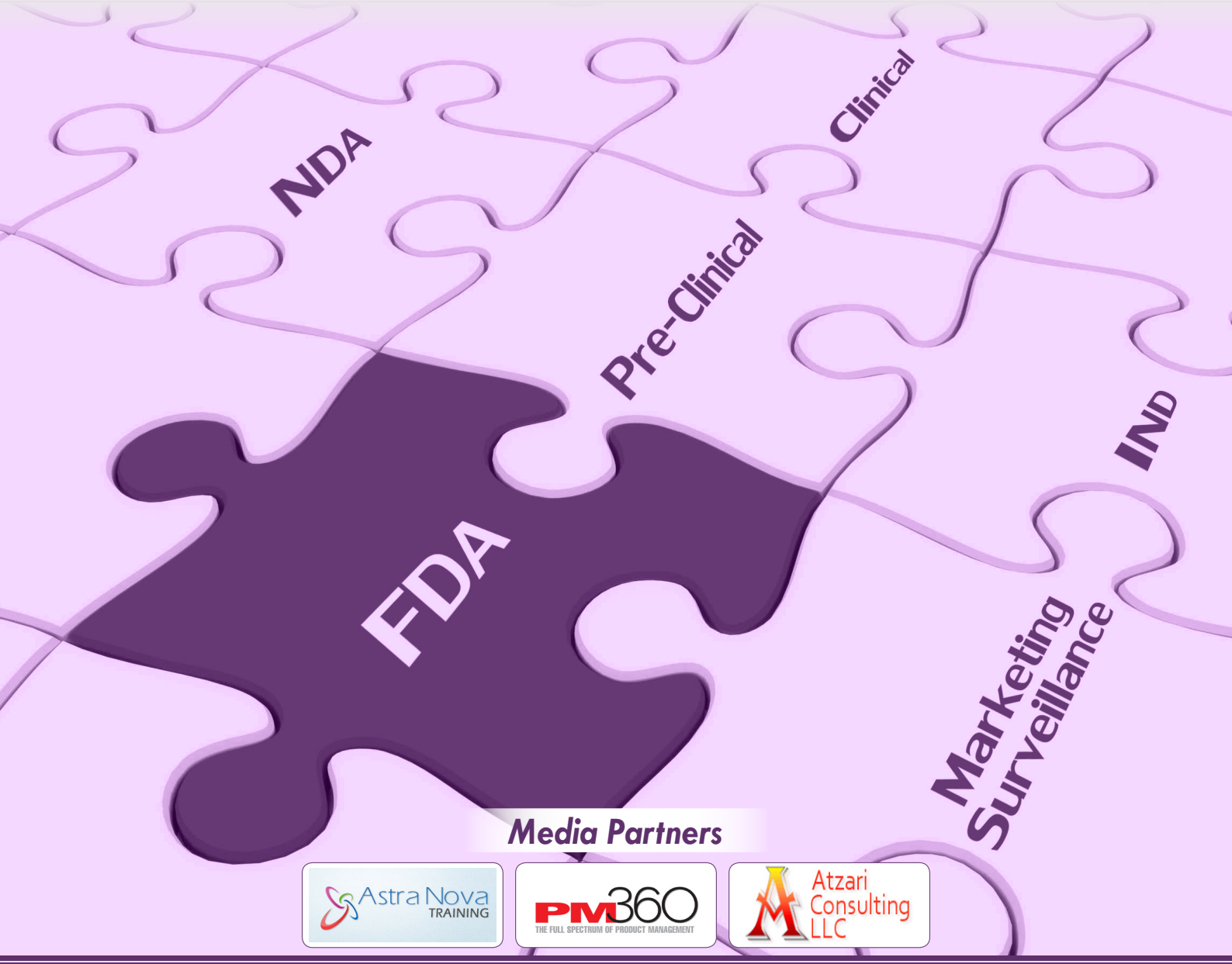
Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Pharmaceutical Regulatory Affairs

October 21-23, 2013 DoubleTree by Hilton Hotel San Francisco Airport, CA, USA



Media Partners

Astra Nova TRAINING | PM360 THE FULL SPECTRUM OF PRODUCT MANAGEMENT | Atzari Consulting LLC

"Organize your Events at OMICS Group Conferences"

Proposals are invited for organizing Symposia/Workshops at OMICS Group Conferences or OMICS Group will sponsor small events at your universities in related areas under the title of your own. These proposals can be sent to respective conference mail ids or to *symposia@omicsonline.org*

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: *regulatoryaffairs2013@omicsgroup.us*

Day 1 October 21, 2013

07:00-09:00 Registrations

Redwood/Sequola

OMICS Group Conferences
Accelerating Scientific Discovery

09:00-09:25 **Opening Ceremony**

Keynote Forum

09:25-09:30 **Introduction**

09:30-09:55 **Steve Jwanouskos**
OptiMedica, USA

Coffee Break 09:55-10:10 @ Sierra Foyer

10:10-10:35 **Mohammed R Khan**
Synergex Consulting, Canada

10:35-11:00 **Chitra Edwin**
Cleveland HeartLab, Inc., USA

11:00-11:25 **Rama K Pidaparti**
Wipro Technologies, USA

Track 1: Regulatory Affairs for Healthcare Products
Track 2: Regulatory Requirements for Pharmaceuticals
Track 3: Requirements for Medical Devices
Track 4: IND, NDA, BLA, and ANDA

Session Chair: Steven Mattos, ALKU Technologies, USA
Session Co-Chair: Linda Yang, KleanGen, LLC., USA

Session Introduction

11:25-11:50 **Title: The master validation plan: A vision of things to come!**
Steven Mattos, ALKU Technologies, USA

11:50-12:15 **Title: Points to consider when managing regulatory submissions in Asia Pacific countries**
Linda Yang, KleanGen, LLC., USA

Lunch Break 12:15-13:00 @ Tiburon/Sausalito

13:00-13:25 **Title: Complaints handling and post marketing surveillance**
Harshit Thakkar, Dekra Certification B.V., USA

13:25-13:50 **Title: USA and EU regulatory submissions for veterinary medicines**
Karolina Bate, Cyton Biosciences Limited, UK

13:50-14:15 **Title: Regulations in the emerging market of nutraceuticals: From paradigms to practice**
Kerry Diaz, Bio-K Plus International Inc., Canada

14:15-14:40 **Title: Who does design control best? (Successful medical device manufacturers do)**
Steve Jwanouskos, OptiMedica, USA

14:40-15:05 **Title: Combination products: Current regulations, challenges and global trends**
Chitra Edwin, Cleveland HeartLab, Inc., USA

15:05-15:30 **Title: Overview and successful strategies for INDs and NDAs**
Michelle Carpenter, Regulatory Consultant, USA

Coffee Break 15:30-15:45 @ Sierra Foyer

15:45-16:10 **Title: Clinical trial agreements: Important or just one more document?**
JoAnn P. Pfeiffer, University of Southern California, USA

16:10-16:35 **Title: Regulatory impact of applying computational predictive models to design, develop, and commercialize drug products**
Mary T. am Ende, Pfizer Inc., USA

16:35-17:00 **Title: Understanding the importance of local knowledge strategy identification**
Mamoona Firdous Naqvi, Gulf Pharmaceutical Industries-Julphar, UAE

17:00-17:25 **Title: FDA process validation guidance & principals vs EMA guidance**
Rober Remon Saad Habashy, Amoun Pharmaceutical Company, Egypt

17:25-17:50 **Title: Globalization of pharmaceutical industry-Need of the hour**
Sunny Chopra, Fresenius Kabi Oncology Ltd., India

17:50-18:15 **Title: Chirality in pharmaceutical product development: A regulatory perceptive**
Kishore Kumar Hotha, Novel Laboratories Inc., USA

19:10-20:10 Cocktails Sponsored by **Pharmaceutical Regulatory Affairs: Open Access**

Day 2 October 22, 2013

Redwood/Sequola

Track 5: Biologics and Other Special Categories
Track 6: Best Industry Practices
Track 7: Business, Law Enforcement, and Education

Session Chair: Netta Fulga, The Hospital for Sick Children, Canada
Session Co-Chair: Chitra Edwin, Cleveland HeartLab, Inc., USA

Session Introduction

09:00-09:25 **Title: Current trends in computerized system validation-Challenges and solutions**
Garikapati Pavan Kumar, Wipro Technologies, India

09:25-09:50 **Title: Challenges in providing adequate high-level education in regulatory affairs, especially in view of small countries**
Elvi Metsaranta, Crown CRO Oy, Finland

09:50-10:15 **Title: Cleaning validation**
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

10:15-10:40 **Title: Liposome characterization required for regulatory approvals**
Donald Kruppa, Azaya Therapeutics, Inc., USA

Coffee Break 10:40-10:55 @ Sierra Foyer

10:55-11:20 **Title: Effective methods for software and systems integration**
Boyd L. Summers, BL Summers Consulting LLC., USA

11:20-11:45 **Title: Australian pharmaceutical patent system under review-To 'balance' the interests of pharmaceutical product innovators and the generics industry?**
Gint Silins, Cullens Patent and Trade Mark Attorneys, Australia

11:45-12:10 **Title: Medicines regulation in Australia and New Zealand-Unique and changing. An industry perspective**
John L. Miller, John Miller Consulting (Aust) Pty. Ltd., Australia

Lunch Break 12:10-12:55 @ Tiburon/Sausalito

12:55-13:20 **Title: Best industry practices-Audits and inspection**
Kahl Melodie, QA/RA Independent Consultant, Switzerland

13:20-13:45 **Title: External price referencing system - Implementation in Albania and consequences**
Ledia Cikopana, Tirana University, Albania

13:45-14:10 **Title: Good distribution practices (cGDP) and related regulatory affairs at the Brazilian supply chain**
Frederico Rapussi, Pfizer, Brazil

14:10-14:35 **Title: The quality journey; from the Stone Age to modern times, and the lessons learned**
Mohammed R Khan, Synergex Consulting, Canada

14:35-15:00 **Title: Analytical test method validation (AMV) of finished pharmaceutical products (FPP) & system suitability requirements**
Rober Remon Saad Habashy, Amoun Pharmaceutical Company, Egypt

15:00-15:25 **Title: Regulatory roadmap for initiating a gene therapy drug into clinical trials in the US**
William Lee, Cato Research, USA

15:25-15:50 **Title: Regulatory submissions for blood products at Saudi FDA**
Ali Mohammed Alsamil, Saudi Food And Drug Authority, KSA

Coffee Break 15:50-16:05 @ Sierra Foyer

16:05-16:30 **Title: *In vivo* antidiarrheal and *ex-vivo* spasmolytic activities of the aqueous extract of the roots of *Echinops kebericho* Mesfin in rodents and isolated guinea-pig ileum**
Fisseha Shiferie, Mekelle University, Ethiopia

16:30-16:55 **Title: Quality management and accreditation in a mixed research and clinical analytical laboratory setting**
Netta Fulga, The Hospital for Sick Children, Canada

16:55-17:20 **Title: Remote internal quality audits-Effective and efficient**
Garikapati Pavan Kumar, Wipro Technologies, India

17:20-17:45 **Title: Biosimilars and non-innovator biotherapeutics in MENA region: Opportunities and challenges**
Ibrahim Aljuffali, King Saud University, Saudi Arabia

17:45-18:10 **Title: EUROPE-New regulations-What impact will the proposed new regulations in Europe have for medical device manufacturer?**
Toni Kennet Jorgensen, Sorin Group, Switzerland

16:10-17:30 **Poster Presentations @ Monterey**
18:50-19:50 Cocktails Sponsored by **Pharmaceutical Regulatory Affairs: Open Access**

Day 3 October 23, 2013

Redwood/Sequola

Track 8: Intellectual Property Management
Track 9: Novel Strategies for Growth in the Pharma and Regulatory Environment

Session Chair: Linda Yang, KleanGen, LLC., USA

Session Introduction

09:00-09:25 **Title: Electronic compliance monitoring and return on investment**
Allan Wilson, Information Mediary Corporation, Canada

09:25-09:50 **Title: Strategic management of global post approval regulatory activities**
Linda Yang, KleanGen, LLC., USA

09:50-10:15 **Title: Regulatory strategy should be business strategy**
Rama K Pidaparti, Wipro Technologies, USA

10:15-10:40 **Title: Pricing policy for a patent medicine? Need for changing the frame work of rewarding an Innovation**
Anantha Naik Nagappa, Manipal University, India

Coffee Break 10:40-10:55 @ Sierra Foyer

10:55-11:20 **Title: Quality risk management system**
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

11:20-11:45 **Title: Management of IP in a multi-collaborative framework: DST/Mintek nanotechnology innovation centre as a case study**
Makhapa Makhafola, Mintek, South Africa

11:45-12:10 **Title: Problems encountered by third world countries especially Pakistan in pharmaceutical regulatory affairs and their remedies**
Shoaib Ahmed, Drug Regulatory Authority, Pakistan

12:10-12:35 **Title: Asia and ASEAN, what will be the result of all the harmonization effort going on in the Asian markets, and how should we as manufacturer deal with all these new regulations?**
Toni Kennet Jorgensen, Sorin Group, Switzerland



2nd International Summit on
GMP, GCP & Quality Control
November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore USA



2nd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
November 18-19, 2013 Hilton San Antonio Airport, USA



Bookmark your dates

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 Philadelphia, 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, 040-47482222
omicsgroup@omicsgroup.org

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