

2010 EDQM SYMPOSIUM: SOUTH AFRICA

Effectively using the European Pharmacopoeia, Pharmaceutical Reference Standards & the Certification Procedure

Duration: 1.5 days

Location: CSIR Convention Centre, Pretoria, South Africa

Working language: English

Sponsored by

South African Association of Pharmacists in Industry (SAAPI)

PROGRAMME

Monday 12 April 2010

9:00-9:15 Opening remarks and general introduction

Dr Andrea Lodi, Head of Laboratory Dept, EDQM, Council of Europe

9:15-9:45 European regulations for medicines: how does the system work?

The place and roles of the EDQM and the European Pharmacopoeia

Dr Andrea Lodi, Head of Laboratory Dept, EDQM, Council of Europe

9:45-10:45 General concepts in the European Pharmacopoeia: theory and rationale

Dr Andrea Lodi, Head of Laboratory Dept, EDQM, Council of Europe

10:45-11:15 Break

Pharmaceutical Reference Standards

11:15-11:45 Scientific Establishment: general concept (definitions, types), analytical characterisation, approval process, participation of industry, continuous fitness-for-use verification programme.

Dr Ulrich Rose, Scientific Administrator, Laboratory Dept, EDQM, Council of Europe

11:45-12:15 Procurement, Manufacturing, Distribution and Use: how presented, catalogue, how to order, storage, shipment, how to get information (leaflet, BVS), customer assistance

Mr Vincent Egloff, Head of Reference Standards and Samples Division, EDQM, Council of Europe

12:15-12:30 Discussion

12:30-13:30 Lunch break

13:30-14:15 Pharmaceutical Reference Standard specific cases: Assay standards, Impurities, Herbals, Biologicals/Microbiologicals

Dr Ulrich Rose, Scientific Administrator, Laboratory Dept, EDQM, Council of Europe

14:15-14:30 Discussion

14:30-15:15 **General presentation of the Certification Procedure: The role of Certification as a regulatory system; Comparison of CEP and Active Substance Master File (ASMF)**

Ms Fiona McLeod, Scientific Administrator, Certification Division, EDQM, Council of Europe

15:15-15:45 **Break**

15:45-16:30 **The EDQM Inspection Programme & consequences of suspensions**

Ms Fiona McLeod, Scientific Administrator, Certification Division, EDQM, Council of Europe

16:30-17:00 **Round Table Discussion**

Tuesday 13 April 2010

9:00-10:30 **Description of the CEP Procedure:**

- **How to prepare a new application – content of the dossier**
- **Revisions/renewals of CEPs**

Ms Fiona McLeod, Scientific Administrator, Certification Division, EDQM, Council of Europe

10:30-11:00 **Break**

11:00-12:00 **Products & Services: European Pharmacopoeia 7th Edition and the EDQM internet sites**

Mr Vincent Egloff, Head of Reference Standards and Samples Division, EDQM, Council of Europe

12:00-12:30 **Round Table Discussion**