# Scientific Program

## Day 1

### Keynote Session

- **08:45-09:15**
  - Keynote Talk 1
- **09:15-09:45**
  - Keynote Talk 2
- **09:45-10:15**
  - Keynote Talk 3
- **10:15-10:45**
  - Keynote Talk 4

### Coffee/Tea Break 10:45-11:00

### Pre-Lunch Session

- **11:00-12:40**
  - Plenary Session 1 | Tracks 1, 2 & 3
  - Regulatory Affairs | Regulatory Affairs in Pharmacovigilance | Clinical Affairs & Regulatory Strategies

### 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

### Keynote Session

- **09:15-09:45**
  - Keynote Talk 5
- **09:45 - 10:15**
  - Keynote Talk 6
- **10:15 - 10:45**
  - Keynote Talk 7

### Coffee/Tea Break 10:45-11:00

### Pre-Lunch Session

- **11:00-12:40**
  - Plenary Session 4 | Tracks 10, 11 & 12
  - Marketing Authorizations | Regulatory Requirements for Pharmaceuticals | Regulatory Challenges for Medical Devices

### Post Lunch Sessions

- **13:30-15:30**
  - Plenary Session 5 | Tracks 13 & 14
  - Medical Device & Combination Products Regulations | Best Industry Practices

### Closing and Award Ceremony

### For More Details:

- [http://regulatoryaffairs.pharmaceuticalconferences.com](http://regulatoryaffairs.pharmaceuticalconferences.com)
- regulatoryaffairs@conferenceseries.net, regulatoryaffairs@pharmaceuticalconferences.org
Glimpses of Regulatory Affairs Conferences

http://regulatoryaffairs.pharmaceuticalconferences.com
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/winners 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

Contact us
America: Conference Series LLC
Regulatory Affairs 2018
One commerce center-1201
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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 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

Conferenceseries.com
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
Opening Ceremony

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

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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**

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

**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

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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 Naqvi**, Gulf Pharmaceutical Industries-Julphar, UAE

Title: FDA process validation guidance & principals vs EMA guidance  
**Rober Remon Saad 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**

| Session Chair: Netta Fulga, The Hospital for Sick Children, Canada  
Session Co-Chair: Chitra Edwin, Cleveland HeartLab, Inc., USA  
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 Stanco Private Limited, Pakistan  
Title: Liposome characterization required for regulatory approvals  
Donald Kruppa, Azaya Therapeutics, Inc., USA  
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  
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  
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 Aljuffali, 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

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

### Day 3  
**October 23, 2013**  
**Redwood/Sequola**

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

*The page also includes a list of additional sessions, tracks, and posters presented during the conference.*
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

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
Scientific Program

4th International Conference on
Pharmaceutical Regulatory Affairs

September 08-10, 2014  DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA
### Keynote Forum

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Company/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title: Assessment of the antibacterial activity of actinomycetes isolated from terrestrial soil of King Saud University campus</strong></td>
<td>Arunachalam Chinnathambi</td>
<td>King Saud University, King Saudi Arabia</td>
</tr>
<tr>
<td><strong>Title: Extractables and leachables: Regulatory perceptive</strong></td>
<td>Kishore Kumar Hotha</td>
<td>Novel Laboratories, USA</td>
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<tr>
<td><strong>Title: Challenges &amp; latest regulations have to know about medical devices in Middle East region</strong></td>
<td>Sara Hegazi</td>
<td>Philips Healthcare, UAE</td>
</tr>
<tr>
<td><strong>Title: Implementation of changes aligned to regulatory framework</strong></td>
<td>Mohammad Iqbal Hossain</td>
<td>Novartis Limited, Bangladesh</td>
</tr>
<tr>
<td><strong>Title: Pharmabiotics: A regulatory hurdle in Europe</strong></td>
<td>Magali Cordaillat-Simmons</td>
<td>Pharmabiotic Research Institute, France</td>
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</tbody>
</table>

### Session Introduction

**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

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<tr>
<td><strong>Title: Combining nanotheranostics and photomedicine: Design and synthesis of nanophotomedicine</strong></td>
<td>Jayeeta Bhaumik</td>
<td>NIPER, India</td>
</tr>
<tr>
<td><strong>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</strong></td>
<td>Krasimira Pekova</td>
<td>Artisan Healthcare Consulting, USA</td>
</tr>
<tr>
<td><strong>Title: Key considerations of orphan products designation and registration regulation</strong></td>
<td>Mona Mohammed</td>
<td>Medac GmbH, Germany</td>
</tr>
<tr>
<td><strong>Title: Consent decree, why, how, and what to do?</strong></td>
<td>Adam Sabouni</td>
<td>PharmaConsultz, USA</td>
</tr>
<tr>
<td><strong>Title: Leadership role in implementing and maintaining pharmaceutical quality systems</strong></td>
<td>Brian Hill</td>
<td>Brian Hill Consulting, USA</td>
</tr>
<tr>
<td><strong>Title: Combination products and convergence: An overview of clinical benefits, regulatory issues &amp; manufacturing challenges</strong></td>
<td>Michael Drues</td>
<td>Vascular Sciences, USA</td>
</tr>
</tbody>
</table>

### Lunch Break @ Sessions Room

**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 Onyeagbala, 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
### Session Introduction

#### Track 8: Intellectual Property Management

**Session Chair:** William Lee, Cato Research, USA

<table>
<thead>
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<tr>
<td>Risk based intercultural property assessment</td>
<td>Jerry Xu</td>
<td>WuXi AppTec, China</td>
</tr>
<tr>
<td>USP monograph modernization-procedure review and development</td>
<td>Donald Min</td>
<td>United States Pharmacopeial Convention, USA</td>
</tr>
<tr>
<td>Regulatory roadmap for initiating a cell therapy drug into clinical trials in the US</td>
<td>William Lee</td>
<td>Cato Research, USA</td>
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<tr>
<td>A quality and regulatory IT strategy for multi division life science companies</td>
<td>Roger E Gould</td>
<td>Compliance Technology Group-South, USA</td>
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#### Track 9: Novel Strategies for Growth in the Pharma and Regulatory Environment

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<tbody>
<tr>
<td>A minimally invasive needle endoscope for the visualization of deep brain tissues in vivo</td>
<td>Jun Ki Kim</td>
<td>Korea Basic Science and Technology, South Korea</td>
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<tr>
<td>Pharmaceuticals &amp; novel drug delivery systems</td>
<td>Tariq Jamshaid</td>
<td>Surge Laboratories Pvt. Ltd., Pakistan</td>
</tr>
<tr>
<td>An investigation about complex formation tendencies of Fe (III) and Fe (II) with antiparkinsonian drug, levodopa at physiological pH</td>
<td>Syed Zafar Abbas Zaidi</td>
<td>University of Karachi, Pakistan</td>
</tr>
<tr>
<td>Regulatory challenges of nano therapeutics</td>
<td>Arpit Patel</td>
<td>Gujarat Forensic Sciences University, India</td>
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</tbody>
</table>

### Coffee Break

@ Pre-function Area

### Lunch Break

@ Sessions Room

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Saudi pharmaceutical market and pharmacy education</td>
<td>Hussam Baghdady</td>
<td>Taibah University, King Saudi Arabia</td>
</tr>
<tr>
<td>Required amendments in the cosmetic products legislation in India</td>
<td>Gupta R N</td>
<td>Birla Institute of Technology, India</td>
</tr>
<tr>
<td>Quality risk management system</td>
<td>Rashid Mahmood</td>
<td>Surge Laboratories Pvt. Ltd., Pakistan</td>
</tr>
<tr>
<td>CHP-complaint handling process an approach in response to the dissatisfaction regarding substandard and a counterfeit drug</td>
<td>Syed Zafar Abbas Zaidi</td>
<td>University of Karachi, Pakistan</td>
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### Award Ceremony

<table>
<thead>
<tr>
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<th>Pre-function Area</th>
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**Bookmark your dates**

### 3rd International Summit on GMP, GCP & Quality Control

**September 25-26, 2014**  
Valencia Convention Centre, Spain

**Bookmark your dates**

### 5th International Conference on Pharmaceutical Regulatory Affairs

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

Tentative Programme
Scientific Program

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

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 Diaz, 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
### Session Introduction

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

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**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  
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*Kishor K Chakraborty,* Riyadh Pharma, Saudi Arabia  

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**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  

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### 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  

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**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:** Urolithiasis-anti urolithic activity of extracts of roots of Ricinus communis  
*Juhi Tiwari,* Jayoti Vidyapeeth Womens’ University, India  

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

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**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

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

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

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

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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

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

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

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

September 29-30, 2016
Orlando, USA

Hosting Organizations: Conference Series LLC
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### Conference Day One | Thursday September 29, 2016

#### Salon 3 & 4

**Registrations**

**Opening Ceremony**

#### Keynote Forum

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| **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 |
Conference Day Two | Friday September 30, 2016

Salon 3 & 4

Session Chair: Jelena Gankina, NPF Materia Medica Holding, Russia
Session Chair: Mohammed R Khan, Synergex Consulting, Canada

Session Introduction

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<th>Title</th>
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<td>Sefinew Migbaru, Addis Ababa University, Ethiopia</td>
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<td>Cleaning validation in pharmaceuticals</td>
<td>Rashid Mahmood, Surge Laboratories Private Limited, Pakistan</td>
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<td>SWOT analysis of the Addis Ababa city administration food, medicine and health care administration and control authority</td>
<td>Meshesha Solomon Getnet, Addis Ababa University, Ethiopia</td>
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<tr>
<td>Food additives and health</td>
<td>Mercy Robert Ekwere, Cross River College of Education, Nigeria</td>
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Refreshments and Networking Break 11:10-11:30

B2B Meetings

Refreshments and Networking Break 15:25-15:45

B2B Meetings and Networking

Award Ceremony

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 Pharmacopoeia 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 & complete 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.
Charles Schmidt
FCMSCSP, Brazil
Title: Recently Developments for Regulatory Clinical Trial Approvals in Brazil

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 Clínicas - 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

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

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, ISO17025:2005, 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
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&
7th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR

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Day 1  September 25, 2017

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

Zurich

09:00-09:25

Opening Ceremony

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

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

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

Lunch Break

Title: Medical device vigilance in EU
Parminder Kaur, RegPak BioPharma Consulting, Netherlands

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

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

Group Photo
Introduction

Keynote Forum

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

Session Introduction

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
Remirez 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 N the national regulatory authorities of regional reference
Lisette Pérez Ojeda, CECMED, Cuba

Panel Discussion
Award and Closing Ceremony