerned with the purchase of materials and products, production (including packaging), quality control, release, storage, the distribution of pharmaceutical products, and the related controls. (Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2. Good manufacturing practices and inspection. Geneva, World Health Organization, 1999.)
Manufacture (3)		
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products, and the related controls.
Manufacture (4)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.
Manufacture (5)		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	All operations of purchase of materials and starting materials, production, quality control, release, storage, shipment of finished starting materials, and the related controls.
Manufacture (6)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	All operations of purchase of materials, production, quality control, release, storage, and distribution of pharmaceutical starting materials, and the related controls.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Manufacture (manufacturing) (7)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	All or any operations of purchase of materials and products, production, quality control, release, storage and distribution of finished products and the related controls.
Manufacturer (1)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	A company that carries out at least one step of manufacture.
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A company that carries out at least one step of manufacture.
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A company that carries out at least one step of manufacture.
	Guidelines on pre-approval inspections. (36th report, 2002)	A company that carries out at least one step of manufacture.
Manufacturer (2)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A company that carries out at least one step of manufacture. (For the different categories of manufacturer, see Appendix 1, explanatory note no. 7.)
Manufacturer (3)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
Manufacture's working cell bank		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A homogeneous suspension of the seed material derived from the master seed bank(s) at a finite passage level, dispensed in aliquots into individual containers for storage. All containers are treated identically and, once removed from storage, are not returned to the seed stock.
Manufacturing process*		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	The transformation of starting materials into finished products (drug substances or pharmaceutical dosage forms) through a single operation or a sequence of operations involving installations, personnel, documentation and environment. * For the purpose of this Annex, "manufacturing process" is used as synonym of "production process".

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Markers (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	Constituents of a medicinal plant material which are chemically defined and of interest for control purposes. Markers are generally employed when constituents of known therapeutic activity are not found or are uncertain, and may be used to calculate the quantity of plant material or preparation in the finished product. When starting materials are tested, markers in the plant material or preparation must be determined quantitatively.
Markers (2)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Markers are chemically defined constituents of a herbal material utilized for control purposes. They may or may not contribute to the clinical efficacy. In the first case, however, evidence that they are solely responsible for the clinical efficacy may or may not be available. Markers are generally employed when constituents of known therapeutic activity are not found or are uncertain, and may be used to identify the herbal material or preparation or calculate their quantity in the finished product.
Marketing authorization (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See product licence.
Marketing authorization (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using international nonproprietary names or national generic names where they exist), the shelf-life and storage conditions and packaging characteristics. It also contains information approved for health professionals and the public, the sales category, the name and address of the licence holder, and the period of validity of the licence.
Marketing authorization (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	An legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "license" or "product license".

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Marketing authorization (product licence, registration certificate) (4)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
Marketing authorization (product licence, registration certificate) (5)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the pharmaceutical product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.
Marketing authorization (product licence, registration certificate) (6)		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, information given on the label, product information and shelf-life. (There is a reference to (should conform with) "Good manufacturing practices for pharmaceutical products")
Master formula		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Master record		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A document or set of documents that serve as a basis for the batch documentation (blank batch record).
Master seed		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A homogeneous suspension of the original cells, already transformed by the expression vector containing the desired gene, dispensed in aliquots into individual containers for storage. All containers are treated identically during storage and once removed from it are not returned to the seed stock.
Material (1)		
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.
Material (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.
Materials		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A term used to denote starting materials, process aids, intermediates, active pharmaceutical ingredients, packaging and labelling materials.
Mean kinetic temperature		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The single test temperature for a drug product corresponding to the effects on chemical reaction kinetics of a given temperature-time distribution. A mean kinetic temperature is calculated for each of the four world climatic zones according to the formula developed by Haynes (Haynes JD. World wide virtual temperatures for product stability testing. Journal of pharmaceutical sciences, 1971, 60:927-929). It is normally higher than the arithmetic mean temperature.
Medicinal plant (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	A plant (wild or cultivated) used for medicinal purposes.
Medicinal plant (3)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Medicinal plants are plants (wild or cultivated) used for medicinal purposes. (In: Good Manufacturing Practices: supplementary guidelines for the manufacture of herbal medicinal products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth report. Geneva, World Health Organization, 1996:109-113, Annex 8 (WHO Technical Report Series, No. 863)).

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Medicinal plant material (crude plant material, vegetable drug) (2)		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	Medicinal plants or parts thereof collected for medicinal purposes.
Medicinal plant materials (4)		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	See herbal materials
Medicine (2)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	See drug.
Method validation/verification		
	Guidelines on pre-approval inspections. (36th report, 2002)	Method validation is conducted where non-compendial analytical methods are included in the application to confirm that the applicants' proposed analytical methods are suitable for regulatory purposes. A side-by-side comparison with a compendial method, if available, should be included. Method verification is conducted where the methods are compendial, to confirm whether the product as compounded can be analysed satisfactorily by the official method.
Microbiology		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A branch of science that refers to microbes of all of types, including bacteria, viruses, rickettsia, protozoa, fungi and prions. Derived words (such as microbiological) have a similar meaning.
Model product		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (35th report, 1999)	A product which simulates a group of similar products
Monitor (1)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Monitor (2)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	A person appointed by, and responsible to, the sponsor for monitoring and reporting the progress of the trial and for the verification of data.
Monitor (3)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A person appointed by, and responsible to, the sponsor or CRO for the monitoring and reporting of progress of the trial and for verification of data.
Mother liquor		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (35th report, 1999)	A concentrated solution from which the product is obtained by evaporation, freezing, and/or crystallization.
Multisource (generic) pharmaceutical product (1)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource (generic) pharmaceutical product (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource pharmaceutical products (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
Multisource pharmaceutical products (4)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.
National drug distribution channels		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	Facilities through which drug products are distributed within a country.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
National list of essential pharmaceutical products		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The list of essential pharmaceutical products (see above) that has been defined, adopted and published at country level. It is normally used by all health facilities, including the main hospitals.
New chemical (or biological) entities		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Actives that have not previously been authorized for marketing as a drug for use in humans in the country in question.
No-impact system		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	This is a system that will not have any impact, either directly or indirectly, on product quality. These systems are designed and commissioned according to GEP only.
Non-critical parameter or component		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A processing parameter or component within a system where the operation, contact, data control, alarm or failure will have an indirect impact or no impact on the quality of the product.
Normal operating range		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The range that the manufacturer selects as the acceptable values for a parameter during normal operations. This range must be within the operating range.
Operating limits		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The minimum and/or maximum values that will ensure that product and safety requirements are met.
Operating range		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Operating range is the range of validated critical parameters within which acceptable products can be manufactured.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Operational condition	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	This condition relates to carrying out room classification tests with the normal production process with equipment in operation, and the normal staff present in the room.
Operational qualification	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
Operational qualification (OQ) (2)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	OQ is the documentary evidence to verify that the equipment operates in accordance with its design specifications in its normal operating range and performs as intended throughout all anticipated operating ranges.
Operational qualification (OQ) (3)	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
Oral solid dosage (OSD)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Usually refers to an OSD plant that manufactures medicinal products such as tablets, capsules and powders to be taken orally.
Order	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	An instruction to process, package and/or ship a certain number of units of an investigational product.
Original manufacturer	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.
Original sample	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample collected directly from the material.
Over-the-counter drugs	Guidelines for inspection of drug distribution channels. (35th report, 1999)	These are drugs that can be sold from licensed dealers without professional supervision and without prescriptions. These drugs are suitable for self-medication for minor diseases and symptoms.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Packaging (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.
Packaging (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product. Note: Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.
Packaging (3)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
Packaging material (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Any material, including printed material, employed in the packaging of a pharmaceutical product, (but) excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	Any material, including printed material, employed in the packaging of a pharmaceutical product, (but) excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Packaging material (2)		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	Any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the product. (There is a reference to (should conform with) "Good manufacturing practices for pharmaceutical products")
Packaging material (3)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Packaging process		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product.
Performance qualification (PQ) (1)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	PQ is the documented verification that the process and/or the total process related to the system performs as intended throughout all anticipated operating ranges.
Performance qualification (PQ) (2)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented verification that the equipment or system operates consistently and gives reproducibility within defined specifications and parameters for prolonged periods. (In the context of systems, the term "process validation" may also be used.)
Pharmaceutical alternatives		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	Products are pharmaceutical alternative(s) if they contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product.
Pharmaceutical equivalence (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	Products are pharmaceutical equivalents if they contain the same amount of the same active substance(s) in the same dosage form; if they meet the same comparable standards; and if they are intended to be administered by the same route. However, pharmaceutical equivalence does not necessarily imply therapeutic equivalence as differences in the excipients and/or the manufacturing process can lead to differences in product performance.
Pharmaceutical equivalence (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	Products are pharmaceutical equivalents if they contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance.
Pharmaceutical equivalents		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Products are pharmaceutical equivalents if they contain the same amount of the same actives in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or manufacturing process and some other variables can lead to differences in product performance.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Pharmaceutical excipient (1)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A substance, other than the active pharmaceutical ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to: <ul style="list-style-type: none">— aid in the processing of the drug delivery system during its manufacture;— protect, support or enhance stability, bioavailability or patient acceptability;— assist in pharmaceutical product identification; or— enhance any other attribute of the overall safety and effectiveness of the drug during its storage or use.
Pharmaceutical excipients (2)		
	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients. (35th report, 1999)	Substances, other than the active ingredient, which have been appropriately evaluated for safety and are included in a drug delivery system to: <ul style="list-style-type: none">— aid in the processing of the drug delivery system during its manufacture;— protect, support or enhance stability, bioavailability or patient acceptability;— assist in product identification; or— enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.
Pharmaceutical product (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
Pharmaceutical product (2)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	Any medicine intended for human use or administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

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<u>Term</u>	<u>Definition</u>
Pharmaceutical product (3)	
Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	For the purpose of this Annex, this term is defined in the same way as in the WHO guidelines on GCP (Guidelines for good clinical practice (GCP) for trials on pharmaceutical products. In: The use of essential drugs. Model List of Essential Drugs (Eighth List). Sixth report of the WHO Expert Committee. Geneva, World Health Organization, 1995:97 - 137(WHO Technical Report Series, No. 850)), i.e. as any substance or combination of substances which has a therapeutic, prophylactic or diagnostic purpose, or is intended to modify physiological functions, and is presented in a dosage form suitable for administration to humans.
Pharmaceutical product (4)	
Good practices for national pharmaceutical control laboratories. (36th report, 2002)	Any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	Any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
Pharmaceutical product (5)	
Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * "Material" is used in the document for "pharmaceutical products and related materials" (WHO guidelines for sampling of pharmaceutical products and related materials.)
WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Any material* or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state. * "Material" is used in the document for "pharmaceutical products and related materials" (WHO guidelines for sampling of pharmaceutical products and related materials.)
Pharmaceutical product (6)	
Good distribution practices for pharmaceutical products. (40th report, 2006)	Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state. (adapted from GMP)
Pharmaceutical product (7)	
A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	See drug.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Pharmaceutical product (8)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Any substance or combination of substances which has a therapeutic, prophylactic or diagnostic use, or is intended to modify physiological functions, and is presented in a dosage form suitable for administration to humans.
Pharmaceutical starting material (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A pharmaceutical starting material is an active pharmaceutical ingredient (API) or an excipient intended or designated for use in the production of a pharmaceutical product.
Pharmaceutical starting material (2)		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials. This includes active pharmaceutical ingredients (APIs) and pharmaceutical excipients.
Pharmaceuticals		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	All products related to pharmacy, including starting materials (active pharmaceutical ingredients and excipients), finished dosage forms, and biological and other specific products.
Pharmacist (1)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	A pharmacist is a holder of a degree or diploma in pharmacy from a recognized higher institution of learning and is registered or licensed to practise pharmacy.
Pharmacist (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	The holder of a degree or diploma in pharmacy from a recognized higher institution of learning who is registered or licensed to practise pharmacy.
Pharmacy-only drugs		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	These are drugs authorized to be sold only in licensed pharmacies under the supervision of licensed or registered pharmacists; they may be sold without a prescription.
Pivotal clinical trials		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Those clinical studies that provide the significant evidence that is the basis for the decision as to the risk–benefit assessment for a particular FDC.
Plant preparations		
	Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicines. (34th report, 1996)	Comminuted or powdered plant material, extracts, tinctures, fatty or essential oils, resins, gums, balsams, expressed juices, etc., prepared from plant material, and preparations whose production involves a fractionation, purification or concentration process, but excluding chemically defined isolated constituents. A plant preparation can be regarded as the active ingredient whether or not the constituents having therapeutic activities are known.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Plasmid	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	An autonomously replicating, circular, extrachromosomal DNA element. It usually carries a few genes, some of which confer resistance to various antibiotics; such resistance is often used to discriminate between organisms that contain the plasmid and those that do not.
Point extraction	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Air extraction to remove dust with the extraction point located as close as possible to the source of the dust.
Poison	Guidelines for inspection of drug distribution channels. (35th report, 1999)	A preparation or substance defined by a national drug law as a poison.
Pre-approval batches	Guidelines on pre-approval inspections. (36th report, 2002)	Pilot or laboratory-scale batches, upon which the application is based, e.g. batches used for pivotal clinical trials and/or those used for bioavailability, bioequivalence and stability studies, and scale-up batches.
Prequalification (1)	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification, and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the approval. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture or registration, but the amount and type of information requested from the supplier for use in the assessment by the procurement agency may differ.
Prequalification (2)	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the Procurement Agency may differ.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Prescription-only drugs		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	These are drugs supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these drugs must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription drugs are further subdivided into controlled drugs (narcotic drugs and psychotropic substances) and non-controlled drugs.
Pressure cascade		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	A process whereby air flows from one area, which is maintained at a higher pressure, to another area at a lower pressure.
Pressurized container		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container suitable for compressed, liquefied or dissolved gas fitted with a device that, after its actuation, produces a controlled spontaneous release of the contents at atmospheric pressure and room temperature.
Principal investigator		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	The investigator serving as coordinator for certain kinds or clinical trials, e.g. multicentre trials.
Process validation		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Documented evidence which provides a high degree of assurance that a specific process will consistently result in a product that meets its pre-determined specifications and quality characteristics.
Processing instructions		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	See master formula.
Procurement		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceuticals for human use. For the purpose of this document, procurement means the pre-selection of products and manufacturers through a procedure of qualification, including prequalification (see above) and continuous monitoring thereafter, purchase of the prequalified products from prequalified manufacturers (linked to the specific product) through defined purchasing mechanisms, storage and distribution.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Procurement agency		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Any organization which is purchasing or otherwise acquiring any pharmaceutical product, vaccine or nutraceutical for human use. In the context of these guidelines it will normally be a not-for-profit organization, a non governmental organization (NGO) or a United Nations organization. A procurement agency in the context of this document is defined as any organization purchasing pharmaceutical products, vaccines, or other health sector goods or is otherwise involved in their prequalification (see above), purchasing, storage and distribution.
Product		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See pharmaceutical product.
Product certificate		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	A document containing the information as set out in Appendix 1 of the guidelines that is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the competent authority in the importing country or - in the absence of such an authority - by the drug procurement authority (see also section 3.5 of the guidelines). Transmission of product certificate: see sections 3.8 and 4.9 of the guidelines. Validity of product certificate: see section 3.9 of the guidelines. When to request a product certificate: see section 3.5 of the guidelines.
Product information (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The approved product information referred to in section 4.7 of the guidelines and item 2A.5 of the Product Certificate. It normally consists of information for health professionals and the public (patient information leaflets), as approved in the exporting country and, when available, a data sheet or a Summary of Product Characteristics (SPC) approved by the regulatory authority.
Product information (2)		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	The information provided by the supplier of an FPP that allows prescribers and consumers to ensure the safe and effective use of drugs. If it is written especially for prescribers, it may be termed prescribing information.
Product information (3)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	In the context of this document, product information means information on pharmaceutical products submitted by manufacturers or suppliers in any of the formats specified in the procurement agency's guidelines (including product dossiers, product questionnaires or other formats) to obtain prequalification for the products.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Product licence (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	An official document issued by the competent drug regulatory authority for the purpose of the marketing or free distribution of a product. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names or national generic names, where they exist), the shelf-life and storage conditions, and packaging characteristics. It also contains all the information approved for health professionals and the public (except promotional information), the sales category, the name and address of the licence holder, and the period of validity of the licence.
Product recall (1)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Product recall (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer, importer, distributor or a responsible agency.
Product specification file(s)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	Reference file(s) containing all the information necessary to draft the detailed written instructions on processing, packaging, labelling, quality control testing, batch release, storage conditions and shipping.
Production (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.
Production (2)		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	All operations involved in the preparation of a pharmaceutical product, from receipt of the starting materials, through processing and packaging, to completion of the finished product.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Production (3)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	All operations involved in the preparation of a pharmaceutical starting material, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished pharmaceutical starting materials.
Production (4)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
Production at finite passage		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A cultivation method involving a limited number of passages or population doublings which must not be exceeded during production.
Product-licence holder		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See licence holder.
Prohibited drugs		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	These are drugs with toxicity or side-effects that outweigh their therapeutic usefulness, so that public health and welfare are protected by prohibiting their production, manufacture, export, import, trade, distribution, supply, possession or use, except in amounts required for medical or scientific research. Prohibited drugs are normally determined by the national or supranational registration/licensing authority.
Prospective validation		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Validation carried out during the development stage on the basis of a risk analysis of the production process, which is broken down into individual steps; these are then evaluated on the basis of past experience to determine whether they may lead to critical situations.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Protocol (1)		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	A document which gives the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. It should be dated and signed by the investigator/institution involved and the sponsor, and can, in addition, function as a contract.
Protocol (2)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	A document which states the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator, the institution involved and the sponsor. It can also function as a contract.
Qualification (1)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word "validation" is sometimes extended to incorporate the concept of qualification.
Qualification (2)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Qualification is the planning, carrying out and recording of tests on equipment and a system, which forms part of the validated process, to demonstrate that it will perform as intended.
Qualification (3)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.
Qualification (4)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Action of proving and documenting that any premises, systems and equipment are properly installed and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation. In the context of this document it is the work done to prove that the supply system will deliver products of the quality required and specified on a routine basis, meeting all the applicable quality requirements.

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Term

Related reference(s)

Definition

Qualification of equipment

Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)

The act of planning, carrying out and recording the results of the tests on equipment to demonstrate that it will perform as intended. Measuring instruments and systems must be calibrated.

Good practices for national pharmaceutical control laboratories. (36th report, 2002)

The act of planning, carrying out and recording the results of the tests on equipment to demonstrate that it will perform as intended. Measuring instruments and systems must be calibrated.

Quality assurance (1)

Good manufacturing practices for pharmaceutical products. (32nd report, 1992)

“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.

Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)

“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development.

Quality assurance (2)

Good practices for national pharmaceutical control laboratories. (36th report, 2002)

A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Guidelines for inspection of drug distribution channels. (35th report, 1999)

A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality assurance (3)

Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)

A wide-ranging concept covering all matters that individually or collectively influence the quality of a product, including pharmaceutical starting materials. It is the totality of the arrangements made with the object of ensuring that pharmaceutical starting materials and pharmaceutical products are of the quality required for their intended use.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Quality assurance (4)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
Quality assurance (5)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
Quality assurance relating to clinical trials		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Systems and quality control procedures that are established to ensure that the trial is performed and the data are generated in compliance with GCP and GLP. These include procedures to be followed which apply to ethical and professional conduct, standard operating procedures (SOPs), reporting, and professional qualifications or skills of personnel .
Quality audit		
	Quality systems requirements for national good manufacturing practice inspectorates. (36th report, 2002)	An examination and assessment of all or part of a quality system with the specific purpose of improving it. A quality audit is usually conducted by outside or independent specialists or a team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors.
Quality control (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Quality control is the part of GMP concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.
Quality control (2)		
	Counterfeit drugs. Guidelines for the development of measures to combat counterfeit drugs. (1999)	That part of good manufacturing practice concerned with sampling, specifications, and testing and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.

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Quality control (3)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics
Quality control (4)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Online - See Part One (pp. 7–35). Printed version - See Page 47.
Quality control (5)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical starting materials conform to established specifications for identity, strength, purity and other characteristics.
Quality control (6)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Quality control (7)		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Quality control is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.
Quality manual		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A handbook that describes the various elements of the system for assuring the quality of the test results generated by a laboratory.
	Quality systems requirements for national good manufacturing practice inspectorates. (36th report, 2002)	A handbook that describes the various elements of the system for assuring the quality of the test results generated by a laboratory.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Quality specification		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	Explicit written test procedures and requirements that must be met.
Quality system (1)		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. (see Part One, sections 2.1 and 3.1).
Quality system (2)		
	Quality systems requirements for national good manufacturing practice inspectorates. (36th report, 2002)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality.
Quality system (3)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.
Quarantine (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Quarantine (2)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection.
Quarantine (3)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing (adapted from GMP).
Random sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample in which the different fractions of the material have an equal probability of being represented.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Raw data		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	All records or certified copies of original observations, clinical findings or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Such material includes laboratory notes, memoranda, calculations and documents, as well as all records of data from automated instruments or exact, verified copies, e.g. in the form of photocopies or microfiches. Raw data can also include photographic negatives, microfilm or magnetic media (e.g. computer diskettes) and optical media (CD-ROMs).
Real-time (long-term) stability studies		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	Experiments on the physical, chemical, biological, biopharmaceutical and microbiological characteristics of a drug, during and beyond the expected shelf-life and storage periods of samples under the storage conditions expected in the intended market. The results are used to establish the shelf-life, to confirm the projected shelf-life, and to recommend storage conditions.
Recall		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Reconciliation (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A comparison, making due allowance for normal variation, between the amount of product or materials theoretically produced or used and the amount actually produced or used.
Reconciliation (2)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A comparison between the theoretical quantity and the actual quantity.
Recovery (1)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use.
Recovery (or blending) (2)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Reference product		
	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A reference product is a pharmaceutical product with which the new product is intended to be interchangeable in clinical practice. The reference product will normally be the innovator product for which efficacy, safety and quality have been established. Where the innovator product is not available, the product which is the market leader may be used as a reference product, provided that it has been authorized for marketing and its efficacy, safety and quality have been established and documented.
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	A reference product is a pharmaceutical product with which the new product is intended to be interchangeable in clinical practice. The reference product will normally be the innovator product for which efficacy, safety and quality have been established. Where the innovator product is not available, the product which is the market leader may be used as a reference product, provided that it has been authorized for marketing and its efficacy, safety and quality have been established and documented.
Registration		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	Any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on to the market.
Registration certificate (1)		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See product licence.
Regulations		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The second stage of the legislative process (the first stage being legislation, see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.
Relabelling		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The process of putting a new label on the material (see also labelling).
Relative humidity		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The ratio of the actual water vapour pressure of the air to the saturated water vapour pressure of the air at the same temperature expressed as a percentage. More simply put, it is the ratio of the mass of moisture in the air, relative to the mass at 100% moisture saturation, at a given temperature.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Reliability		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	An expression of the degree to which a measurement performed by different people at different times and under different circumstances produces the same results (see also validity).
Reliable quantification of drug needs		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A careful evaluation of the quantities needed of each drug, based on either adjusted past consumption or anticipated pattern of diseases and standard treatment, which can be expected to match actual needs reasonably well.
Repackaging		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The action of changing the packaging of the material.
Representative sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or the different properties of a non-uniform material are proportionately represented.
Reprocessing (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.
Reprocessing (2)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Subjecting all or part of a batch or lot of an in-process drug, bulk process intermediate (final biological bulk intermediate) or bulk product of a single batch/lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary for biological drugs and, in such cases, are validated and pre-approved as part of the marketing authorization.
Retention sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample collected as part of the original sampling process and reserved for future testing. The size of a retention sample should be sufficient to allow for at least two confirmatory analyses. In some cases statutory regulations may require one or more retention samples, each of which should be separately identified, packaged and sealed.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Retest date		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The date when a material should be re-examined to ensure that it is still suitable for use.
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	The date when a material should be re-examined to ensure that it is still suitable for use.
Retrospective validation		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Involves the evaluation of past experience of production on the condition that composition, procedures, and equipment remain unchanged.
Returned product		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Finished product sent back to the manufacturer.
Revalidation (1)		
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements.
Revalidation (2)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements.
Reworking		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Subjecting an in-process or bulk process intermediate (final biological bulk intermediate) or final product of a single batch to an alternate manufacturing process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and is not pre-approved as part of the marketing authorization.
Sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	A portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to allow all anticipated test procedures to be carried out, including all repetitions and retention samples. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector should record that the sampled material is the available sample (see Sampling record) and the evaluation of the results should take account of the limitations that arise from the insufficient sample size.
Sampler		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Person responsible for performing the sampling operations.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Sampling (1)		
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Operations designed to obtain a representative portion of a pharmaceutical starting material based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release, etc.
Sampling (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release.
Sampling method		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	That part of the sampling procedure dealing with the method prescribed for withdrawing samples.
Sampling plan		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Description of the location, number of units and/or quantity of material that should be collected, and associated acceptance criteria.
Sampling procedure		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	The complete sampling operations to be performed on a defined material for a specific purpose. A detailed written description of the sampling procedure is provided in the sampling protocol.
Sampling record		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Written record of the sampling operations carried out on a particular material for a defined purpose. The sampling record should contain the batch number, date and place of sampling, reference to the sampling protocol used, a description of the containers and of the materials sampled, notes on possible abnormalities, together with any other relevant observations, and the name and signature of the inspector.
Sampling unit		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Discrete part of a consignment such as an individual package, drum or container.
Selected sample		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	Sample obtained according to a sampling procedure designed to select a fraction of the material that is likely to have special properties. A selected sample that is likely to contain deteriorated, contaminated, adulterated or otherwise unacceptable material is known as an extreme sample.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Self-contained area		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings.
Serious adverse event		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	An event that is associated with death, admission to hospital, prolongation of a hospital stay, persistent or significant disability or incapacity, or is otherwise life threatening in connection with a clinical trial.
Shelf-life (1)		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The period of time during which a drug product, if stored correctly, is expected to comply with the specification* as determined by stability studies on a number of batches of the product. The shelf-life used to establish the expiry date of each batch. * "Shelf-life specification" means the requirements to be met throughout the shelf-life of the drug product (should not be confused with "release specification").
Shelf-life (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.
Shipping/dispatch		
	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	The assembly, packing for shipment, and sending of ordered medicinal products for clinical trials.
Single-dose container		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container for single doses of solid, semi-solid or liquid preparations.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Skip lot (periodic) testing	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The performance of specified tests at release on preselected batches and/or at predetermined intervals, rather than on a batch-to-batch basis, with the understanding that those batches not tested must still meet all the acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified, presented to, and approved by, the regulatory authority before implementation. When tested, any failure of the starting material to meet the acceptance criteria established for the periodic (skip lot) test should be handled by proper notification of the appropriate regulatory authority (authorities). If these data demonstrate a need to restore routine testing, then batch-by-batch release testing should be reinstated.
Specification (1)	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.
Specification (2)	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	A document describing in detail the requirements with which the pharmaceutical products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.
Specification (3)	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
Specifications	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See Appendix 3, explanatory note 7.
Specifications archive	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	An up-to-date collection of all quality specifications and related documents (see Part Two, section 9).
Sponsor (1)	Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans. (34th report, 1996)	An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Sponsor (2)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	An individual, a company, an institution or an organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.
Stability		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The ability of a pharmaceutical product to retain its chemical, physical, microbiological and biopharmaceutical properties within specified limits throughout its shelf-life.
Stability tests		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	A series of tests designed to obtain information on the stability of a pharmaceutical product in order to define its shelf-life and utilization period under specified packaging and storage conditions.
Standard operating procedure (SOP) (1)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
	Quality systems requirements for national good manufacturing practice inspectorates. (36th report, 2002)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Standard operating procedure (SOP) (2)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Standard operating procedure (SOP) (3)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	An authorized written procedure, giving instructions for performing operations, not necessarily specific to a given product or material, but of a more general nature (e.g. operation of equipment, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Standard operating procedure (SOP) (4)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master batch production documentation.
Standard operating procedure (SOP) (5)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.
Standard operating procedures (SOPs) (6)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Standard, detailed, written instructions for the management of clinical trials. They provide a general framework enabling the efficient implementation and performance of all the functions and activities for a particular trial as described in this document.
Starting material (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.
	Guidelines on import procedures for pharmaceutical products. (34th report, 1996)	Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Starting material (2)		
	WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation. (38th report, 2004)	See pharmaceutical starting material
Statement of licensing status		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 3.13 of the guidelines and Appendix 2.
Storage (1)		
	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	The storing of pharmaceutical products and materials up to their point of use.
Storage (2)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	The storing of pharmaceutical products up to the point of use.
Strip		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A multi-dose container consisting of two layers, usually provided with perforations, suitable for containing single doses of solid or semi-solid preparations. Blisters are excluded.
Study director		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	According to the Organisation for Economic Co-operation and Development (OECD) Principles of good laboratory practice: the individual responsible for the overall conduct of the nonclinical health and environmental safety study. In a bioequivalence trial, the individual responsible for the conduct of the bioanalytical part of the study.
Study product		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	See investigational product
Summary Basis of Approval		
	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	The document prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.7 of the guidelines and explanatory note 9 of the Product Certificate contained in Appendix 1).

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Summary of Product Characteristics (SPC) (1)	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	Product information as approved by the regulatory authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising (see also Product information).
Summary of product characteristics (SPC) (2)	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	A term used in the European Union. Product information or data sheets in the European Union should be based on the approved SPC.
Supplier (1)	Guide to good storage practices for pharmaceuticals. (37th report, 2003)	A person providing pharmaceutical products and materials on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where possible, suppliers should be authorized by a competent authority.
Supplier (2)	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc.
Supplier (3)	Good distribution practices for pharmaceutical products. (40th report, 2006)	persons or company providing pharmaceutical products on request. Suppliers include distributors, manufacturers or traders.
Supporting stability data	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	Supplementary data, such as stability data on small-scale batches, related formulations, and products presented in containers other than those proposed for marketing, and scientific rationales that support the analytical procedures, the proposed retest period or the shelf-life and storage conditions.
System	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	A regulated pattern of interacting activities and techniques that are united to form an organized whole.
Tenders and brokers	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 4.6 of the guidelines.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Test report		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	The report of the results, including the final conclusion of the analysis of a sample which has been submitted by a laboratory in another country or in the field not having appropriate facilities to perform certain tests, and issued by the official pharmaceutical control laboratory that performed the test. This is often in the same style as a certificate of analysis. (see Part Three, section 17.3).
Therapeutic activity		
	Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines. (40th report, 2006)	Therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and mental illnesses; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body and development of a sense of general well-being. (In: General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2000).
Therapeutic equivalence (1)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (Not on the new website) (34th report, 1996)	Two pharmaceutical products are therapeutically equivalent if they are pharmaceutically equivalent and after administration in the same molar dose their effects, with respect to both efficacy and safety, will be essentially the same, as determined from appropriate studies (bioequivalence, pharmacodynamic, clinical or in vitro studies).
Therapeutic equivalence (2)		
	Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. (40th report, 2006)	Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies.
Traceability		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	Traceability aims at ensuring that the results of laboratory measurements using procedures of lower metrological order are reproducible and scientifically acceptable by referring to an internationally agreed denominator by means of a reference procedure of highest metrological order and/or a primary reference material (see Part Two, section 13).
Transparency		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	The term transparency means: — defining policies and procedures in writing and publishing the written documentations; and — giving reasons for decisions to the public (see also accountability above).

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Trial subject		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	An individual who participates in a clinical trial, either as a recipient of the pharmaceutical product under investigation or as a control. The individual may be: –a healthy person who volunteers to participate in a trial; –a person with a condition unrelated to the use of the investigational product; –a person (usually a patient) whose condition is relevant to the use of the investigational product.
Tube		
	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A container for multi-dose semi-solid pharmaceutical forms consisting of collapsible material; the contents are released via a nozzle by squeezing the package.
Turbulent flow		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Turbulent flow, or non-unidirectional airflow, is air distribution that is introduced into the controlled space and then mixes with room air by means of induction.
Unauthorized market (in some countries called parallel market)		
	Guidelines for inspection of drug distribution channels. (35th report, 1999)	The unauthorized market consists of wholesale establishments and retail outlets distributing or selling drugs without authorization from a competent authority.
Unidirectional airflow (UDAF)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	Unidirectional airflow is a rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (see also turbulent flow). (Modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow.)
Uniformity		
	WHO guidelines for sampling of pharmaceutical products and related materials. (39th report, 2005)	A starting material may be considered uniform when samples drawn from different layers do not show significant differences in the quality control tests which would result in non-conformity with specifications. The following materials may be considered uniform unless there are signs to the contrary: organic and inorganic chemicals; purified natural products; various processed natural products such as fatty oils and essential oils; and plant extracts. The assumption of uniformity is strengthened by homogeneity, i.e. when the consignment is derived from a single batch.
Utilization period		
	Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms. (34th report, 1996)	The period of time during which a reconstituted preparation or finished dosage form in an opened multidose container can be used.

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Validation (1)		
	Good manufacturing practices for pharmaceutical products. (32nd report, 1992)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
	Good trade and distribution practices for pharmaceutical starting materials. (38th report, 2004)	The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.
Validation (2)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The collection and evaluation of data, beginning at the process development stage and continuing through the production phase, which ensure that the manufacturing processes — including equipment, buildings, personnel and materials — are capable of achieving the intended results on a consistent and continuous basis. Validation is the establishment of documented evidence that a system does what it is supposed to do.
	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	The collection and evaluation of data, beginning at the process development stage and continuing through the production phase, which ensure that the manufacturing processes — including equipment, buildings, personnel and materials — are capable of achieving the intended results on a consistent and continuous basis. Validation is the establishment of documented evidence that a system does what it is supposed to do.
Validation (3)		
	Good Manufacturing Practices for pharmaceutical products: main principles. (37th report, 2003)	Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).
Validation (4)		
	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	The documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results.
Validation (5)		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results .
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results .
Validation (6)		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	Action of proving, in accordance with the principles of GCP and GLP, that any procedure, process, equipment (including the software or hardware used), material, activity or system actually and consistently leads to the expected results.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Validation (7)	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	Action of proving and documenting, in accordance with the principles of good manufacturing practice, that any procedure, process, or method actually and consistently leads to the expected results (see also qualification above).
Validation master plan (VMP) (1)	Supplementary guidelines on good manufacturing practice for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (40th report, 2006)	VMP is a high-level document which establishes an umbrella validation plan for the entire project, and is used as guidance by the project team for resource and technical planning (also referred to as master qualification plan).
Validation master plan (VMP) (2)	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	VMP is a high-level document that establishes an umbrella validation plan for the entire project and summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's validation work programme and defines details of and timescales for the validation work to be performed, including statement of the responsibilities of those implementing the plan.
Validation of analytical procedures/methods	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	The documented evidence that analytical procedures or methods are suitable for their intended purpose. (Department of Health and Human Services, Food and Drug Administration. International Conference on Harmonisation; guidelines on validation of analytical procedures: definitions and terminology; availability. Federal Register, 1995, 60(40):11260–11262.).
Validation protocol (or plan) (1)	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process - or a part thereof - for routine use.
Validation protocol (or plan) (VP) (2)	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process - or a part thereof - for routine use.
Validation report (1)	Good manufacturing practices: guidelines on the validation of manufacturing processes. (Not on the new website) (34th report, 1996)	A document in which the records, results and evaluation of a completed validation programmed are assembled. It may also contain proposals for the improvement of processes and/or equipment.

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<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Validation report (VR) (2)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	A document in which the records, results and evaluation of a completed validation programme are assembled and summarised. It may also contain proposals for the improvement of processes and/or equipment.
Validity		
	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	An expression of the degree to which a measurement performed actually measures the characteristic which the investigator wishes to measure (see also reliability above).
Vector		
	Guidelines for assuring the quality of pharmaceutical and biological products prepared by recombinant DNA technology. (Not on the new website) (32nd report, 1992)	A piece of DNA that can direct its own replication within a host cell and to which other DNA molecules can be attached and thus amplified. Many vectors are bacterial plasmids, but in other instances a vector may be integrated into the host-cell chromosome following its introduction into the cell and is maintained in this form during the growth and multiplication of the host organism.
Vehicle		
	Good distribution practices for pharmaceutical products. (40th report, 2006)	Vehicle refers to trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.
Verification (1)		
	Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals. (37th report, 2003)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.
Verification (2)		
	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the GMP principles.
Verification (validation) of data		
	Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms. (40th report, 2006)	The procedures carried out to ensure that the data contained in the final report match original observations. These procedures may apply to raw data, data in case-report forms (in hard copy or electronic form), computer printouts and statistical analysis and tables.
Verification of methods		
	Good practices for national pharmaceutical control laboratories. (36th report, 2002)	Verification is conducted where the methods are compendial to confirm whether the pharmaceutical product as compounded can be analysed satisfactorily by the official method.

QAS Terminology db - List of Terms and related guidelines

<u>Term</u>	<u>Related reference(s)</u>	<u>Definition</u>
Vial	Guidelines on packaging for pharmaceutical products. (36th report, 2002)	A small container for parenteral medicinal products, with a stopper and overseal; the contents are removed after piercing the stopper. Both single-dose and multi-dose types exist.
Well-established drugs	Guidelines for registration of fixed-dose combination medicinal products. (39th report, 2005)	Actives that: — have been marketed for at least 5 years in countries that undertake active postmarket monitoring; — have been widely used in a sufficiently large number of subjects to permit the assumption that safety and efficacy are well known; and — have the same route of administration and strength and the same or similar indications as in those countries.
WHO responsibility	Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. (34th report, 1996)	See section 5.4 of the guidelines.
WHO-type certificate	A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products. (40th report, 2006)	A certificate of pharmaceutical product of the type defined in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce* . *World Health Organization. WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva, World Health Organization, 2000 WHO/EDM/QSM/2000.2. (http://www.who.int/medicines/organization/qsm/activities/drugregul/certification/certifschemes.html).
Worst case	Supplementary guidelines on good manufacturing practices: validation. (40th report, 2006)	A condition or set of conditions encompassing upper and lower processing limits for operating parameters and circumstances, within SOPs, which pose the greatest chance of product or process failure when compared to ideal conditions. Such conditions do not necessarily include product or process failure.