



PREQUALIFICATION OF
MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME
MANAGED BY WHO



World Health
Organization

2nd Meeting with Medicine Manufacturers

Tuesday, 5 April 2011

Centre International de Conférences (CICG), 17 Rue de Varembé, Geneva

Proposed Agenda

DOSSIER ASSESSMENT WORKSHOP Meeting room: Salle 1 Moderator: Dr Matthias Stahl			GMP WORKSHOP Meeting room: 5/6 Moderator: Dr Andre van Zyl		
09:00-09:05	Welcome and introduction	Dr Matthias Stahl	09:00-09:05	Welcome and introduction	Dr Andre van Zyl
09:05-09:35	New generic quality guideline and templates	Mrs Lynda Paleshnuik	09:05-09:40	Inspection of API manufacturers	Mr Deus Mubangizi
09:35-10:05	API prequalification and APIMFs	Dr Antony Fake	09:40-10:10	Approach to QC laboratory inspections and common findings	Ms Stephanie Croft
10:05-10:20	Variations - updates	Mrs Yin Hua	10:10-10:45	Panel discussion	All
10:20-10:50	Coffee/tea break	Outside Salle 1	10:45-11:15	Coffee/tea break	Outside Salle 1

10:50-11:20	<p>Bioequivalence</p> <p>a. Comparators; update of lists, where to source, examples of documentation to be provided to support the comparator (package label, etc.) and</p> <p>b. When the BE study should be conducted as fasted and when fed with specific mention of APIs falling into each group.</p>	Dr John Gordon/ Dr Jan Welink	11:15-12:00	Good documentation and quality management principles (including deviations, change control, quality risk management and product quality review)	Mr Vimal Sachdeva
11:20-12:30	Panel discussion	All	12:00-12:30	Follow-up to manufacturer survey: Discussion on WHO GMP versus EU or US FDA GMP requirements.	Dr Andre van Zyl
			12:30-13:00	Panel discussion	All
Afternoon (starting 12.30pm)	<p>Appointments with individual manufacturers¹</p> <p>Meeting room 15</p>	All	Afternoon	<p>Appointments with individual manufacturers²</p> <p>Meeting room: 7</p>	All