

IDMA - IPC - USP 9th Annual Scientific Meeting 2010 - Report

The IDMA-IPC-USP 9th Annual Scientific meeting 2010 (ASM) was held on 18th and 19th February 2010 at Hyatt Regency Hotel, Mumbai. Around 350 participants from the diverse sections such as Quality Control, Quality Assurance, Regulatory, Production, R&D, Marketing etc attended the convention. Invitees from the FDA Maharashtra, FDA Gujarat, CDSCO, US -FDA, IPC, USP, USP-India Advisory group members were also present. The main theme of this year's meeting was **"Standards without Borders: Protecting the Public Health in the Modern World"**. This meeting aimed at fostering constructive scientific dialogue that will lead to stronger public standards for medicines and food ingredients used around the world.

Prior to the Annual Scientific Convention, the following important meetings took place on 17th February 2010:

- USP India Stakeholder Forum
- USP India Advisory Group
- IPC-USP Monographs/ Reference standards Advisory Panel
- IPC-USP Biologics & Biotechnology: Proteins & Polysaccharides Advisory Panel
- Pharmexcil-IPC-USP Advisory Panel on Monographs for Herbal Ingredients & Products

Dr. Roger Williams, CEO of USP convention inaugurated the exhibit area.

Mr. Daara B Patel, Secretary General of IDMA facilitated the inaugural session. The meeting commenced with the lighting of the lamp by Dr. Roger Williams & other dignitaries such as Dr. G.N. Singh, Secretary cum Scientific Director, IPC; Mr. N R Munjal, President, IDMA; Dr. Swati Piramal, Director, Strategic Alliances & Communications, Piramal Healthcare; Mr Ajit Singh, Chairman, ACG Worldwide. Dr. Roger Williams also did the honor of releasing the souvenir. The IDMA President Mr Munjal made opening remarks and welcomed all the participants & the dignitaries. He informed that this meeting will provide an opportunity to better understand the scope of Pharmacopoeias scientific work and provide inputs on key standards-setting issues.

Mr. Ajit Singh, the moderator of the opening business session introduced the speakers of the session. Dr. Williams appreciated IDMA in organizing this meeting. He spoke about the role of the compendia and highlighted to improve the health of people around the world through public standards & related programs that help to ensure the quality, safety & benefits of medicines & foods. Dr. G N Singh mentioned about the strategic goals & focus area of Indian Pharmacopoeia Commission in maintaining the standards of Indian medicines. Mr. Bruce Ross, Director-India Office, US FDA outlined the "Call to arms" for FDA to establish foreign offices and discuss the priorities and purposes of the India Office in particular. He mentioned that the Indian companies reportedly exported \$1.38 billion worth of medicines to the U.S. in 2007-08, 39 per cent (in dollar terms) per annum growth is observed in recent years and India has more FDA-approved plants than any other country. Ms Deepanwita Chattopadhyay, MD & CEO, IKP Knowledge Park made a presentation on *Promoting Innovative Pharma Startups*. Dr Sen Gupta from CII made a presentation on *Quality Requirements to attain Global Competence For Pharmaceutical & Biotechnology Sector*.

The keynote speaker Dr. Swati Piramal made an interesting presentation on *Discovery & Development of New Medicines in India*. She discussed about the current Indian Pharma scenario and policies such as maintaining the transparent & speedy regulatory system, bridging a gap between graduating students & industry, Tax incentives of R&D etc needed to create an ecosystem for innovation. She mentioned that by 2015 the Indian industry will use partnerships to transform itself completely.

Various speakers gave informative and thoughtful presentations at the plenary & concurrent sessions such as;

At the Plenary Session I on Advances in Medicines Regulation:

Dr. Albinus D'Sa, Deputy Director, India office, US FDA made a presentation on *USFDA-Advances in Medicines Regulation*; Dr. R. Ramakrishna, Deputy

Drugs Controller (India), West Zone, CDSCO gave presentation on *Advances in Indian Medicines Regulation with Special Focus on Pharmacopoeial Standards*; Dr. Taslimarif Saiyed, Director, Business Development and Strategic Alliances, C-CAMP gave presentation on *C-CAMP: Enabling Scientific Success in India* and Dr. Roger Williams made a presentation on *Role of the Compendia: USP*.

At the Plenary Session II on Approaches to Combat Counterfeit and Substandard Medicines:

Dr. Anthony DeStefano, Vice President, General Chapters, USP made two presentations, first on *Worldwide Landscape of Counterfeit Drugs* and second on *Progress Toward Establishing e-pedigree for Drug Products*; Mr. S. M. Mudda, Executive Director, Technical & Operations, Micro Labs Ltd made a presentation on *Anti-counterfeiting Initiatives*; Dr. R. K. Sanghavi, Chairman of Medical Subcommittee, IDMA gave a presentation on *The Fake Syndrome : Spurious, Adulterated, Misbranded & Substandard Medicines*.

At the Plenary Session III on Environmental Monitoring and Control in Manufacturing Area :

Mr. R. Raghunandan, Pharma Consultant made a presentation on *Environmental Monitoring & Controls For Sterile Product Manufacturing*; Mr. Vijay Kshirsagar, Executive Vice President and Corporate Quality Assurance & Regulatory Affairs of Unichem Laboratories made a presentation on *Environmental Monitoring for Non Sterile Manufacturing* and Dr. Radhakrishna S. Tirumalai, Senior Scientific Liaison, Documentary Standards Division, USP made a presentation on *USP Perspectives on Contamination Control and Monitoring in Non-Sterile Product Manufacturing*.

At the Plenary Session IV on Compendial Initiatives and Updates:

Dr. G.N. Singh and Dr. Roger Williams overviewed and updated on the Indian Pharmacopoeia Commission and United States Pharmacopeia.

At the Concurrent Session Track I on Measurement Science: General Approaches / Analytical Methods:

Dr. William Koch, Chief Standards Acquisition & Metrology Officer, USP made a presentation on

Traceability and also discussed on *Special Analytical Methods*; Dr. Barbara Jones, Director of RSE, USP made a presentation on *Certified Reference Materials*; Mr. P. Raghuram, Head – Regulatory Affairs, Shasun Chemicals & Drugs Ltd made a presentation on *Statistical Applications In Quality Control Laboratories*; Dr. K. Shivram, Vice President, Analytical Development Department, Sun Pharma gave presentation on *Impurity profiling of Drugs: Analytical Challenges*; Mr. Ch. Lakshmi Narayana, Diacel Chiral Technologies gave presentation on *Chiral Chromatography separations – milligram to MT scale*; Dr. Jan Castrop, Product Manager, Metrohm Autolab B V gave presentation on *Surface Plasmon Resonance: Principles and Applications*; Mr. Arun Kumar .S , Application Chemist; Agilent Technologies made a presentation on *The Future of Pharmacopoeia Testing for metal impurities*; Dr. Kevin Hool, Vice President - Applied Compendial Research, USP made presentation on *Advanced Mass Spectrometry at USP*.

At the Concurrent Session Track II on Biologics: Quality of Manufactured Medicines / Monoclonal Antibodies, Recombinant Therapeutics:

Dr. Jammi Narasimham, GM – Head Biotechnology, Shasun Chemicals & Drugs Ltd gave the presentation on *Host Cell Impurities: Quantitative assays for detection of HCP and HC-DNA*; Dr. Krishna Menon, Sr. Scientist, Analytical Development Lab, Intas Biopharmaceuticals Ltd. made a presentation on *Estimating Host Cell Proteins in Biopharmaceuticals*; Dr. G Nadamuni, Director- R&D, Gland Pharma made presentation on *Quality Control of Heparin & LMWHs*; Dr. Wes Workman, Chairman, USP Heparin Ad Hoc Advisory Panel made a presentation on *Heparin Monographs and Reference Standard Modernization*; Dr. Jaby Jacob, Associate Director, Biologics Development Center, Dr. Reddy's Lab made a presentation on *Comparative analysis of biosimilar monoclonal antibodies with reference products*; Dr. Venkat Mukku, Chief Scientific officer, Global Cellular Analytic Solutions Inc, USA made a presentation on *Binding Assays as Surrogate Potency Tests*; Dr. Tina Morris, Vice President, Biologics & Biotechnology, USP made presentation on *USP Horizontal Standards: Procedural Standards and Standards for Ancillary Materials* and Mr. Kapil Bhargava, Ex- Dy Drugs Controller (India) made presentation on *GMPs for Vaccines and Biologics*.

At the Concurrent Session Track III on Herbals/ Excipients/Food Ingredients:

Dr. James Griffiths, VP Excipients, Foods and Dietary Supplements, USP made two presentations, first on *Food Ingredients, Excipients, Dietary Supplements: Overview* and second on *Global Traditional Medicines*; Dr. Markus Lipp, Director Food Standards, USP gave presentation on *Trade in Food: Codex and International Standards Setting Activities*; Dr. Milind Joshi, President - Global Regulatory Management, JB Chemicals & Pharmaceuticals Ltd made presentation on *Herbals/ Excipients/Food Ingredients: Indian Manufacturer Perspectives*; Dr. Amit Agarwal, Director, Natural Remedies made a presentation on *Indian Manufacturers' Perspective; Herbal monographs*; Dr. Vaishali Tawde, Manager, Technical services, South Asia, Asean and ANZ, BASF India Ltd made a presentation on *Excipient innovation classification & regulatory acceptance*; Dr. M.K. Raina, Pharmaceutical Consultant gave presentation on *Indian Herbals - History, Tradition, and Opportunities*; Dr. Dhanabal Palanisamy, Professor & HOD, JSS University made a presentation on *HPTLC as a Tool for Standardization of Herbal Dietary Supplements*; Dr. Markus Lipp & Dr. James Griffiths jointly made the presentation on *Functional Foods*.

Concurrent Session Track IV on GMP/Supply Chain Management/ Transportation:

Mr. Antony Raj Gomes, Head, Corporate Quality Management & Regulatory, Shasun Chemicals & Drugs Ltd made presentation on *Quality Aspects in Pharmaceutical Supply Chain Management*; Mr. Sridharan Rangachari, National Procurement Officer, UNOPS gave presentation on *Quality Aspects of Supply Chain Management*; Dr. Srini Srinivasan made presentation on *USP's Verification Programs Conformity Assessments*; Dr. Sivaramakrishna, Asst. Vice President (QC & R) Malladi Drugs & Pharmaceuticals Ltd made presentation on *USP Verification Program : Our Perspective*; Mr. Subodh Priolkar, General Manager, Colorcon Asia Private Limited made presentation on *Supplier Certification – Industry Approaches and Initiatives*; Dr. Anthony DeStefano gave three presentations viz *Pitfalls in Establishing an Ethical Supply Chain, Good Storage and Shipping Practices for Drug Products,*

USP Chapter <1079> and Meeting the Requirements of IATA Perishable Cargo Regulations (Chapter 17): Air Transport Logistics for Time and Temperature Sensitive Healthcare Products; Mr. Anil Kabra, Country Account Manager – Life Sciences & Healthcare, DHL Express (I) Pvt Ltd made presentation on *Guidelines for Temperature Control of Drug Products during Storage and Transportation* and Mr. Kalyana Krishnan, Vice President – Supply Chain Management, Dr. Reddy's Labs gave presentation on *Challenges of Handling Pharmaceutical Compendia – SCM perspective*.

The various Plenary & Concurrent sessions were well moderated by the moderators such as Dr. B. Suresh, President, PCI; Dr. William Koch, Chief Standard Acquisition & Metrology Officer, USP; Dr. Tina Morris, Vice President, Biologics & Biotechnology, USP, Dr. V. Prakash, Director, Central Food Technology Research Institute; Dr. Premnath Shenoy, Director Regulatory Affairs, Astra Zeneca; Dr. Albinus D'Sa, Country Deputy Director, US FDA; Dr. Wes Workman, Chairman, USP Heparin Ad Hoc Advisory Panel; Dr. James Griffiths, VP Excipients, Foods and Dietary Supplements, USP; Dr. Ajit Dangi, President and CEO of Danssen Consulting; Mr. Devinder Pal, President & CEO of Catalyst Pharma Consulting and Dr. Milind Joshi, President – Global Regulatory Management, JB Chemicals & Pharmaceuticals Ltd.

The participants also interacted actively with the speakers. All the speakers & moderators were presented the mementos. Mr. Daara Patel presented a special memento to Dr. Roger Williams for his Dynamic vision & Perseverance in bringing USP to India & helping the Indian Pharma Industry to achieve Global Standards. "Maximum Delegate's Registration" for the IDMA- IPC- USP 9th ASM 2010 was presented to "Cipla Ltd".

In his concluding remarks the Secretary General, Mr. Daara Patel appreciated the presentations made by all the speakers & moderators. He thanked all the participants, invitees, USP & IDMA staff, members of press & other associations and sponsors for making this event a grand success. He further added that in the last many years Mumbai Pharma Industry has not seen a record registration of over 350 participants at a Conference.

