



**World Health
Organization**

QSM/EC/10.01

**EXPERT COMMITTEE ON SPECIFICATIONS
FOR PHARMACEUTICAL PREPARATIONS
Geneva, 18-22 October 2010**

Original: English

Draft agenda

1. General policy

- Cross-cutting pharmaceuticals quality assurance issues
 - WHO Expert Committee on Biological Standardization
 - WHO Expert Committee on the Selection and Use of Essential Medicines
 - Herbal and complementary medicines
- International collaboration:
 - International organizations and agencies
 - Pharmacopoeial Discussion Group (PDG)
 - International Conference on Harmonisation (ICH)
 - International Conference of Drug Regulatory Authorities (ICDRA)
- Spurious/falsely-labelled/falsified/counterfeit medical products

2. Quality Control – Specifications and Tests

- *The International Pharmacopoeia*
- Specifications for medicines, including paediatrics
- General monographs for dosage forms and associated method texts

3. Quality Control – International Reference materials (International Chemical Reference Substances and Infrared Reference Spectra)

- Update on transfer of International Chemical Reference Substances
- Report of the host organization

4. Quality Control – National Laboratories

- External Quality Assurance Assessment Scheme
- WHO good practices for pharmaceutical microbiology laboratories

5. Quality Assurance – Good Manufacturing Practices

- WHO good manufacturing practices (GMP): main principles for pharmaceutical products
- WHO GMP for biologicals
- WHO GMP for blood establishments
- Discussion on updates of other WHO GMP texts:
 - Heating, ventilation and air-conditioning (HVAC) systems for non-sterile pharmaceutical dosage forms
 - Water for pharmaceutical use

6. Quality Assurance – New approaches

- Risk analysis
- WHO guideline on technology transfer

7. Quality assurance – distribution and trade of pharmaceuticals

- WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce
- Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services

8. Prequalification of priority essential medicines

- Update on the Prequalification Programme managed by WHO
- Update on the procedure

9. Prequalification of quality control laboratories

- Update on the prequalification of quality control laboratories
- Update on the Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies.
- Update on the WHO guidelines for preparing a laboratory information file (LIF)

10. Prequalification of active pharmaceutical ingredients

- Update on the prequalification of active pharmaceutical ingredients

11. Regulatory guidance

- Pharmaceutical development for multisource (generic) pharmaceutical products
- Guideline on submission of documentation for a multisource finished product:
 - general format
 - quality part
- Development of paediatric medicines: pharmaceutical development
- Guideline for the production and control of specified starting materials
- Site master file (SMF)

12. Nomenclature, terminology and data bases

- Quality assurance terminology
- International Nonproprietary Names (INN) for pharmaceutical substances

13. Miscellaneous

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