Draft agenda

Private session (invited participants and observers)

OPENING

Election of chairpersons and rapporteurs

Open session

Introduction and welcome

1. General policy

   – Cross-cutting pharmaceuticals quality assurance issues
     (including local manufacturing, GHPP, MSM, ECBS, EC-EML, AMR)
   – International collaboration

Private session (invited participants and observers)

2. Quality control – specifications and tests

   – The International Pharmacopoeia
   – General policy
   – General chapters
   – General monographs for dosage forms and associated method texts
   – Specifications and draft monographs for medicines, including paediatrics and radiopharmaceuticals

   – Update on International Chemical Reference Substances, including report of the dedicated Expert Committee on Specifications for Pharmaceutical Preparations subgroup on International Chemical Reference Substances
   – Report of the custodian centre
   – General policy

4. Quality control – national laboratories

   – External Quality Assurance Assessment Scheme
   – Considerations for requesting analysis of medicines samples and model certificate of analysis
   – Guidance on testing of “suspect” substandard/falsified medical products
   – Update and recommendations from laboratory specialists’ meeting

5. Prequalification of quality control laboratories

   – Update on the prequalification of quality control laboratories
   – Update on World Health Organization (WHO) quality monitoring projects

6. Quality assurance – collaboration initiatives

   – International meetings of world pharmacopoeias
   – Good pharmacopoeial practices
   – Inspection guidelines and good practices

7. Quality assurance – good manufacturing practices

   – Guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems (HVAC)
   – WHO good manufacturing practices: validation, including main principles and specific texts (water, cleaning, computerized systems, qualification of systems and equipment, non-sterile)
8. **Regulatory guidance**

- Regulatory requirements on *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products*
- Biowaiver list based on the WHO List of Essential Medicines
- Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities
- Good practices for implementing the collaborative procedures
- Good regulatory practices
- Recommendations from the meeting on regulatory guidance for multisource products

9. **Prequalification of priority essential medicines and active pharmaceutical ingredients**

- Update on the prequalification of medicines
- Update on the prequalification of active pharmaceutical ingredients

10. **Nomenclature, terminology and databases**

- Quality assurance terminology
- Guidelines and guidance texts adopted by the Expert Committee
- International Nonproprietary Names for pharmaceutical substances
- Revision of guidance on representation of graphic formulae

11. **Miscellaneous**

- WHO Department of Essential Medicines and Health Products strategic vision
- Communication strategy and networking