6th International Conference and Exhibition on

GMP, GCP & Quality Control

September 25-26, 2017  Chicago, Illinois, USA
# Day 1  September 25, 2017

## Hall

### 08:00-09:00 Registrations

### 09:00-09:25 Opening Ceremony

### 09:25-09:30 Introduction

### 09:30-10:00 Title: Government and industry response to the US opioid epidemic
Robert P Bianchi, Prescription Drug Research Center, USA

### 10:00-10:30 Title: Conducting effective FDA pre-sub meetings: Tell don’t ask… lead don’t follow!
Michael Drues, Vascular Sciences, USA

### 10:30-11:00 Title: Essential do’s and don’ts for an effective good manufacturing practices extractables and leachables strategy
Shane P Smith, ExtLe Solutions Limited, UK

### Networking and Refreshment Break 10:45-11:05

### 11:20-11:50 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

### Sessions:

**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 Chair: TBA

### 11:50-12:10 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

### 12:10-12:30 Title: Role of FSMA (Food Safety Modernization Act) GMP requirements in human and animal food safety
Ramakrishnan Narasimhan, Perry Johnson Registrar, USA

### 12:30-12:50 Title: Quality control in statistical programming under GCP
Sharmeen Reza, Statistical Programming Cytel Inc., USA

### Lunch Break – 12:50-13:40

### 13:40-14:00 Title: Data integrity requirements for GxPs
Chris Wubbolt, QAQC CONSULTING, USA

### 14:00-14:20 Title: Regulatory compliance readiness
Mayra Guzman-Kaslow, GK Regulatory, Compliance, & Engineering Consulting Corporation, USA

### 14:20-14:40 Title: Quality risk management system
Rashid Mehmood, Surge Laboratories Private Limited Pakistan, Pakistan

### Sessions:

**Regulatory Affairs | Biologics and Biosimilars | Regulatory Requirements for Biosimilars | Regulatory Communications and Submissions | Global Guidelines for the Development of Biologics**

Session Chair: Yavuz S SILAY, ICG (Istanbul Consulting Group), USA
Session Chair: Michael Drues, Vascular Sciences, USA

### 14:40-15:00 Title: Medical device vigilance in EU
Parminder Kaur, RegPak BioPharma Consulting, Netherlands
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 - 15:40-16:00

Title: Traditional plant drugs as potential immunomodulators
P Brindha, Sastra University, India

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

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

Day 2    September 26, 2017
HALL

Keynote Forum

09:25-09:30    Introduction

09:30-10:00    Title: Good supply practices: Why are we still vulnerable?
Troy Fugate, Compliance Insight, Inc., USA

10:00-10:30    Title: Global regulatory challenges and implications
Eliana Silva de Moraes, ABPVS, Brazil

10:30-11:00    Title: Convergence of regulatory affairs and reimbursement/market Access
Stephen F Amato, North Eastern University, USA

Networking Break -11:00-11:20

Sessions:
Quality Assurance| The Role of c in cGMP | Current GMP Guidelines (cGMP) | Validation
Session Chair:
Session Co-chair:

11:20-11:40    Title: Cleaning validation: Process life cycle approach
Paul Lopolito, STERIS Corporation, USA

11:40-12:00    Title: GxP/GMP and its consequences for documentation and information technology systems
Eleonora Babayants, Galaxy Consulting, USA

12:00-12:20    Title: Impurity profiles of API - validations and challenges for GMP inspection
Balakrishna Chakravarthy, Capic Laboratories Pvt Ltd., India

12:20-12:40    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

12:40-13:00    Title: Quality control and validation
Chintan V Pandya, KSV University, India

Lunch Break  13:00-13:50

13:50-14:10    Title: GMP deficiencies found by ANVISA in foreign inspections
Andrea Geyer, Universidade de Brasilia and Brazilian Health Regulatory Agency (ANVISA), Brazil
Sessions:
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 Chair: Eliana Silva de Moraes, ABPVS, Brazil

14:10-14:30
Title: Pharmacogenetic: Regulatory considerations. cuban guidance
Remirez Diadelis, Devices and medical equipments (CECMED), Cuba

14:30-14:50
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

14:50-15:10
Title: Prevalence of anemia in pregnancy among women visiting antenatal clinic in bingham university teaching hospital
Olorunfunmi; Bingham University, Nigeria

15:10-15:30
Title: Biochemical diagnosis of acute pancreatitis
Anil Batta, GGS Medical College, India

15:30-15:50
Title: Strengthening health regulation in the americas: The experience of N the national regulatory authorities of regional reference
Lisette Pérez Ojeda, CECMED, Cuba

Networking Break 15:50-16:10

16:10-16:30
Title: Hepatoprotective effect of Aloe vera against radiation induced damage in Swiss albino mice
Dadupanthi P, Biyani Girls College, India

16:30-16:50
Title: Effect of cobalt oxide as a nano practice in growth of bacteria
Nagham Mahmood Alijami, Iraq

16:50-17:10
Title: Regulatory affairs
Aram Kallougian, FMD K&L Europe, Armenia

17:10-17:30
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, Greater Georgetown

17:30-17:50
Title: Investigation of the biochemical mechanism of action of antioxidants in the prevention of cancer
Kissi Mudie; Ethiopian Public Health Institute (EPHI), Ethiopia

17:50-18:10
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

Poster Presentations @ Conference Hall

Poster Judge:

RAGMP-001
Title: GMP deficiencies found by ANVISA in foreign inspections
Andrea Geyer, Universidade de Brasilia and Brazilian Health Regulatory Agency (ANVISA), Brazil

RAGMP-002
Title: Herbal medicines pre-marketing registration process in the state of Kuwait: An up-to-date overview of the process
Azhar H Alostad, M-Pharm, UK

RAGMP-003
Title: Increasing medicinal compounds of Althaea Officinalis I. using UV light In vitro
Hashim K Mohammed Al-oubaidi, Al-Mustansiriyah University, Iraq

RAGMP-004
Title: A paradigm shift in drug regulations in Taiwan
Sachin Parasiya; Biocon Limited, India

RAGMP-005
Title: Synergic antibacterial effect of curcumin SLN's with ampicillin SLN's
Solmaz Ghafrari, IAUPS Tehran, Iran

RAGMP-006
Title: Survival and predictors of mortality among patients under multi-drug resistant tuberculosis treatment in Ethiopia: St. peter's specialized tuberculosis hospital, Ethiopia
Theodros Getachew, Ethiopian Public Health Institute, Ethiopia

Closing Ceremony