8th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR
June 08-09, 2018   Philadelphia, USA

Tentative Program

http://regulatoryaffairs.pharmaceuticalconferences.com

300+ Participation

14+ Interactive Sessions 15+ Keynote Lectures 75+ Plenary Lectures 5+ Workshops

***For available speaker slots***
regulatoryaffairs@pharmaceuticalconferences.org
# 8th International Conference and Exhibition on Pharmaceutical Regulatory Affairs and IPR

**June 08-09, 2018   Philadelphia, USA**

## SCIENTIFIC PROGRAM

### DAY 1

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>08:45-09:15</td>
<td>Keynote Session</td>
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<td>09:15-09:45</td>
<td>Keynote Talk 1</td>
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<td>09:45-10:15</td>
<td>Keynote Talk 2</td>
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<td>10:15-10:45</td>
<td>Keynote Talk 3</td>
</tr>
</tbody>
</table>

Coffee/Tea Break 10.45-11.00

Pre-Lunch Session 11.00-12.00

Plenary Session 1 | Tracks 1, 2 & 3
- Regulatory Affairs
- Regulatory Affairs in Pharmacovigilance
- Clinical Affairs & Regulatory Strategies

Networking Lunch 12.40-13.30

Networking Lunch 12.40-13.30

Post Lunch Sessions 13.30-15.30

Plenary Session 2 | Tracks 4, 5 & 6
- Regulatory Strategies and Developments
- Penalties for Regulatory Non-compliance
- Biologics & Biosimilars

Coffee/Tea Break 15.30-15.45

Evening Sessions 15.45-18.00

Plenary Session 3 | Tracks 7, 8 & 9
- Global Regulatory Intelligence
- Impact of Brexit on Regulatory Framework
- Regulatory Communications and Submissions
- Panel Discussions | Extended Networking

### DAY 2

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>09:15-09:45</td>
<td>Keynote Talk 5</td>
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<tr>
<td>09:45 - 10:15</td>
<td>Keynote Talk 6</td>
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<tr>
<td>10:15 - 10:45</td>
<td>Keynote Talk 7</td>
</tr>
</tbody>
</table>

Coffee/Tea Break 10.45-11.00

Pre-Lunch Session 11.00-12.40

Plenary Session 4 | Track 10, 11 & 12
- Marketing Authorizations
- Regulatory Requirements for Pharmaceuticals
- Regulatory Challenges for Medical Devices

Networking Lunch 12.40-13.30

Networking Lunch 12.40-13.30

Post Lunch Sessions 13.30-15.30

Plenary Session 5 | Tracks 13 & 14
- Medical Device & Combination Products Regulations
- Best Industry Practices

Coffee/Tea Break 15.30-15.45

Evening Sessions 15.45-18.00

Plenary Session 6 | Track 15, 16 & 17
- Intellectual Property Rights
- Newly added guidance documents
- Regulatory guidance drug registration and listing
- Panel Discussions | Extended Networking

Closing and Award Ceremony

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For More Details: [http://regulatoryaffairs.pharmaceuticalconferences.com](http://regulatoryaffairs.pharmaceuticalconferences.com)

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Glimpses of Regulatory Affairs Conferences

http://regulatoryaffairs.pharmaceuticalconferences.com
Glimpses of Regulatory Affairs Conferences
Major Scientific Sessions

- Regulatory Affairs
- Regulatory Affairs in Pharmacovigilance
- Clinical Affairs & Regulatory Strategies
- Regulatory Strategies and Developments
- Penalties for Regulatory Non-compliance
- Biologics & Biosimilars
- Global Regulatory Intelligence
- Impact of Brexit on Regulatory Framework
- Regulatory Communications and Submissions
- Marketing Authorizations
- Regulatory Requirements for Pharmaceuticals
- Regulatory Challenges for Medical Devices
- Medical Device & Combination Products Regulations
- Best Industry Practices
- Intellectual Property Rights

Best Poster Award

- You will be given about 5-7 minutes to present your poster including questions and answers. Judges may pose questions during the evaluation of the poster.
- Judges will even evaluate the student’s enthusiasm towards their study, interest and knowledge in the area of their research.
- The winners will be announced at the closing ceremony of the conference. The decision of the winner will be withdrawn if the winner/winner is/are not present at the time of announcement.
- Apart from the judging time, you may also be present at the poster to share your research with interested delegates.

Young Researchers Forum

- Present your research through oral presentations.
- Learn about career development and the latest research tools and technologies in your field.
- This forum will give pertinent and timely information to those who conduct research and those who use and benefit from research.
- Develop a foundation for collaboration among young researchers.
- The forum will provide an opportunity for collegial interaction with other young investigators and established senior investigators across the globe.
- Interact and share ideas with both peers and mentors.

General Queries
regulatoryaffairs@pharmaceuticalconferences.org

Conference Venue
Philadelphia, USA
Best Tourist Destinations in Philadelphia

- Liberty Bell
- Pennsylvania Academy of Fine Arts Museum
- Philadelphia Museum of Art
- Society Hill Historic District
- Patterson Park

http://regulatoryaffairs.pharmaceuticalconferences.com
Proposals are invited for organizing Symposia/Workshops at Conference Series LLC Ltd 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

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Email: regulatoryaffairs2013@omicsgroup.us
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

Keynote Forum

Introduction
Steve Jwanouskos
OptiMedica, USA

Mohammed R Khan
Synergex Consulting, Canada
Chitra Edwin
Cleveland HeartLab, Inc., USA
Rama K Pidaparti
Wipro Technologies, USA

Coffee Break @ Sierra Foyer

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

Title: The master validation plan: A vision of things to come!
Steven Mattos, ALKU Technologies, USA
Title: Points to consider when managing regulatory submissions in Asia Pacific countries
Linda Yang, KleanGen, LLC., USA

Coffee Break @ Sierra Foyer

Mohammed R Khan
Synergex Consulting, Canada
Chitra Edwin
Cleveland HeartLab, Inc., USA
Rama K Pidaparti
Wipro Technologies, USA

Lunch Break @ Tiburon/Sausalito

Title: Complaints handling and post marketing surveillance
Harshit Thakkar, Dekra Certification B.V., USA
Title: USA and EU regulatory submissions for veterinary medicines
Karolina Bate, Cyton Biosciences Limited, UK
Title: Regulations in the emerging market of nutraceuticals: From paradigms to practice
Kerry Diaz, Bio-K Plus International Inc., Canada
Title: Who does design control best? (Successful medical device manufacturers do)
Steve Jwanouskos, OptiMedica, USA
Title: Combination products: Current regulations, challenges and global trends
Chitra Edwin, Cleveland HeartLab, Inc., USA
Title: Overview and successful strategies for INDs and NDAs
Michelle Carpenter, Regulatory Consultant, USA

Coffee Break @ Sierra Foyer

Title: Clinical trial agreements: Important or just one more document?
JoAnn P. Pfeiffer, University of Southern California, USA
Title: Regulatory impact of applying computational predictive models to design, develop, and commercialize drug products
Mary T. am Ende, Pfizer Inc., USA
Title: Understanding the importance of local knowledge strategy identification
Mamoon Firdous Naqui, Gulf Pharmaceutical Industries-Julphar, UAE
Title: FDA process validation guidance & principals vs EMA guidance
Rober Rémon Saaid Habashy, Amoun Pharmaceutical Company, Egypt
Title: Globalization of pharmaceutical industry-Need of the hour
Sunny Chopra, Fresenius Kabi Oncology Ltd., India
Title: Chirality in pharmaceutical product development: A regulatory perceptive
Kishore Kumar Hotha, Novel Laboratories Inc., USA
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

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

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

Title: Cleaning validation
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

Title: Liposome characterization required for regulatory approvals
Donald Krupa, Azoya Therapeutics, Inc., USA

Coffee Break @ Sierra Foyer

Title: Effective methods for software and systems integration
Boyd L. Summers, BL Summers Consulting LLC., USA

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

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 @ Tiburon/Sausalito

Title: Best industry practices-Audits and inspection
Kahl Melodie, QA/RA Independent Consultant, Switzerland

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

Title: Good distribution practices (cGDP) and related regulatory affairs at the Brazilian supply chain
Frederico Rapussi, Pfizer, Brazil

Title: The quality journey: from the Stone Age to modern times, and the lessons learned
Mohammed R Khan, Synergex Consulting, Canada

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

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

Title: Regulatory submissions for blood products at Saudi FDA
Ali Mohammed Alsamii, Saudi Food And Drug Authority, KSA

Coffee Break @ Sierra Foyer

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

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

Title: Remote internal quality audits-Effective and efficient
Garikapati Pavan Kumar, Wipro Technologies, India

Title: Biosimilars and non-innovator biotherapeutics in MENA region: Opportunities and challenges
Ibrahim Aljuiffali, King Saud University, Saudi Arabia

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

Poster Presentations @ Monterey

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

Title: Electronic compliance monitoring and return on investment
Allan Wilson, Information Mediary Corporation, Canada

Title: Strategic management of global post approval regulatory activities
Linda Yang, KleanGen, LLC., USA
Bookmark your dates

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

Title: Regulatory strategy should be business strategy
Rama K Pidaparti, Wipro Technologies, USA

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 @ Sierra Foyer

Title: Quality risk management system
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

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

Title: Problems encountered by third world countries especially Pakistan in pharmaceutical regulatory affairs and their remedies
Shoaib Ahmed, Drug Regulatory Authority, Pakistan

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

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Toni Kennet Jorgensen, Sorin Group, Switzerland

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014  Philadelphia, USA
Scientific Program

4th International Conference on Pharmaceutical Regulatory Affairs

September 08-10, 2014  DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA
Opening Ceremony

Keynote Forum

Introduction

Adam Sabouni
PharmaConsultz, USA

David Hawley
IS Compliance and Validation, North America

Michael Drues
Vascular Sciences, USA

Track 1: Regulatory Affairs for Healthcare Products
Track 2: Regulatory Requirements for Pharmaceuticals
Track 3: Requirements for Medical Devices

Session Chair: Jerry Xu, WuXi AppTec, China
Session Co-Chair: Kishore Kumar Hotha, Novel Laboratories, USA

Session Introduction

Title: Assessment of the antibacterial activity of actinomycetes isolated from terrestrial soil of King Saud University campus
Arunachalam Chinnathambi, King Saud University, King Saudi Arabia

Title: Extractables and leachables: Regulatory perceptive
Kishore Kumar Hotha, Novel Laboratories, USA

Title: Challenges & latest regulations have to know about medical devices in Middle East region
Sara Hegazi, Philips Healthcare, UAE

Title: Implementation of changes aligned to regulatory framework
Mohammad Iqbal Hossain, Novartis Limited, Bangladesh

Title: Pharmabiotics: A regulatory hurdle in Europe
Magali Cordaillat-Simmons, Pharmabiotic Research Institute, France

Lunch Break @ Sessions Room

Title: Combining nanotheranostics and photomedicine: Design and synthesis of nanophotomedicine
Jayeeta Bhaumik, NIPER, India

Title: Have FDA expedited programs really shortened drug review time? an analysis of newly approved therapies and how FDA expedited programs have impacted drug development timelines
Krasimira Pekova, Artisan Healthcare Consulting, USA

Title: Key considerations of orphan products designation and registration regulation
Mona Mohammed, Medac GmbH, Germany

Title: Consent decree, why, how, and what to do?
Adam Sabouni, PharmaConsultz, USA

Title: Leaderships role in implementing and maintaining pharmaceutical quality systems
Brian Hill, Brian Hill Consulting, USA

Title: Combination products and convergence: An overview of clinical benefits, regulatory issues & manufacturing challenges
Michael Drues, Vascular Sciences, USA

Coffee Break @ Pre-function Area

Cocktails sponsored by Pharmaceutical Regulatory Affairs: Open Access @ Pre-function Area
Day 2  September 09, 2014

Washington Room

Keynote Forum

Jerry Xu
WuXi AppTec, China

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

Session Chair: Adam Sabouni, PharmaConsultz, USA
Session Co-Chair: Arunachalam Chinnathambi, King Saud University, King Saudi Arabia

Session Introduction

Title: Business and regulatory environment of biopharmaceuticals and biosimilars in Latin America
Ricardo Ibarra-Cabrera
INBIOXICA SA de CV/Asociacion Mexicana de Comites de etica en Investigacion, Mexico

Title: Herbal medicines: Product licence to traditional herbal registration in the UK
Mariam Aslam, ESCOP, UK

Coffee Break @ Pre-function Area

Title: Implementing a periodic validation review program: A case study
Charles Stock, Integrated Project Services Inc., USA

Title: Biomedical nanotechnology: The smaller the thing, the bigger the challenge!
Michael Drues, Vascular Sciences, USA

Title: CAPA program management via the DMAIC methodology
Roger E Gould, Compliance Technology Group-South, USA

Title: Applied QbD hybrid approach: A case study
Charles Stock, Integrated Project Services Inc., USA

Title: Validation of a software as a service ERP System: Compliant use of cloud computing
David Hawley, IS Compliance and Validation, North America

Title: Investigating problems, applying risk management and creating sustainable solutions
Brian Hill, Brian Hill Consulting, USA

Lunch Break @ Sessions Room

Title: Global regulatory best practices: Companion diagnostics
Abhishek Harde, Cognizant Technology Solutions Limited, USA

Title: Improving clinical research operations: Optimizing the use of current biomarkers
Augustine Onyeaghalu, Afriglobal Medicare, Nigeria

Title: Hidden danger of few extensively used vegetables and herbs renowned for the treatment of diabetes
Nasreen Fatima, University of Karachi, Pakistan

Title: A guide to an effective clinical trial protocol in cGMP & cGCP as a tool for sustenance of ethical principles and regulatory requirements in the pharmaceutical and research
Peter Odeh, SNBL Clinical Pharmacology Center, USA

Title: Production and analysis of biosimilars and follow-on biologics in developing countries
Wael Ebied, SEDICO Pharmaceuticals, Egypt
Rama Krishna Pidaparti, Wipro Technologies, USA

Poster Presentations

Coffee Break @ Pre-function Area

Cocktails sponsored by Journal of Bioanalysis & Biomedicine @ Pre-function Area

Day 3  September 10, 2014

Washington Room
Washington Room

Track 8: Intellectual Property Management
Track 9: Novel Strategies for Growth in the Pharma and Regulatory Environment
Session Chair: William Lee, Cato Research, USA

Session Introduction

Title: Risk based intercultural property assessment
Jerry Xu, WuXi AppTec, China

Title: USP monograph modernization-procedure review and development
Donald Min, United States Pharmacopeial Convention, USA

Title: Regulatory roadmap for initiating a cell therapy drug into clinical trials in the US
William Lee, Cato Research, USA

Title: A quality and regulatory IT strategy for multi division life science companies
Roger E Gould, Compliance Technology Group-South, USA

Coffee Break @ Pre-function Area

Title: A minimally invasive needle endoscope for the visualization of deep brain tissues in vivo
Jun Ki Kim, Korea Basic Science and Technology, South Korea

Title: Pharmaceutics & novel drug delivery systems
Tariq Jamshaid, Surge Laboratories Pvt. Ltd., Pakistan

Title: An investigation about complex formation tendencies of Fe (III) and Fe (II) with antiparkinsonian drug, levodopa at physiological pH
Syed Zafar Abbas Zaidi, University of Karachi, Pakistan

Title: Regulatory challenges of nano therapeutics
Arpit Patel, Gujarat Forensic Sciences University, India

Lunch Break @ Sessions Room

Title: Saudi pharmaceutical market and pharmacy education
Hussam Baghdady, Taibah University, King Saudi Arabia

Title: Required amendments in the cosmetic products legislation in India
Gupta R N, Birla Institute of Technology, India

Title: Quality risk management system
Rashid Mahmood, Surge Laboratories Pvt. Ltd., Pakistan

Title: CHP-complaint handling process an approach in response to the dissatisfaction regarding substandard and a counterfeit drug
Syed Zafar Abbas Zaidi, University of Karachi, Pakistan

Award Ceremony

Coffee Break @ Pre-function Area
Tentative Programme

5th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs
August 03-05, 2015  Orlando, USA
Day 1 August 03, 2015

Registrations

Sciphol

Opening Ceremony

Keynote Forum

Introduction

Essential consensus and scientific definitions for advancement in pharmaceutical regulatory affairs
Ting-Chao Chou, PD Science LLC, USA

Regulatory issues for validation and qualification for new human-on-a-chip systems
James J Hickman, University of Central Florida, USA

Networking and Refreshment Break: @ Foyer

Commercializing disruptive medical technologies in an evolutionary world
Michael Drues, Vascular Sciences, USA

Track 1: Regulatory Affairs for Healthcare Products
Track 2: Best Industry Practices
Track 3: Novel Strategies for Growth in the Pharma and Regulatory Affairs

Session Chair: Ting-Chao Chou, PD Science LLC, USA
Session Co-Chair: Hudson Nakamura, Goias Eye Bank Foundation, Brazil

Session Introduction

Title: The life cycle approach to cleaning validation
Elizabeth Rivera, STERIS Corporation, USA

Title: The premarket notification a.k.a. 510k: Using substantial equivalence to your advantage!
Michael Drues, Vascular Sciences, USA

Title: Regulatory intelligence: Industry’s best practice
Mariam Aslam, PAREXEL International, UK

Lunch Break @ Lobby North

Title: Mexico: Lessons learned from the “external review process” and the “recognition schemes” on the reduction of timelines for the approval of marketing authorizations
Antonio Trejo Díaz, Teva Pharmaceuticals, Mexico

Title: Combined scleral buckle and pars plana vitrectomy as a primary procedure for pseudophakic retinal detachments
Hudson Nakamura, Goias Eye Bank Foundation, Brazil

Title: First to file (FTF) regulatory challenge to QbD adoption
Kishor K Chakraborty, Riyadh Pharma, Saudi Arabia

Networking & Refreshment Break @ Foyer

Title: Pharmacogenomics: The future of clinical trials, new product development and the practice of medicine
Michael Drues, Vascular Sciences, USA

Title: Cosmetics regulations in Saudi Arabia
Mishal A Altamimi, SFDA, Saudi Arabia
Track 1: Regulatory Affairs for Healthcare Products
Track 2: Best Industry Practices
Track 3: Novel Strategies for Growth in the Pharma and Regulatory Affairs

Session Chair: Ting-Chao Chou, PD Science LLC, USA
Session Co-Chair: Hudson Nakamura, Goias Eye Bank Foundation, Brazil

Session Introduction

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Elizabeth Rivera, STERIS Corporation, USA

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Lunch Break @ Lobby North

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Antonio Trejo Diaz, Teva Pharmaceuticals, Mexico

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Hudson Nakamura, Goias Eye Bank Foundation, Brazil

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Kishor K Chakraborty, Riyadh Pharma, Saudi Arabia

Networking & Refreshment Break @ Foyer

Title: Pharmacogenomics: The future of clinical trials, new product development and the practice of medicine
Michael Drues, Vascular Sciences, USA

Title: Cosmetics regulations in Saudi Arabia
Misal A Altamimi, SFDA, Saudi Arabia

Day 2 August 04, 2015

Sciphol

Keynote

Title: Scientific definitions and computerized algorithms for advancement of medical and pharmaceutical regulatory affairs
Ting-Chao Chou, PD Science LLC, USA

Workshop

Title: Commercializing disruptive medical technologies in an evolutionary world
Michael Drues, Vascular Sciences, USA

Networking & Refreshment Break @ Foyer

Track 4: Regulatory Requirements for Pharmaceuticals
Track 5: Requirements for Medical Devices
Track 6: Biologics and Other Novel Therapies

Session Chair: Michael Drues, Vascular Sciences, USA
Session Co-Chair: Antonio Trejo Diaz, Teva Pharmaceuticals, Mexico

Title: Toward better and efficient equilibrium dynamics of research, development, and regulation
Ting-Chao Chou, PD Science LLC, USA

Title: Urolithiases-anti urolithic activity of extracts of roots of Ricinus communis
Juhi Tiwari, Jayoti Vidyapeeth Women’s University, India

Title: The practice of Regulatory Intelligence: Case studies
Mariam Aslam, PAREXEL International, UK

Lunch Break @ Lobby North

Title: Prospects and challenges of providing pharmacovigilance services in resource limited countries
Avong, Institute of Human Virology, Nigeria

Title: Enabling, people and businesses to improve the quality of life, to do so faster and better
Demet Sag, ClearRoadMap, USA
Title: Anti-oxidant intake in antenatal cases high-risk for pregnancy induced hypertension and intrauterine growth restriction
Rajiv Mahendru, B.P.S. Government Medical College for Women, India

Title: Poisoning lightening creams in Morocco: Epidemiological profile
Bellaje R, University Ibn Tofail, Morocco

Networking & Refreshment Break @ Foyer

Title: Challenges & latest regulations have to know about medical devices in Middle East region
Sara Hegazi, Philips Healthcare, UAE

Title: Poisoning by hydrogen peroxide hair bleaching: Moroccan Poison Control Center data
Bellaje R, University Ibn Tofail, Morocco

Title: SWOT analysis of the Addis Ababa City administration food, medicine and health care administration and control authority
Solomon Getnet Meshesha, Addis Ababa University, Ethiopia

Poster Presentations @ Lobby North Foyer

Track 6: Intellectual Property Management
Track 7: Marketing Authorizations, Advertising and Marketing Practices
Track 8: Drug Designing and Development

Session Chair: Rajiv Mahendru, B.P.S. Government Medical College for Women, India
Session Co-Chair: Brian Hill, Brian Hill Consulting, USA

Title: A review on autism
Juhi Tiwari, Jayoti Vidyapeeth Women's University, India

Title: The effectiveness of the spontaneous reporting system
Avong, Institute of Human Virology, Nigeria

Title: Understanding your supply chain
Brian Hill, Brian Hill Consulting, USA

Networking & Refreshment Break @ Foyer

Title: Stem cells and its basic use in medicinal field
Sai Sankar Prabhu Kella, K. J. R. College of Pharmacy, India

Title: Want to eliminate events & predict quality near misses; reduce deviation rate by >90% & gain >25% production efficiency simultaneously?
Amy Peterson, Quality Systems, USA

Title: New perspective on how to discover drugs from herbal medicines: Simulating wild animals self medication by human diseased-animal models to screen new therapeutics
Wael Ebied, SQA Services Inc., USA

Lunch Break 5 @ Lobby North

Title: Formation of nucleation and coalescence of bubbles in different benzene and liquid solutions by liquid - liquid extraction using partial miscible mixtures
Nadeem Ahmad, Advanced product design services, Canada

Title: Sharing regulatory data as tools for strengthening health systems in the region of the Americas
Damaris Silveira, University of Brasilia, Brazil

Title: Facial cosmetics & role of pharmacist in client education
Mamoona Firdous Naqvi, Gulf Pharmaceutical Industries, UAE

Networking & Refreshment Break @ Foyer

Title: Quality assessment and in vitro dissolution profile: Comparison of different brands of amoxicillin
Lantider Kassaye Bekele, GlaxoSmithKline Ltd., Ethiopia

Title: Quality risk management system
Rashid Mahmood, Surge Laboratories Private Limited, Pakistan

Title: Pharmaceutics & novel drug delivery systems
Tariq Jamshaid, Surge Laboratories Private Limited, Pakistan

Award Ceremony
6th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR

September 29-30, 2016
Orlando, USA

Hosting Organizations: Conference Series LLC Ltd
47 Churchfield Road, London, UK, W3 6AY
Toll Free: +1-800-014-8923
Phone: +1-702-508-5200, Fax: +1-650-618-1417, Toll free: +1-800-216-6499

Email: regulatoryaffairs@conferenceseries.net
## Conference Day One | Thursday September 29, 2016

### Salon 3 & 4

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<thead>
<tr>
<th>Registrations</th>
<th>Opening Ceremony</th>
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### Keynote Forum

#### Introduction

| Title: Regulatory requirements and filing considerations for Type II master files  
**Ramnarayan Randad**, Food and Drug Administration, USA |
|-------------|

| Title: Localization of foreign medicinal products manufacturing in Russia  
**Jelena Gankina**, NPF Materia Medica Holding, Russia |
|-------------|

### Refreshments and Networking Break 11:20-11:40

| Title: Pharmaceutical regulatory environment with perspective on the International GMP's  
**Mohammed R Khan**, Synergex Consulting, Canada |
|-------------|

| Title: Future medical applications in 3-D printing: Clinical benefits, regulatory issues & manufacturing challenges™  
**Michael Drues**, Vascular Sciences, USA |
|-------------|

### Lunch Break 13:00-13:45

#### Session Introduction

| Session Chair: Mohammed R Khan, Synergex Consulting, Canada  
Session Chair: Ramnarayan Randad, Food and Drug Administration, USA |
|-----------------|

| Title: Risks of inadequate regulatory intelligence  
**Priya Bhutani**, RegDesk, Inc., USA |
|-------------|

| Title: Evaluating a novel drug delivery system for oral amoxicillin  
**Nadeem Ahmad**, Advanced Product Design Services, Canada |
|-------------|

| Title: Communication with FDA: What do we say and how do we say it?™  
**Michael Drues**, Vascular Sciences, USA |
|-------------|

| Title: The regulatory affairs as a bridge between government regulatory authorities and pharmaceutical companies  
**Elene Chikobava**, Quadrium Pharmhouse Ltd., Georgia |
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<tbody>
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<td>09:00</td>
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<td>09:00-09:15</td>
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| 09:15              | Title: ABC-VEN matrix analysis of pharmaceutical inventory management in Tikur Anbessa specialized hospital for the years 2009 to 2013, Addis Ababa, Ethiopia  
Sefinew Migbaru, Addis Ababa University, Ethiopia |
| 09:30              | Title: SWOT analysis of the Addis Ababa city administration food, medicine and health care administration and control authority  
Meshesha Solomon Getnet, Addis Ababa University, Ethiopia |
| 09:45              | Title: Food additives and health  
Mercy Robert Ekwere, Cross River College of Education, Nigeria |
| 10:00              | B2B Meetings and Networking                                           |
| 10:30              | Award Ceremony                                                       |
| 11:00              | Lunch Break                                                           |
| 11:15              | Refreshments and Networking Break 15:25-15:45                          |
| 11:30              | B2B Meetings                                                          |
| 13:00              | Lunch Break                                                           |
Organizing Committee Members

Kenneth Christie  
VTS Consultants, Inc.,  
USA

Elene Chikobava  
Quadrium Pharmhouse  
Georgia

Boyd L Summers  
BL Summers Consulting LLC  
USA

Mark Kindy  
University of South Florida  
USA

David Amor  
Medgineering Inc.,  
USA

Mohammed R Khan  
Synergex Consulting  
Canada
Ramnarayan Randad
Food and Drug Administration, USA

Title: Regulatory requirements and filing considerations for type II master files

Biography
R. S. Randad, Ph.D. (Ram) is Quality Assurance Leader and Master Review Chemist in the office of Life Cycle API, ONDP. In addition to the CMC reviews, he has served on number of working group such as Risk-Based Review, Complex Drug Substance, Question based Review (QbR), Quality by Design based QbR revision, the Office of Generic Drugs Education and Training committee, DMF Completeness assessment team, Center for Science and advancement, and US Pharmacopeia monograph development committees. He has frequently represented Agency on CMC issues and regulatory science in public speaking engagements. He is an author of “FDA Drug Review and Regulation” to the “Burger’s Medicinal Chemistry, Drug Discovery and Development”. Prior to joining FDA, Ram worked in the private sector for 15 years as a Research Chemist, Principal Investigator, Group Leader, and Director of Chemistry. Randad has authored more than 25 scientific papers in the peer reviewed journals and has > 10 US patents to his credit. His work has led to the design and development of a drug lead. He received Ph.D. from National Chemical laboratory, Poona University, India in 1985. Soon after, he came to US as a Postdoctoral Associate of Prof. Herbert C Brown, Nobel Laureate, Purdue University.

Mohammed R Khan
Synergex Consulting, Canada

Title: Pharmaceutical regulatory environment with perspective on the international GMP’s

Biography
Mohammed Khan is a Quality Management Consultant and Principal Synergex Consulting in Ontario, Canada. He has earlier served as Director QA, QC & Regulatory Compliance with DuPont Pharmaceuticals, Canada, and on the Board of the Pharmaceutical Manufacturers Association of Canada, Plant Operations Section. He has also served on the DIA’s Advisory Council of North America and chaired the DIA’s Canadian Programming Steering Committee and is the recipient of the DIA Outstanding Service Award. He has served as Program Coordinator, Program Committee Member, Session Chair and Speaker at numerous national and international DIA events, as well as Presenter for the PDA, OMICS Group, IQPC, PSG Canada, UK based International Society of Ethnopharmacology, and the Indian Pharmaceutical Congresses.

Michael Drues
Vascular Sciences, USA

Title: Future medical applications in 3-D printing: clinical benefits, regulatory issues & manufacturing challenges

Biography
Michael Drues is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programing, brain-storming sessions, prototype design, product development, benchtop & animal testing, innovative regulatory strategy & competitive regulatory intelligence, clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment. Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development.
Jelena Gankina
NPF Materia Medica Holding, Russia

Title: Localization of Foreign Medicinal Products Manufacturing in Russia

Biography
Jelena Gankina has extensive experience in the pharmaceutical industry. Having graduated as a pharmacist in Moscow, she started her professional career as a scientist in R&D (Scientific Research Institute of Pharmacology, Moscow) and got her Ph.D. in molecular pharmacology. She has presented her scientific results during professional events and in scientific press in Russia and abroad. Since 1994, Jelena has been working in the regulatory field, where she has gathered experience in generic (LEK Pharmaceuticals, PLIVA Hrvatska d.o.o., Polpharma), innovative (Bristol-Myers Squibb) and Russian domestic companies (Akrikhin) in Russia, CIS and the EU in different areas: registration (APIs, medicinal products, medical devices, para-pharmaceuticals), quality, pharmacovigilance and clinical operations.

Charles Schmidt
FCMSCSP, Brazil

Title: Recently Developments for Regulatory Clinical Trial Approvals in Brazil

Biography
Pediatrician with Master and Doctorate degree. He has been practicing and teaching while working in the biopharma for the past 25 years. He had developed and managed successfully big and medium size CROs in Latin America and at their global level for more than 15 years. His experience also includes leadership roles in Medical Affairs, Pharmacovigilance, and Medical Monitoring in Pharmaceutical companies. Charles has an extensive background in clinical development efforts in many therapeutic areas in LatAm. He is an attending physician in coordinating the post-graduation program in clinical research at Santa Casa Medical School in Sao Paulo - Brazil since 2007. Also, he is the medical manager of the central institute of clinical research at Hospital de Clinicas - Sao Paulo. Charles was the founder and ex-president of the Brazilian Association of CROs and director of Brazilian Association of Pharmaceutical Physicians - SBMF.

Elene Chikobava
Quadrium Pharmhouse Ltd., Georgia

Title: The Regulatory Affairs as a bridge between Government Regulatory Authorities and Pharmaceutical Companies

Biography
Elene Chikobava is a Master Chemistry, with 10 years of working experience as a biochemist in the Scientific-Research Centre of Biophysics and Biotechnology, where she has completed her PhD in Biologic Science. She became a senior specialist of the Pharmacopoeia Committee of Drug Agency of the Ministry of health, Labor and Social affairs of Georgia after its creation in 2003. After being actively involved in renovation of the Pharmacopoeia Committee, where she worked as a senior specialist of Pharmacopoeia Department. Then she started to work as a Head of Regulatory Affairs specialist for the domestic manufacturer of generic and herbal products - “Biopolus” Ltd (Georgia), along with it she was consulting Georgian wholesalers “GPC” about pharmaceutical products registrations of pharmaceutical products in Georgia and different companies; clinical researches and manufacturing technology. Dr. Chikobava had been a participant of numerous scientific conferences, including those conducted by WHO, she has published more than 20 scientific papers.

Rashid Mahmood
Surge Laboratories Private Limited, Pakistan

Title: Cleaning validation in pharmaceuticals

Biography
Rashid Mahmood has 13 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, NDA, ANDA, BLA, GMP Requirements, Drugs Laws, Statistical Methodology, Method Validation, Process & Cleaning Validation, Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, ISO/IEC 17025:2005, 14001:2004, OHSAS 18001:2007, SA 8000 and 9001:2008 with strong scientific, analytical, statistical, planning, managerial and training skills, have written several articles and attended many international conferences as a speaker and presented various speeches in USA & China on Clean ing Validation, cGMP Guidelines, Quality Risk Management etc.
Scientific Program

Proceedings of
6th International Conference and Exhibition on
GMP, GCP & Quality Control

&
7th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR

SEPTEMBER 25-26, 2017 | CHICAGO, USA

Sponsor & Exhibitor

GMP Trends

Abbott
**Day 1  September 25, 2017**

08:00-09:00 Registrations @ East wing pre-function area

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**Keynote Forum**

**Introduction**

**Title:** Government and industry response to the US opioid epidemic  
Robert P Bianchi, Prescription Drug Research Center, USA

**Title:** Conducting effective FDA pre-sub meetings: Tell don’t ask… lead don’t follow!  
Michael Drues, Vascular Sciences, USA

**Title:** Six essential do’s and don’ts for an effective GMP extractables and leachables strategy  
Shane P Smith, ExtLe Solutions Ltd., UK

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**Group Photo**

Networking Break 11:00-11:20 @ Athens Room

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**Session 1:**  
GMP in Food Industry | Current GMP Guidelines (cGMP) | Quality Assurance | Quality Control | Clinical Affairs & Regulatory Strategies Implementation

**Session Chair:** Paul J Cummings, PJC Pharma Consulting Ltd, UK

**Session Co-chair:** Felix Amiri, (GCSE-FHP), Canada

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**Session Introduction**

**Title:** Food industry Good Manufacturing Practices (GMPs) and the Safety, Security and Quality Assurance (SSQA) concept  
Felix Amiri, Global Coalition for Sustained Excellence in Food & Health Protection (GCSE-FHP), Canada

**Title:** Quality control in statistical programming under GCP  
Sharmeen Reza, Cytel Inc, USA

**Title:** Data integrity requirements for GxPs  
Chris Wubbolt, QACV Consulting LLC, USA

**Title:** Regulatory compliance & notified bodies inspection readiness  
Mayra Guzman-Kaslow, GK Regulatory, Compliance, & Engineering Consulting Corporation, USA

**Title:** Quality risk management system  
Rashid Mehmood, Surge Laboratories Private Limited, Pakistan

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**Lunch Break**

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**Session 2:**  
Good Laboratory Practices | Good Pharmacovigilance Practices | Audits and inspections | Regulatory & Pharmacovigilance | FDA and related regulatory agencies

**Session Chair:** Eliana Silva de Moraes, ABPVS, Brazil

**Session Co-chair:** Diadelis Remirez Figueredo, Devices and medical equipments (CECMED), Cuba

**Title:** Antimicrobial activity of the ethanolic and aqueous extract of Vicia faba L. (Fabaceae)  
R C Jagessar, University of Guyana, Guyana

**Title:** The many connotations of risk and the consequences of getting them wrong  
Michael Drues, Vascular Sciences, USA
| Title: Traditional plant drugs as potential immunomodulators  
| P Brindha, Sastra University, India |
| Title: Cleaning validation in pharmaceuticals  
| Rashid Mahmood, Surge Laboratories Private Limited, Pakistan |

### Networking Break

| Title: Roadmap to pharmaceutical regulatory harmonization in Pakistan  
| Muhammad Naeem, Indus Pharma (Pvt.) Ltd, Pakistan |
| Title: Early access to unapproved medicines in EU  
| Parminder Kaur, RegPak BioPharma Consulting, Netherlands |

### Video Presentation

| Title: Strategic trends, current and future competitive landscape in biologics and biosimilars (follow-on biologics) drug development in USA and emerging markets—a brief snapshot from 2012 through 2022  
| Yavuz S Silay, ICG (Istanbul Consulting Group), USA |

### Panel Discussion

**Day 2        September 26, 2017  
Zurich**

#### Keynote Forum

- **Introduction**
- **Title: Global regulatory challenges and implications**
  Eliana Silva de Moraes, ABPVS, Brazil
- **Title: Convergence of regulatory affairs and reimbursement/market Access**
  Stephen F Amato, North Eastern University, USA

#### Session 1:  
**Quality Assurance | The Role of c in cGMP | Current GMP Guidelines (cGMP) | Validation**

**Session Chair: Eleonora Babayants, Galaxy Consulting, USA**  
**Session Co-chair: Paul Lopolito, STERIS Corporation, USA**

- **Title: Cleaning validation: Process life cycle approach**
  Paul Lopolito, STERIS Corporation, USA
- **Title: Develop and implement effective methods of teaching and convenient procedures for the implementation of new methodology student centered learning to drive the institute to new heights by satisfying more and more students and industrial needs**
  Sudhakar Sagaram, BDR Pharmaceuticals Internationals Pvt. Ltd., India

### Networking Break

- **Title: Quality control and validation**
  Chintan V Pandya, HVHP Institute, India
- **Title: GMP deficiencies found by ANVISA in foreign inspections**
  Andrea Geyer, Universidade de Brasilia, Brazil
- **Title: Pharmacogenetic: Regulatory considerations, cuban guidance**
  Ramirez Diadelis, Devices and medical equipments (CECMED), Cuba

### Lunch Break

- **Title: GxP/GMP and its consequences for documentation and information technology systems**
  Eleonora Babayants, Galaxy Consulting, USA
Session 2:
Global Regulatory Affairs | Regulatory Enforcement & Inspection | Audits and inspections | Good Laboratory Practices | Good Pharmacovigilance Practices

Session Chair: Stephen F Amato, North Eastern University, USA
Session Co-chair: Eliana Silva de Moraes, ABPVS, Brazil

Session Introduction

**Title:** Development of the molecular diagnostics considering the quality of damaged nucleic acids from formalin-fixed paraffin-embedded tissue samples  
**Young Kee Shin,** Seoul National University, Korea

**Title:** Prevalence of anemia in pregnancy among women visiting antenatal clinic in bingham university teaching hospital  
**Olorunfunmi,** Bingham University, Nigeria

**Title:** Antimicrobial activity of the ethanolic and aqueous extract of passion fruit (*Passiflora edulis* Sims) in the absence and presence of transition metal salts  
**R C Jagessar,** University of Guyana, Guyana

**Title:** Formulation and evaluation of herbal tablets and capsules containing *Urtica dioica* extract  
**Farah Khalil Yousef,** Damascus University, Syria

Poster Presentations

**Poster Judge:** Paul J Cummings, PJC Pharma Consulting Ltd, UK

**Title:** GMP deficiencies found by ANVISA in foreign inspections  
**Andrea Geyer,** Universidade de Brasilia, Brazil

**Title:** Herbal medicines pre-marketing registration process in the state of Kuwait: An up-to-date overview of the process  
**Azhar H Alostad,** The University of Manchester, UK

Video Presentations

**Title:** Antibacterial activity of *lawsonia inermis* (Sudanese Henna) leaves extracts against *staphylococcus aureus*, *escherichia coli* and *pseudomonas aeruginosa* among recurrent urinary tract infection patients  
**Hanaa A M Elgailany,** Sudan University of Science and Technology, Sudan

**Title:** Biochemical diagnosis of acute pancreatitis  
**Anil Batta,** GGS Medical College, India

**Title:** Strengthening health regulation in the americas: The experience of the national regulatory authorities of regional reference  
**Lisette Pérez Ojeda,** CECMED, Cuba

Panel Discussion

Award and Closing Ceremony