

Towards New Challenges in Global Regulatory Perspectives

2010
IPA/EDQM/IPC
TECHNICAL CONFERENCE

28th- 29th January, 2010 at Hyatt Regency, Mumbai



Organized by



Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400098. India.
Phone : +91-22-2667 1072, Telefax : +91-22-2667 0744
E.mail : ipacentre@ipapharma.org, Website : www.ipapharma.org

Jointly with



Indian Pharmacopoeia Commission

Agenda Day - 1

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Thursday
28 January, 2010

08.30 – 09.00	Registration
09.00 – 09.10	Welcome Address
09.10 to 09.40	Keynote Address – Recent Global initiatives from USFDA – Overview of activities in India – Dr. Albinus D'sa, Deputy Director, USFDA India
09.40 to 10.00	Awards
10.00 to 10.30	Tea Break

Session 1 : Monograph Development & Recent Advances in Pharmacopoeial Sciences

10.30 to 11.00	: EU Pharmaceutical legislation - Dr. Claude Coune, Head of Publications & Multimedia Division, EDQM, Council of Europe
11.00 to 11.30	: How to use the General Monograph 'Substances for pharmaceutical use' and chapter 5.10 'control of impurities' - Mr. Stefan Almeling, Deputy Head of Laboratory Department, EDQM, Council of Europe
11.30 to 12.00	: General Concepts in the European Pharmacopoeia: theory and rationale - Dr. Claude Coune, Head of Publications & Multimedia Division, EDQM, Council of Europe
12.00 to 12.30	: Impurities characterization and controls – Genotoxic, catalyst, heavy metals and residual solvents - Mr. Manish Gangrade (EU/US comparisons)

12.30 to 01.30 Lunch Break

Session 2 : Reference Standards and Impurities

01.30 to 02.00	: Industry Perspective of characterization and use of reference standards – Dr. Antony Gomes
02.00 to 02.45	: Identification of the need and uses of a Reference Standard. Overview of the policy and process used to establish and distribute a reference standard - Mr. Stefan Almeling, Deputy Head of Laboratory Department, EDQM, Council of Europe

02.45 to 03.00 Tea Break

Session 3 : Applications of New Techniques in Supply Chain Management

03.00 to 03.30	: Development of non-destructive methods for qualifying raw materials and APIs – Smart Supply Chain Management – Mr. Ken Williams
03.30 to 04.00	: Rapid Techniques in microbiological analysis and contamination control – Mr. Ramesh Raju, Technical Manager, Millipore – Bioprocess

Session 4 : Pharmacopoeia Harmonization

04.00 to 04.30	: What's new in IP 2010 – Dr. Raman Singh
04.30 to 05.00	: Specific Monographs; a guide through the different sections - Dr. Claude Coune, Head of Publications & Multimedia Division, EDQM, Council of Europe



Agenda Day - 2

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Session 5 : Global GMP Inspection : EU, USA, WHO-India

09.00 to 09.45 : What's most recent in EDQM Inspections ? – **Dr. Andrew McMath, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe**

09.45 to 10.15 : GMP Challenges to Global : Pharma Companies – Regulatory impact of application of Q8/Q9/Q10 ICH Guidelines – **Mr. Muralidhara Gavini, Sr. Asst. Country Director, USFDA (FDA), Dept. of Health & Human Services**

10.15 to 10.30 Tea Break

10.30 to 11.15 : Recent Focus in WHO Inspection – **Dr. Venugopal Somani, Deputy DCGI**

Session 6 : Certification procedures and submissions of dossiers/DMFs

11.15 to 11.45 : e-CTD norms for INDs, DMFs and CTA study Report – **Dr. Nandkumar Chodankar**

11.45 to 12.15 : General Presentation of the certification procedure :

- The place of Certification as a Regulatory Tool
- Comparison of CEP and Active Substance Master File (ASMF)
- Description of the CEP Procedure – **Dr. Andrew McMath, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe**

12.15 to 01.00 : How to prepare a new application – content of the dossier - **Mrs Nathalie Vicente, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe**

01.00 to 2.00 Lunch Break

Session 7 : Pharmacovigilance & Drug Safety/Labeling Norms

02.00 to 02.45 : Pharmacovigilance : work undertaken by the International Standard Organisation in co-operation with the ICH - **Dr. Claude Coune, Head of Publications & Multimedia Division, EDQM, Council of Europe**

02.45 to 03.30 : Indian perspective of pharmacovigilance and drug safety – **Dr. Darshan Bhatt**

03.30 to 03.45 Tea Break

Session 8 : Recent advancements in pharmacopoeial and collaborative studies : EP 7.0

03.45 to 04.45 : EDQM publications and services : special focus on the European Pharmacopoeia 7th edition – **Mrs. Caroline Larsen Le Tarnec, Head of Public Relations & Documentation Division, EDQM, Council of Europe**

04.45 to 05.45 : Panel Discussion and Conclusion

Friday

29 January, 2010



Indian Pharmaceutical Association (IPA)

Indian Pharmaceutical Association (IPA) is the premier professional association of pharmacists in India, with a member base of over 10,000, spread across the length & breadth of the nation. IPA operates in India through 17 state branches & more than 33 local branches. The members represent various facets of pharmaceutical profession viz. Industry, regulatory, community pharmacy, hospital pharmacy & education. IPA is also actively associated in managing several academic programs. IPA is affiliated with international pharma associations like FIP, FAPA, CPA, AAPS, AAiPS, IPSF & WHO, for carrying out various collaborative professional activities which include organizing training programs for professionals from industry, academics, regulatory & practice, making representations to the authorities on matters of professional interest & working towards constantly upgrading the standards of professional services offered by the pharmacists.

European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

The EDQM is a key European organisation involved in the harmonisation and co-ordination of standardisation, regulation and quality control of medicines, blood transfusion, organ transplantation, pharmaceuticals and pharmaceutical care, cosmetics and food packaging. It is responsible for the Technical Secretariat of the European Pharmacopoeia Commission and other support activities related to the use of the European Pharmacopoeia (PhEur), such as the Certification of Suitability of Monographs and the European Network of Official Control Laboratories (OMCL) for medicines for human and veterinary use. It provides official reference standards for use in conducting official Ph. Eur. tests and assays.

Website: www.edqm.eu and www.edqm.eu/store.

Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution under the Ministry of Health & Family Welfare, Govt. of India dedicated for setting of standards for drugs, pharmaceuticals and healthcare devices/ technologies etc besides providing Reference Substances and Training.

About the Program

The theme of the Conference is **Towards New Challenges in Global GMP & Regulatory Perspectives**. The program aims at providing a common platform to visiting officials from EDQM, senior members from the Indian Pharmacopoeia Commission & the top brass from the regulatory & QA sectors of the Indian pharma industry, to deliberate on some of the burning issues plaguing the regulatory submissions, approvals & inspection procedures. The Convention would be the ideal forum to explore opportunities for joint exercises between the European & Indian regulatory authorities & would help in charting out a comprehensive roadmap for big & mid-size Indian pharma companies for successful forays into the European & global markets.

The program of the conference is geared to address the concerns of the Indian industry with regards to complying with the EU regulatory specifications & would have sessions focused on providing the latest updates on the recent developments in EDQM & Indian Pharmacopoeia, current approval, inspection & certification procedures & monograph development & evaluation processes.

Who should Attend

- Bulk Drug Manufacturers
- Regulatory Officials
- Regulatory Experts
- Academia
- R & D Executives from Pharma Industry
- QA/QC Personnel
- Pharma Consultants
- Pharmacy Students

Registration Fees:

IPA MembersRs. 5,000/-
Non IPA Members.....Rs. 6,000/-
Academia/ Students.....Rs. 3,000/-
Spot Registration (All).....Rs. 6,000/-
Foreign Delegates.....US \$150
Highest participation award for company.
No cancellation however, substitution acceptable.

Sponsorship:

Scientific sessions (4).....Rs. 50,000 each
Tea/Coffee (4).....Rs. 25,000 each
Lunch (2).....Rs. 50,000 each
Table Space (12).....Rs. 50,000 each
Gala Dinner (1).....Rs. 1,00,000

Please sent your remittance by Cheque / DD in favor of "IPA Mumbai" Payable at Mumbai

Organizing Committee

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President, IPA

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Director, EDQM

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Kaushik Desai

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