

# Theme – Towards New Challenges in Global Regulatory Perspectives



28<sup>th</sup> - 29<sup>th</sup> January, 2010 at Hyatt Regency, Mumbai

## Day - 1: 28 January 2010, Thursday

| Time  | Program   |
|---|---|
| 08:30 to 09:00  | Registration  |
| 09:00 to 09:10  | Welcome Address   |
| 09:10 to 09:40  | Keynote Address - Recent Global initiatives from USFDA - Overview of activities in India - <b>Dr. Albinus D'sa, Deputy Director, USFDA India</b>  |
| 09:40 to 10:00  | Felicitations   |
| 10:00 to 10:30  | Tea Break   |
| <b>Session 1 - Monograph Development &amp; Recent Advances in Pharmacopoeial Sciences</b> |   |
| 10:30 to 11:00  | EU Pharmaceutical Legislation - <b>Dr. Claude Coune, Head of Publications &amp; Multimedia Division, EDQM, Council of Europe</b>  |
| 11:00 to 11:30  | How to use the General Monograph "Substances for Pharmaceutical use" and Chapter 5.10 "Control of Impurities" - <b>Mr. Stefan Almeling, Deputy Head of Laboratory Department, EDQM, Council of Europe</b>   |
| 11:30 to 12:00  | General Concepts in the European Pharmacopoeia : Theory and Rationale - <b>Dr. Claude Coune, Head of Publications &amp; Multimedia Division, EDQM, Council of Europe</b>  |
| <b>Session 2 - Applications of New Techniques in Smart Supply Chain Management</b>        |   |
| 12:00 to 12:30  | Development of non-destructive methods for qualifying raw materials and APIs - Smart Supply Chain Management - <b>Mr. Ken Williams</b>  |
| 12:30 to 01:00  | Rapid Techniques in microbiological analysis and contamination control - <b>Mr. Ramesh Raju, Technical Manager, Millipore - Bioprocess</b>  |
| 01:00 to 01:30  | Impurities characterization and controls - Genotoxic, catalyst, heavy metals and residual solvents - <b>Mr. Manish Gangrade (EU/US comparisons)</b>   |
| 01:30 to 02:30  | Lunch Break   |
| <b>Session 3 - Reference Standards and Impurities</b>                                     |   |
| 02:30 to 03:00  | Industry Perspective of characterization and use of reference standards - <b>Dr. Antony Gomes</b>   |
| 03:00 to 03:30  | Identification of the need and uses of a Reference Standard. Overview of the policy and process used to establish and distribute a reference standard - <b>Mr. Stefan Almeling, Deputy Head of Laboratory Department, EDQM, Council of Europe</b> |
| 03:30 to 04:00  | Tea Break   |
| <b>Session 4 - Pharmacopoeia Harmonization</b>  |   |
| 04:00 to 04:30  | What's new in IP 2010 - <b>Dr. Raman Singh</b>  |
| 04:30 to 05:00  | Specific Monographs; a guide through the different sections - <b>Dr. Claude Coune, Head of Publications &amp; Multimedia Division, EDQM, Council of Europe</b>  |
| 05:00 to 05:30  | PANEL DISCUSSION  |

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## Day - 2 : 29 January 2010 - Friday

| Time   | Program  |
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| <b>Session 5 - Global GMP Inspection : EU, USA, WHO-India</b>  |  |
| 09:00 to 09:45   | What's most recent in EDQM Inspections ? - <b>Dr. Andrew McMath, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe</b>   |
| 09:45 to 10:15   | GMP Challenges to Global : Pharma Companies - Regulatory impact of application of Q8/Q9/Q10 ICH Guidelines - <b>Mr. Muralidhara Gavini, Sr. Asst. Country Director, USFDA (FDA), Dept. of Health &amp; Human Services</b>  |
| 10:15 to 10:30   | Tea Break  |
| 10:30 to 11:15   | Recent Focus in WHO Inspection - <b>Dr. Venugopal Somani, Deputy DCGI</b>  |
| <b>Session 6 - Certification procedures and submissions of dossiers/DMFs</b>                         |  |
| 11:15 to 11:45   | e-CTD norms for INDs, DMFs and CTA study Report - <b>Dr. Nandkumar Chodankar</b>   |
| 11:45 to 12:15   | General Presentation of the certification procedure : <ul style="list-style-type: none"> <li>● The place of Certification as a Regulatory Tool</li> <li>● Comparison of CEP and Active Substance Master File (ASMF)</li> <li>● Description of the CEP Procedure - <b>Dr. Andrew McMath, Scientific Administrator, Certification of Substances Division, EDQM, Council of Europe</b></li> </ul> |
| 12:15 to 01:15   | Lunch Break  |
| <b>Session 7 - Pharmacovigilance &amp; Drug Safety/Labeling Norms</b>                                |  |
| 01:15 to 02:00   | Norms for EU Nations - <b>Dr. Claude Coune, Head of Publications &amp; Multimedia Division, EDQM, Council of Europe</b>  |
| 02:00 to 02:45   | Indian perspective of pharmacovigilance and drug safety - <b>Dr. Darshan Bhatt</b>   |
| 02:45 to 03:00   | Tea Break  |
| <b>Session 8 - Recent advancements in pharmacopoeial and collaborative studies : EP 7.0, IP 2010</b> |  |
| 03:00 to 04:00   | EDQM publications and services : special focus on the European Pharmacopoeia 7 <sup>th</sup> edition - <b>Mrs. Caroline Larsen Le Tarnec, Head of Public Relations &amp; Documentation Division, EDQM, Council of Europe</b>   |
| 04:00 to 05:00   | PANEL DISCUSSION   |

