Tentative Program

8th International Conference on
cGMP, GCP & Regulatory Affairs
June 08-09, 2018   Baltimore, Maryland, USA

***For available speaker slots***
regulatoryaffairs@pharmaceuticalconferences.org

300+ Participation

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

Conference Secretariat
One commerce center-120, Orange st. #600 Wilmington, Delaware, USA
Tel: 7025085200, Zip: 19899
Email: regulatoryaffairs@pharmaceuticalconferences.org

http://regulatoryaffairs.pharmaceuticalconferences.com
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Track</th>
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<tbody>
<tr>
<td>10:15-10:45</td>
<td>Keynote Talk 4</td>
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<td>10:45-11:00</td>
<td>Coffee/Tea Break</td>
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<td>11:00-12:40</td>
<td>Pre-Lunch Session</td>
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<td>12:40-13:30</td>
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<td>13:30-15:30</td>
<td>Post Lunch Sessions</td>
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<td>Coffee/Tea Break</td>
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<td>15:45-18:00</td>
<td>Evening Sessions</td>
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**Day 1**

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<td>09:00 - 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>
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<td>08:45-09:15</td>
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<td>09:00 - 09:45</td>
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<td>09:45 - 10:15</td>
<td>Keynote Talk 6</td>
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<td>10:15 - 10:45</td>
<td>Keynote Talk 7</td>
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<td>08:45-09:15</td>
<td>Keynote Talk 8</td>
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**For More Details:** [http://regulatoryaffairs.pharmaceuticalconferences.com](http://regulatoryaffairs.pharmaceuticalconferences.com)

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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

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
Chicago, Illinois, USA

Contact us
America: Conference Series LLC
Regulatory Affairs 2018
One commerce center-1201
Orange st. #600
Wilmington, Delaware, USA
Tel no: 7025085200, Zip: 19899
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Best Tourist Destinations in Baltimore

American visionary Art Museum

Chicago Ta Fort McHenry National Monument and Historic Shrine heatre

John Hopkins University

Walters Art Gallery

Patterson Park
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

Media Partners

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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

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*

**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
*Michele Carpenter, Regulatory Consultant, USA*

**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
*Mamoona 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*

Registrations

Day 1  October 21, 2013

Redwood/Sequola

**Opening Ceremony**

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

Lunch Break @ Tiburon/Sausalito

Coffee Break @ Sierra Foyer
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

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: 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

Cocktails Sponsored by Pharmaceutical Regulatory Affairs: Open Access

Day 3  
October 23, 2013  
Redwood/Sequola

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

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

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

Title: Pricing policy for a patent medicine? Need for changing the framework 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 Kenneth Jorgensen, Sorin Group, Switzerland

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

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

4th International Conference on
Pharmaceutical Regulatory Affairs

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

Media Partners
Keynote Forum

Introduction

Adam Sabouni
PharmaConsultz, USA

David Hawley
IS Compliance and Validation, North America

Michael Drues
Vascular Sciences, USA

Coffee Break @ Pre-function Area

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

Coffee Break @ Pre-function Area

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: Leadership’s 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 Onyeaghala, 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
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

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**Bookmark your dates**

3rd International Summit on GMP, GCP & Quality Control  
September 25-26, 2014  Valencia Convention Centre, Spain

5th International Conference on Pharmaceutical Regulatory Affairs  
August 03-05, 2015  Florida, USA
Tentative Programme

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

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

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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

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

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

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 Women’s University, India

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

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

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 Vidya Peeth Womens' 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
Conference Day One | Thursday September 29, 2016

Salon 3 & 4

Registrations

Opening Ceremony

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
## 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

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
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<tr>
<td>Recently developments for regulatory clinical trial approvals in Brazil</td>
<td>Charles Schmidt</td>
<td>FCMSCSP, Brazil</td>
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<tr>
<td>Cleaning validation in pharmaceuticals</td>
<td>Rashid Mahmood</td>
<td>Surge Laboratories Private Limited, Pakistan</td>
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#### Refreshments and Networking Break 11:10-11:30

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
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</thead>
<tbody>
<tr>
<td>ABC-VEN matrix analysis of pharmaceutical inventory management in Tikur Anbessa specialized hospital for the years 2009 to 2013, Addis Ababa, Ethiopia</td>
<td>Sefinew Migbaru</td>
<td>Addis Ababa University, Ethiopia</td>
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<tr>
<td>SWOT analysis of the Addis Ababa city administration food, medicine and health care administration and control authority</td>
<td>Meshesha Solomon Getnet</td>
<td>Addis Ababa University, Ethiopia</td>
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<tr>
<td>Food additives and health</td>
<td>Mercy Robert Ekwere</td>
<td>Cross River College of Education, Nigeria</td>
</tr>
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#### B2B Meetings

<table>
<thead>
<tr>
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</tbody>
</table>

#### Refreshments and Networking Break 15:25-15:45

### B2B Meetings and Networking

### Award Ceremony

### Lunch Break
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 & 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

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 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

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, OHSAWS 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
### 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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### 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

**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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### Opening Ceremony

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### Group Photo

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

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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

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 anteatal 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