

82<sup>nd</sup> OMICS Group Conference

# *Scientific Program*



2<sup>nd</sup> International Conference and Exhibition on

# Pharmaceutical Regulatory Affairs

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



## **“Organize your Events at OMICS Group Conferences”**

Proposals are invited for organizing Symposia/Workshops at OMICS Group Conferences in related areas under the scheme title of your own. These proposals can be sent to respective conference mail ids or to [symposia@omicsonline.com](mailto:symposia@omicsonline.com)

## **OMICS Group Conferences**

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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, USA

Co-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 (Tg) 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: Comparison 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 biologics 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. Singhania, 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'Agnol, 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

**OMICS Group** 3<sup>rd</sup> International Conference and Exhibition on  
**Conferences** **Pharmaceutical Regulatory Affairs**  
Accelerating Scientific Discovery

November 4-6, 2013 California, USA



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