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Tentative Program

8th International Conference on

cGMP, GCP & Regulatory Affairs

June 08-09, 2018 Baltimore, Maryland, USA



For available speaker slots

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300+ Participation

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

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http://regulatoryaffairs.pharmaceuticalconferences.com

8th International Conference on

cGMP, GCP & Regulatory Affairs

June 08-09, 2018 Baltimore, Maryland, USA

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
Netwroking 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 | Track 7, 8 & 9* Global Regulatory Intelligence| Impact of Brexit on Regulatory Framework| Regulatory Communications and Submissions Panel Discussions | Extended Networking
DAY 2		
Keynote Session		
09:00 - 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| Track 10, 11 & 12* Marketing Authorizations| Regulatory Requirements for Pharmaceuticals| Regulatory Challenges for Medical Devices
Netwroking 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		

For More Details: http://regulatoryaffairs.pharmaceuticalconferences.com

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Glimpses of Regulatory Affairs Conferences





















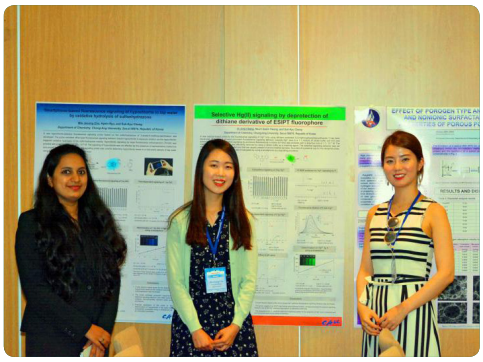




Glimpses of Regulatory Affairs Conferences













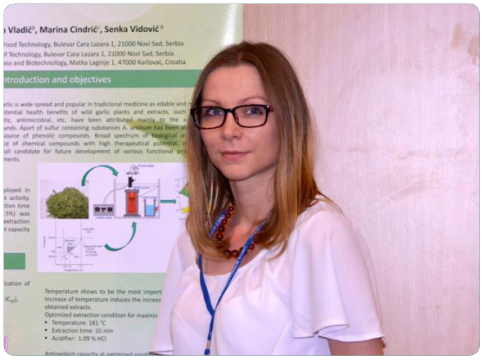












Major Scientific Sessions

- 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/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

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John Hopkins University



Walters Art Gallery



Patterson Park

Scientific Program

3rd International Conference on

Pharmaceutical Regulatory Affairs

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



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Registrations

Redwood/Sequola

Opening Ceremony

Keynote Forum

Introduction

Steve Jwanouskos
OptiMedica, USA

Coffee Break @ Sierra Foyer

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

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

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

Cocktails Sponsored by **Pharmaceutical Regulatory Affairs: Open Access**

Day 2 October 22, 2013

Redwood/Sequola

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

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

Session Introduction

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 Kruppa, Azaya 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 Alsamil, 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 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

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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

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



2nd International Summit on

GMP, GCP & Quality Control

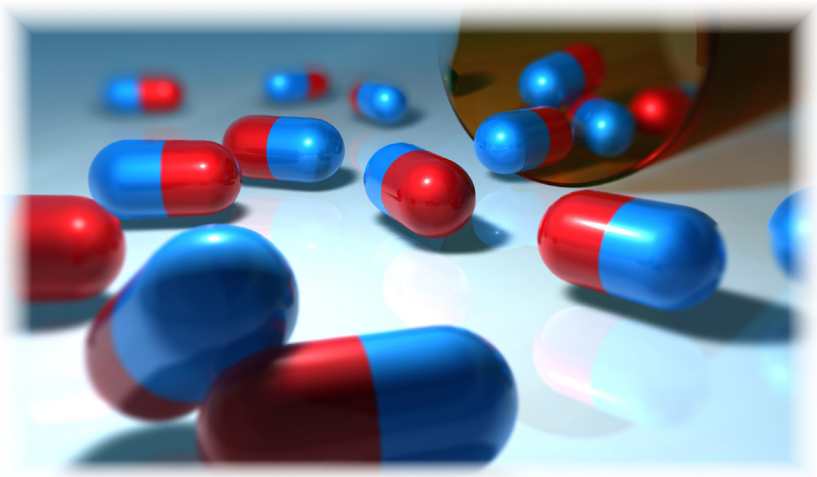
November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore USA



2nd International Conference and Exhibition on

Pharmacovigilance & Clinical Trials

November 18-19, 2013 Hilton San Antonio Airport, USA



Bookmark your dates

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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



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Day 1 September 08, 2014

Registrations

Washington Room

Opening Ceremony

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

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 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**

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

Bookmark your dates

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

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

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5th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs

August 03-05, 2015 Orlando, USA



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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

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

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: Urolithiasis-anti urolithic activity of extracts of roots of Ricinus communis
Juhi Tiwari, Jayoti Vidya Peeth Womens' 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

Day 3 August 05, 2015

Sciphol

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 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

conferenceseries.com

Scientific Program

6th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs and IPR

September 29-30, 2016
Orlando, USA





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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

Refreshments and Networking Break 15:25-15:45

Title: Recently developments for regulatory clinical trial approvals in Brazil
Charles Schmidt, FCMSCSP, Brazil

Title: Cleaning validation in pharmaceuticals
Rashid Mahmood, Surge Laboratories Private Limited, Pakistan

B2B Meetings

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

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

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

Title: Food additives and health
Mercy Robert Ekwere, Cross River College of Education, Nigeria

Refreshments and Networking Break 11:10-11:30

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 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 laboatory, 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 & completive 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 Medicare 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 mediun 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 wholesaler “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.

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

Zurich

conferenceseries.com 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

Group Photo

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

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: Regualtory 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

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 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

Networking Break

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

