

82nd OMICS Group Conference

Scientific Program



2nd International Conference and Exhibition on

Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India



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OMICS Group Conferences

5716 Corsa Ave., Suite 110, Westlake Los Angeles, CA 91362-7354, USA

Phone: +1-650-268-9744, Fax: +1-650-618-1414, Toll free: +1-800-216-6499

Email: pharma2012@omicsonline.us



10:00-10:30

Opening Ceremony

Keynote Forum

10:30-10:35 Introduction

10:35-10:55 **Prakash Nagarkatti**

University of South Carolina, USA

10:55-11:15 **Patrick L. Leoni**

Euromed Management, France

Coffee Break 11:15-11:30

11:30-11:50 **Jagat R. Kanwar**

Deakin University, Australia

11:50-12:10 **Michael Alexander**

MIDI Inc., USA

12:10-12:30 **Shivanand P. Puthli**

Panacea Biotec Ltd., India

12:30-12:50 **S. V. Krishna Prasad**

Cito Healthcare P Ltd, India

Lunch Break 12:50-01:35

Track 3: Drug Development and NDDS

Chair: **Mitzi Nagarkatti**, University of South Carolina, USACo-Chair: **Jagat R Kanwar**, Deakin University, Australia

Session Introduction

- 01:35-01:55 **Title: Dietary indoles serve as novel therapeutic agents by targeting inflammation through epigenetic modulation and miRNA expression in T cells and there by suppressing inflammatory diseases**
Mitzi Nagarkatti, University of South Carolina, USA
- 01:55-02:15 **Title: High molecular weight (HMW) lactoferrin from bovine colostrum have anti-cancer potentials**
Jagat R Kanwar, Deakin University, Australia
- 02:15-02:35 **Title: Personalised medicine: Introduction of genomics, proteomics and metabolomics in novel drug development and therapy**
Baharudin Ibrahim, Universiti Sains Malaysia, Malaysia
- 02:35-02:55 **Title: Does sleeping brain help consolidate associative conditioned memory in the rat?**
Sushil Jha, Jawaharlal Nehru University, India
- 02:55-03:15 **Title: Glass transition temperature (T_g) as a measure of sperm fertility: Effect of antifertility drug nifedipine and its analogues**
Sudha Srivastava, Tata Institute of Fundamental Research, India
- 03:15-03:35 **Title: Investigations on synthesis and bioactivity of novel organometallic complexes**
Akella Sivaramakrishna, VIT University, India
- 03:35-03:55 **Title: Preparation and characterization of self-emulsifying drug delivery system (SEDDS) of indomethacin**
Damineni Saritha, Jawaharlal Nehru Technological University, India

Coffee Break 03:55-04:10

- 04:10-04:30 **Title: Modeling Studies of HCV protease Inhibitors: Understanding their efficacy in mutant forms**
Vema Aparna, Sree Chaitanya Institute of Pharmaceutical Sciences, India
- 04:30-04:50 **Title: Supramolecular biovectors: Novel nanopolymers for drug delivery and gene therapy**
Suryakanta Swain, Roland Institute of Pharmaceutical Sciences, India
- 04:50-05:10 **Title: Brain targeting potential of carbamazepine SNEDDS**
Gannu Praveen Kumar, St. Peter's Institute of Pharmaceutical Sciences, India
- 05:10-05:30 **Title: The role of hydrophilic porphyrin-[C60] fulleropyrrolidine dyads as nano-assisted photosensitizers towards cancer photo dynamic therapy (PDT)**
Devashish Sengupta, Assam University, India
- 05:30-05:50 **Title: Coprocessed excipients: A cogent tool for gastroretentive drug delivery**
Hardikar Sharwaree Rajan, Seth Govind Raghunath Sable College of Pharmacy, India
- 05:50-06:10 **Title: Stability, activation and antimycobacterial activity of pyrazinoic acid esters**
Constantino. L, University of Lisbon, Portugal
- 06:10-06:30 **Title: Comparision of disintegrants and super disintegrants activity in oral disintegration tablets**
T. Vedavathi, CMR College of Pharmacy, India
- 06:30-06:50 **Title: Analysis of anti neoplastic activity for detoxified monocrotaline analogue through insilico docking studies**
K. Sandeep Solmon, GITAM University, India
- 06:50-07:10 **Title: Design of polymeric nanocapsules for raloxifene hydrochloride by multiple emulsion method (w/o/w) using rotatable central composite design model**
Punna Rao Ravi, BITS-Pilani, India
- 07:10-07:30 **Title: Newer treatment approaches in cardiac disease tirofiban in acute coronary syndrome – The re-defined role**
Yesh Paul sharma, PGIMER, India

MR G.01

Track 4: Drug Interactions and Toxicity

Track 5: Biologics, Novel Therapies and other Special Categories

Chair: Silvia Lima Costa, Federal University of Bahia, Brazil

Co-Chair: Nazim Serdar Turhal, Marmara University School of Medicine, Turkey

Session Introduction

- 01:35-01:55 **Title: Flavonoids as modulators of glia/glioma interaction: Role of inflammatory cytokines and MEC/MMP expression**
Silvia Lima Costa, Federal University of Bahia, Brazil
- 01:55-02:15 **Title: The Turkish experience with sunitinib in metastatic renal cell cancer**
Nazim Serdar Turhal, Marmara University School of Medicine, Turkey
- 02:15-02:35 **Title: Immunity, immunotherapy and immunomodulators - Their mechanism in modifying drug & disease response**
Anupama Koneru, Sultan-ul-uloom College of Pharmacy, India
- 02:35-02:55 **Title: Pharmacokinetic parameters of iontophoretic delivery of alfuzosin hydrochloride**
Prasanthi. D, G. Pulla Reddy College of Pharmacy, India
- 02:55-03:15 **Title: A proposal for more affordable biologicals in developing countries**
Nazim Serdar Turhal, Marmara University School of Medicine, Turkey
- 03:15-03:35 **Title: An overview of regulatory expectation and guidance on incurred sample analysis**
D.Vijaya Bharathi, Dr. Reddys Laboratories Ltd., India
- 03:35-03:55 **Title: Studies on beta-Galactosidase production**
Pavani A, C M College of Pharmacy, India

Coffee Break 03:55-04:10

04:00-05:00 **Poster Sessions**

Hall 6

Day 2

November 24, 2012

08:30-09:00 **Registrations**

Hall No.5

Track 1: Regulatory Affairs for Healthcare Products

Track 2: Biologics and Medical Devices

Chair: Dawei Li, Shanghai Jiao Tong University, China

Chair: Shivanand P. Puthli, Panacea Biotec Ltd., India

Session Introduction

- 09:00-09:20 **Title: Agtuzumab, a humanized monoclonal antibody blocks AGR2 function through conformational epitopes around its catalytic center**
Dawei Li, Shanghai Jiao Tong University, China

- 09:20-09:40** **Title: Regulatory Affairs for pharmaceuticals**
Hasumati Rahalkar, Metina Consultants, India
- 09:40-10:00** **Title: Bioprocess development for production of biopharmaceuticals from plant origin**
Prasad A. Wadegaonkar, Sant Gadge Baba Amaravati University, India
- 10:00-10:20** **Title: Role of regulatory affairs for health care products**
T.S. Jaishankar, Quest Life Sciences Pvt. Ltd., India
- 10:20-10:40** **Title: Biosimilar regulations in India: Current scenario**
Smita S. Singhanian, Bio Pharmaceutical Industry, India

Coffee Break 10:40-10:55

Track 9: Biomedical Intellectual Property Management

Track 10: Regulatory Compliances in Health Care

Track 11: Novel Strategies for Growth in the Pharma and Regulatory Environment

Chair: Bobby George, Reliance Life Sciences, India

Co-Chair: Nagesh Maddula, Biovision Consultants Ltd., UK

Session Introduction

- 10:55-11:15** **Title: Effective regulatory information management**
Bobby George, Reliance Life Sciences, India
- 11:15-11:35** **Title: EU Regulatory Affairs**
Nagesh Maddula, Biovision Consultants Ltd., UK
- 11:35-11:55** **Title: Challenges in patentability for incremental innovation in the Pharmaceutical industry**
Komal Shah-Bhukhanwala, Indian School of Business, India
- 11:55-12:15** **Title: The rise of Indian generics, globally and at home**
Kamaraju Chitrapu, Indian School of Business, India
- 12:15-12:35** **Title: Managing US Food and Drug Administration inspections at Indian clinical trial sites- CRO perspective**
Ashutosh Jani, Accutest Research Labs, India
- 12:35-12:55** **Title: On-site audits approach: A tool for Quality Risk Management**
V. Siva Kumar, Micro Labs Ltd., India

Lunch Break 12:55-01:40

- 01:40-02:00** **Title: A convergence of regulatory policies at FDA and EMA**
Mallika Rajasekaran, Aris Global Software Pvt. Ltd., India
- 02:00-02:20** **Title: Common regulatory issues and challenges in dealing with e submissions through FDA electronic submissions gateway**
Jayprakash, Virtify Inc., India
- 02:20-02:40** **Title: Informed consent process, the bane of unethical clinical research**
Augustine Onyeaghala, University College Hospital, Nigeria
- 02:40-03:00** **Title: Patent law compliant research methodology in pharmaceutical research**
Vipin Mathur, Lachoo Memorial College of Science & Technology, India

MR G.01

Track 6: OTC Drug Products, Herbal Medicines, and Homeopathic Medicines

Track 7: Safety and Quality Regulation

Track 8: Business and Law Enforcement and Education

Chair: Pradeep K. Karla, Howard University, USA

Co-Chair: N. Rajasekar, SiliCycle Inc., Canada

Session Introduction

- 10:55-11:15** **Title: Discovery of new drug efflux transporters in human cornea - prominence in ocular drug delivery and decreased blindness**
Pradeep K. Karla, Howard University, USA
- 11:15-11:35** **Title: Silica-based products: New tools to simplify synthesis, purification & metal removal**
N. Rajasekar, SiliCycle Inc., Canada
- 11:35-11:55** **Title: The regulation of herbal medicines in Brazil**
Laerte Dall'Agno, DALL Solucoes Analíticas e Empresariais, Brazil
- 11:55-12:15** **Title: Role of value chain in easing regulatory processes and approvals for herbal products**
Suma Krishnaswamy, Cambium Biotechnologies, India
- 12:15-12:35** **Title: Saudi pharmaceutical market; Current, future and R&D**
Naser L. Rezk, King Saud bin Abdul-Aziz University for Health Sciences, KSA
- 12:35-12:55** **Title: Explorations of power laws in pharmacy: Implications for Adverse Drug Events (ADEs)**
Rao S. Pippalla, Talla Padmavathi College of Pharmacy, India

Lunch Break 12:55-01:40

- 01:40-02:00 **Title: Importance of personnel training and education in Regulatory Affairs**
Sapna L Kanth, Lipient Software Private Ltd., India
- 02:00-02:20 **Title: Holistic pharma for all**
S. V. Eswaran, University of Delhi, India
- 02:20-02:40 **Title: Development and initial standardization of ayurveda child personality inventory**
Suchitra S P, SVYASA University, India
- 02:40-03:00 **Title: 2D-QSAR study of natural coumarin against human bladder carcinoma cell line EJ**
N.V. Anil Kumar, Manipal University, India

Hall 6

Poster Sessions - 02:30-03:30 & 03:30-04:00

Coffee Break 04:00-04:15

Hall 5

Best Posters Felicitation Ceremony

Bookmark your dates



3rd International Conference and Exhibition on

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November 4-6, 2013 California, USA



OMICS Group Inc.
2360 Corporate Circle, Suite 400
Henderson, NV 89074-7722, USA
Ph: +1-888-843-8169
Fax: +1-650-618-1417
omicsonline@omicsonline.com

OMICS Publishing Group
5716 Corsa Ave., Suite 110, Westlake
Los Angeles, CA 91362-7354, USA
Ph: +1-650-268-9744
Fax: +1-650-618-1414
omicsonline@omicsonline.org

OMICS Group
SEZ Unit, Building No. 20, 9th Floor,
APIIC Layout, HITEC City,
Hyderabad-500081, AP, INDIA
Ph: 040-40131823, 47482222
omicsgroup@omicsgroup.org

Toll free
USA & Canada: 1-800-216-6499
Australia: 1-800-651-097
Europe: 0805-080048