

IDMA APA PAC 2006

23-24 January 2006
Mumbai

“THE EUROPEAN PHARMACOPOEIA”

NEW FEATURES AND THE LATEST DEVELOPMENTS IN THE EUROPEAN PHARMACOPOEIA 5TH EDITION

FINAL PROGRAMME

Monday 23 January 2006

9.00 am to 9.30 am Registration

9.30 am to 10.45 am INAUGURAL SESSION

Introductory remarks (Mr Daara B Patel)
Welcome address
Address by Chief Guest
Awards
Key Note Speaker
Vote of thanks

10.45 am to 11.00 am Coffee / tea break

General introduction to the European regulatory requirements for registration of medicines

11.00 am to 11.30 am Dr Agnès Artiges, Director, EDQM, Council of Europe

Monograph development process for the European Pharmacopoeia. How to participate in the work programme of the European Pharmacopoeia?

11.30 am to 12.00 noon Dr Claude Coune, Head of Publications Division, EDQM, Council of Europe

EP-IP Collaboration Opportunities

12.00 noon -12.30 am Dr P R Pabrai

12.30 pm to 1.15 pm LUNCH

How to use the European Pharmacopoeia: general monographs /general chapters / specific monographs

1.15 to 1.45 pm Dr Claude Coune, Head of Publications Division, EDQM, Council of Europe

The new impurity policy of the European Pharmacopoeia: General principles & case studies

1.45 to 2.30 pm Dr Andrea Lodi, Deputy Head of Laboratory, EDQM, Council of Europe

2.30 pm to 3.00 pm Open discussion with the audience

3.00 pm to 3.30 pm Coffee/ tea break

Opportunities for Indian Laboratories' Participation in Development & Synthesis of Impurities

3.30 pm to 4.00 pm Eminent Indian Speaker

Pharmacopoeial harmonisation – dream or reality?

4.00 pm to 4.30 pm Dr Agnès Artiges, Director, EDQM, Council of Europe

Panel Discussion

4.30 pm to 6.00 pm

Tuesday 24 January 2006

Certification of suitability to the European Pharmacopoeia monograph: Methodology, process to obtain a certificate. Common Deficiencies

9.00 am to 10.00 am Dr Andrew McMath, Certification Unit, EDQM, Council of Europe
10.00 pm to 10.30 am Indian experience – Dr Manoj Patel
10.30 am to 11.00 am Coffee/ tea break

Certification of suitability Programme of inspections: why it was established, who is involved and how it works. Variations, revision, update and renewals to certificates. Technical advice: how to obtain advice and the benefits of exchanging information

11.00 am to 11.30 am Mrs Hélène Bruguera, Certification Unit, EDQM, Council of Europe

Mutual recognition and collaboration at international level: the Canadian experience

11.30 am to 12.00 am The Canadian representative (EDQM proposition: Dr Sultan Ghani, Director, Health Canada)
12.00 am to 12.30 am The Indian experience – Dr Nandakumar Chodankar
12.30 pm to 1.30 pm LUNCH

European Pharmacopoeia publications: The 5th Edition, New developments to be included in the 6th Edition, Pharmeuropa printed and online (new), Pharmeuropa Scientific Notes (new), List of Standard terms printed and online (new)

1.30 pm to 2.30 pm Dr Claude Coune, Head of Publications Division, EDQM, Council of Europe

European Pharmacopoeia reference standards: Terminology, how they are established, how they are distributed and how they are to be used.

2.30 pm to 3.30 pm Dr Andrea Lodi, Deputy Head of Laboratory, EDQM, Council of Europe

Opportunities for collaboration of Indian firms with the European Pharmacopoeia by an Indian representative

3.30 pm to 4.00 pm Mr Anthony Gomes

4.00 pm to 4.30 pm Coffee/ tea break

European Pharmacopoeia Internet sites: Features which will help you conduct your regulatory surveillance. How to make the best use of the online services, specialised databases and the new users' support: the HELPDESK

4.30 pm – 5.15 pm Mrs Caroline Larsen Le Tarnec, Head of Public Relations Unit, EDQM, Council of Europe

Panel Discussion

5.15 pm to 6.15 pm

6.15 pm to 6.30 pm

Concluding Remarks