

Eleventh IDMA - APA PAC 2008: A Report

The Eleventh IDMA- APA Pharmaceutical Analysts Convention (PAC) 2008 was held on 10th and 11th October 2008 in Mumbai. A large number of participants from the diverse sections such as Quality Control, Quality Assurance, Regulatory, Production, R&D, Marketing etc attended. A numbers of invitees from the Industry, senior members, Past Presidents, and Executive Committee Members from IDMA were also present. The main theme of the Convention was “NEW PRODUCT DEVELOPMENT – FROM CONCEPTUALISATION TO COMMERCIALISATION”.

was presented to Dr Ravishankara MN, Assistant Manager, Analytical Development Department, Sun Pharma Advanced Research Center. “Eminent Pharmaceutical Analyst Award 2008” was presented to Dr Saranjit Singh, Dean of the National Institute of Pharmaceutical Education and Research (NIPER) and the Head of the Department of Pharmaceutical Analysis. Mr Prabhdeep Singh, son of Dr Saranjit Singh was requested to receive this award on his behalf. “Maximum Delegates Registration” for the IDMA APA PAC 2008 was conferred on Glenmark Pharmaceuticals Ltd. The awards were

presented at the hands of the Chief Guest and the citations were read by **Dr Mary Francis**, Executive Director Cum Dean, International Centre for Training in Clinical Research.

Following the awards ceremony **Mr. Habil F Khorakiwala**, Chairman, Wockhardt Ltd delivered a very interesting keynote address on ‘New Product Development from Conceptualization to Commercialization’. He spoke about the changes and innovations taking place in pharmaceutical biotechnological companies, Mr. Khorakiwala cited the

example of Philips, one of the leading players in the area of imaging and medical equipments in the Research centre, has developed a plastic capsule with drug embedded into it and has an ultrasound imaging system to check the movement of capsules. The drug has to be triggered for the entire process and it can be triggered by pressing a button outside. The drug can get delivered exactly at that point.

Mr. Khorakiwala cited another example of one more product by Philips - a drug with micro air bubbles where, through the ultrasound, the drug will be released. He said that Imaging MRI is one of the most advanced technology today where any change taking place in any part of the body and in the cell can be diagnosed. Hence disease can be predicted in advance by imaging through MRI and the disease can be diagnosed before it can manifest. The players in Disease management are not only the



Mr J. L. Sipahimalani, Chairman, Quality Management and Regulatory & Technical IDMA Subcommittees giving an Opening Remark. To his left are: Mr Daara B Patel, Secretary – General, IDMA, Mr Habil Khorakiwala, Chairman, Wockhardt Ltd and Mr B N Singh, President, IDMA

Mr J. L. Sipahimalani, Chairman, Quality Management and Regulatory & Technical IDMA Subcommittees made his Opening Remarks. Mr B N Singh, President, IDMA gave a brief welcome address. Mr Daara B Patel, Secretary–General, IDMA introduced the Chief Guest, Mr Habil Khorakiwala, Chairman, Wockhardt Ltd. The Chief Guest inaugurated and released the Souvenir of PAC 2008, IDMA APA Forum Newsletter, Technical Monograph No. 3 “Investigation of Out of Specification (OOS) Test Results” and Technical Monograph No. 4 “Pharmaceutical Preformulation Analytical Studies”.

The Convention then proceeded with the Awards session. “Outstanding Pharmaceutical Analyst Award 2008” was presented to Dr Vishwanath B. Malkar, Head-Regulatory, Reliance Pharmaceuticals Pvt Ltd. “Young Pharmaceutical Analyst Award 2008”

traditional pharmaceutical companies but many other companies like Philips who are involved in research and development of such advanced equipments.

A lot of work in research and innovation is fundamentally taking place in areas where there are unmet needs in diseases. One of the unmet needs is brain disease such as Alzheimer, Brain Trauma etc. Another unmet need is Blood and Hematology diseases such as Thalasaemia and Sickle cell anemia. A major revolution has taken place where with the power of information technology, the human genome project which was supposed to be completed in 2005 got completed in 1999. But now no revolution but significant improvement would take place evolving the change in Health care disease management, he said.

Predicting the trend, he said that there will be a convergence of Pharmaceutical companies, Biotechnology companies, Medical Diagnostics companies and Hospitals to have a fully integrated Disease Management System and global changes would take place in next 10 – 20 yrs, the work has been started and this would happen. India would have a unique recognition and position ourselves next to global leaders in the coming decades

He said that a revolution would take place in disease management and with the expertise in our industry in clinical and various sciences; we can reorient ourselves to meet these challenges and be leader in 30 – 40 years.

The Guest of Honor, **Dr Surinder Singh**, Drugs Controller General of India & **Mr Debasish Panda**, Jt Secretary, Ministry of Health and Family Welfare (Department of Health), appreciated the industry, specially IDMA for supporting the Indian Pharmacopoeia Commission and for the release of Indian Pharmacopoeia 2007. They mentioned about the new initiatives taken by the DCG (I) and also about the newly constructed FDA Bhavan. They advocated more transparency and direct contact with the Pharmaceutical Industry. The Chief Guest and the Guest of Honor had a round of the Exhibit Area where a large number of sponsors had participated and displayed their equipments and services. The Guest and all the delegates were very appreciative of the equipments displayed.

The Technical Sessions

Mr Gidy Asrani, Vice Chairman, Quality Management Sub Committee, IDMA facilitated the

Technical sessions of the convention and initiated its proceedings. Following presentations were made in this session

Dr Alok Dobriyal, Consultant, International Management and IT, USA address on the “Innovation in Product Development and Positive mindset: Blueprint for excellence” His presentation gave an insight on how “MindSet” may impede creativity instead of flourishing it and how to undergo a “MindReset” to ensure success.

Dr Praful Naik, Chief Scientific Officer, Bilcare Limited made a presentation on “Technology advances and value of packaging during Development of Product” In his presentation he pointed What makes a life saving drug susceptible to Counterfeiting, What limits a Drug from differentiating itself from the rest or even from its own spurious copy, How packaging innovations and Technology play an important role in enabling change, Overview on some upcoming high end technology solutions and the need of moving from supportive to Integrated approach for a Drug product.

Dr Venugopal G Somani, Dy. Drugs Controller India (West Zone) made a presentation on “WHO Perspective on “New Product Development”. He said the New Drug discovery & formulation development is usually done by following standard path starting from-lead selection, combinatorial Chemistry, preclinical studies preformulation development, formulation development to clinical development depending on success and failure at each stage. General Regulatory expectation in this area (including from WHO) specially in generic development are primarily based on pharmaceutical & clinical equivalence with the comparator product. In order to achieve these objectives scientific approach is required on various aspects of development and comparison like Development Strategy, Product development, Component of drug product and Manufacturing process development.

Mr Ram Balani, CEO, FDASmart Inc, USA made a presentation on “Not Business as USUAL”- Changes to the US FDA Asia Pacific Policy”. In his presentation he mentioned about the US FDA CFR bootcamp (Code for Federal Regulations) for Biologics and how US FDA operates in terms of pharmaceutical cGMP inspections. He suggested the Type of inspections and Type of Inspections Charts and briefed about cGMP retrospective that include GMP history, practice, trends and statistics from



Dr Venugopal G Somani, Dy. Drugs Controller India (West Zone) making a presentation on “WHO Perspective on “New Product Development”. To his left are Mr. Gidy Asrani, Chairman of the session Mr. R S Iyer, Member of Scientific Body, Indian Pharmacopoeia Commission and the next speaker Mr Ram Balani, CEO, FDASmart Inc, USA



Chairman of the session, Dr D. B. Anantha Narayana, Head Herbas Research, Hindustan Unilever Research Centre, Bangalore, giving his introductory remark. To his left are: Mr Gidy Asrani and the speakers of the session, Dr Ashok Vaidya, Medical Research Centre, Kasturba Health Society and Mr Wulff Niedner, Dionex Corporation, Germany

countries in the Asia Pacific region such as India and China as well as Korea, Malaysia and Singapore.

Dr P V Kanitkar, PhD Director Plant Operations, Pfizer Limited made a presentation on “My expectations of Indian Pharmacopoeia”. In his presentation he gave a brief idea on Why need for Pharmacopoeia, Evolution of Indian Pharmacopoeia, Industry Position, Time for Change, The issue, My Expectations of IP, Status on Regulated Markets and the Pharmacopoeial Consistency.

Dr K.V.Surendra Nath, Vice President, USP-India gave the presentation on the “Navigating

Residual Solvents <467> USP”. He mentioned about the Introduction and History of Residual Solvents, Path to USP <467> Residual Solvents, Residual Solvents (classes, limits, options), Analytical Procedures, Typical Chromatographs, Reference Standards, Regulatory expectations.

Mr R S Iyer, Member of Scientific Body, Indian Pharmacopoeia Commission made a presentation on “Quality by Design - New Product Development”. He provided information on Quality by Design consist of designing and developing a product and associated manufacturing processes that will be used during product development to ensure that the product consistently attains a predefined quality at the end of the manufacturing process. He mentioned about the Quality system and the key Concepts of the Quality System such as Quality, Quality by Design, Quality Risk Management, CAPA (Corrective and Preventive Action), Change Control and Quality Assurance. He said Quality by design, in conjunction with a quality system, provides a sound framework for the transfer of product knowledge and process understanding from drug development to commercial manufacturing processes.

Dr Mary Francis, Executive Director Cum Dean, International Centre for Training in Clinical Research made a presentation on “Laboratory Accreditation-why?” In her presentation she said Accreditation is the formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do and NABL which was initially established with the objective to provide accreditation to testing and calibration laboratories, later on extended its services to the clinical laboratories in our country. The presentation concluded to have various systems in place for independent evaluation of laboratory quality and to have Transparent approach. Finally True quality depends on laboratory implementation and commitment.

Dr Ashok Vaidya, Medical Research Centre, Kasturba Health Society gave a presentation on “Challenges to Pharmaceutical Analysts for Phytopharmaceutical New Drugs”. In his presentation he pointed out the Indian Health system, R & D Paths for natural products, then drug development process and Reverse pharmacology. He said India has proposed a new category of phyto-pharmaceuticals, by amendment to the Drug Act. This category necessitates quality, adequate safety and evidence based activity of such Herbal drugs. He mentioned

a pharmaceutical analyst to have a core education on “Ayurveda” in pharmacy/ clinical bioscreening, Reverse pharmaceuticals in the curriculum for bhasmas,asavas,lehya, Phytochemical education for isolation & characterization of markers, Sessions on standardized phytopharmaceuticals by IDMA-APA , Awards for innovative monographs/ phytoproducts to scientists and Advanced training in LC-MS-MS,MALDI-TOF,SFC-MS.APCI/APPI,FTMS etc

Mr Wulff Niedner, Dionex Corporation, Germany made a presentation on “Speeding up Pharmaceutical UHPLC Method Development with an Integrated Ultrafast Automated Method Scouting Solution”. He said one of the crucial bottlenecks in HPLC is the method development. The wide selection of parameters makes method scouting time-consuming. Hence Automated Method Scouting in UHPLC mode is used UHPLC enables ultrafast method development (e.g. gradient separations within 5 minutes or less)

Dr Imran Ali, Reader in Department of Chemistry, Jamia Millia Islamia (University), New Delhi made a presentation on “Role of HPLC in Chiral Drugs Development”. In his presentation he pointed out the Toxicities and Harmful Effects of Some Homochiral Drugs Enantiomers and also Comparison of Different Methods for Chiral Drugs Development. Among few methodologies, Liquid chromatography (LC) is one of the best techniques for the preparation of optically active (Chiral drugs) drugs. His presentation highlighted the definition of chiral drugs, their importance, an international market survey and protocol, analytical to preparative concept, to develop chiral drugs using different chiral stationary phases (CSPs) such as polysaccharides, proteins, etc.

Mr Vijay Kshirsagar, Executive Vice President, Corporate Quality Assurance & Regulatory Affairs, Unichem Lab Ltd gave a presentation on “Stability – Forced Degradation study”. In his presentation he pointed out the Case studies related to Degradation/ Development of Stability indicating methods,

Theoretical aspects of Forced Degradation, Theoretical aspects of stability indicating method development/Validation and Result Interpretation

Dr. Hemant Borgaonkar, Technical Consultant, Nano Bio Process Division, Labindia Instruments Pvt. Ltd. made a presentation on “Basics and Application of Raman Spectroscopy in Pharma Industry. He pointed out Raman spectroscopy helps to have simpler, faster and accurate 100% Raw Material Identity Verification. He said Lab India Raman spectroscopy helps in Pharma API Research. Formulation Development, Quality Control of incoming Raw Material, Analysing Finished Formulations and Detection of Counterfeit Drugs.

The various technical sessions were chaired by experts **Mr R S Iyer**, Member of Scientific Body, Indian Pharmacopoeia Commission, **Mr Gidy Asrani**, Vice Chairman, Quality Management Sub Committee, IDMA, **Dr Milind Joshi**, Member, Regulatory & Technical Sub Committee, IDMA, **Mr J. L. Sipahimalani**, Chairman, Quality Management and Regulatory & Technical Subcommittees, IDMA and Chairman APA (Association of Pharmaceutical Analysts), **Dr D. B. Anantha Narayana**, Head Herbals Research, Hindustan Unilever Research Centre, Bangalore, **Dr. P.S. Ramanathan**, Director-Corporate Analytical Operations, Gharda Chemicals Ltd., Mumbai.

Finally the participants actively interacted at the Panel Discussion on - “Globalization – Outsourcing opportunities in New Product Development”. The session was chaired by **Dr M Venkateswarlu**, Former DCG (I) and the panelists included **Dr Arun Bhatt**, President, Clininvent Research Pvt. Ltd and **Dr R. Rajan**, Head CQA, Elder Pharmaceuticals Ltd.

The Convention concluded with **Mr Gidy Asrani**, the Programme Facilitator, IDMA proposing the vote of thanks to all those who had made the Convention a grand success.

