Joint Event

8th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs and IPR

&

8th International Conference and Exhibition on

Pharma Audit, GMP, GCP & Quality Control

June 08-09, 2018 | Philadelphia, USA

Day 1 June 08, 2018

CONFERENCE HALL : INDEPENDENCE A

08:00-08:45 Registrations

08:45-9:00 Opening Ceremony

Keynote Forum

09:00-09:05 **Introduction**

09:05-09:45 **Title: A blueprint for outsourcing audits of approved GxP validations**
Michael D Spangler, Spangler Consulting LLC, USA

09:45-10:25 **Title: Quality management and quality audit according to GxP/GMP requirements**
Eleonora Babayants, Galaxy Consulting, USA

Group Photo

Panel Discussion 10:25-10:30

Networking & Refreshment Break 10:30-10:50 @ Foyer

Sessions:
Good Manufacturing Practices: The Gap within | Current GMP Guidelines (cGMP) & GxP in Pharmaceuticals | Good Clinical Practices & Good Laboratory Practices | Validation | Quality Control | Quality Assurance | Regulatory Communications and Submissions | Impact of Brexit on Regulatory Framework | Regulatory Communications and Submissions | Regulatory Requirements for Pharmaceuticals

Session Chair: Eleonora Babayants, Galaxy Consulting, USA
Session Co-chair: Joel Finkle, ACUTA LLC, USA

Session Introduction

10:50-11:15 **Title: Development of fluticasone propionate spray dried powder formulation containing different carriers as an excipient for the treatment of asthma**
Aysu Yurdasiper Erdem, Ege University, Turkey

11:15-11:40 **Title: Accelerating patient access to medicines in Africa**
OumKaltoum Lahlou, University of Barcelona, Spain

Panel Discussion 11:40-11:50

Keynote Forum

11:50-12:30 **Title: A personal history of regulatory submissions technology**
Joel Finkle, ACUTA LLC, USA

Panel Discussion

Lunch Break 12:30-13:30 @ Benjamin's

13:30-14:10 **Title: Pharma regulatory affairs as well as importance of ISO 9001:2015, ISO 14001:2004, ISO 18001:2007 standards and related audits for quality pharma products**
Manavalan R, RVS College of Pharmaceutical Sciences, India

Special Sessions

14:10-14:35 **Title: Planning for and complying with the IDMP standard for Europe**
Joel Finkle, ACUTA LLC, USA

14:35-15:35 **Title: GxP/GMP and its consequences for documentation and information technology systems**
Eleonora Babayants, Galaxy Consulting, USA

Panel Discussion 15:35-15:45

Networking & Refreshment Break 15:45-16:05 @ Foyer

Video presentations

16:05 -16:30 **Title: Navigating government healthcare reforms and their impact in USA, Europe, Turkey & emerging markets**
Yavuz Selim SILAY, Istanbul Consulting Group, Turkey

16:30-16:55 **Title: Regulatory affairs**
Syed Abid Hassan, Jamjoom Pharmaceuticals Company, KSA

Panel Discussion

Day 2 June 09, 2018

CONFERENCE HALL : INDEPENDENCE A

Keynote Forum

08:30-08:35 Introduction

08:35-09:15 Title: Investigations, root cause analysis, corrective & preventive actions and why "human error" is not the true root of the problem
Joe Helmstetler, Rhizo Sciences, USA

09:15-09:55 Title: Good manufacturing practices for sterile pharmaceutical products
Rashid Mahmood, SURGE Laboratories Private Limited, Pakistan

Panel Discussion 09:55-10:10

Networking & Refreshment Break 10:10-10:30 @ Foyer

Sessions:
Regulatory Affairs | Current Regulations and Quality Standards | Regulatory Challenges for Medical Devices | Regulatory Affairs in Pharmacovigilance | Quality Control | Quality Assurance | Quality Assurance Audits in Pharma Industries | Quality Management System in Testing Laboratories

Session Chair: Joe Helmstetler, Rhizo Sciences, USA

Session Introduction

10:30-10:55 Title: The status of diabetes in Guyana, its herbal and synthetic drug treatments
Jagessar R C, University of Guyana, Guyana

10:55-11:20 Title: Risk based manufacture of pharmaceutical products
Muhammad Naeem, Indus Pharma (Pvt.) Ltd., Pakistan

11:20-11:45 Title: Quality risk management: Quality control perspective
Jacob Adegboyega Kolawole, University of Jos, Nigeria

11:45-12:05 Title: Antimicrobial activity of the uncombined and combined aqueous extract of *Phyllanthus acidus, Sphagneticola trilobata* leaves and *Doliocarpus dentatus*'s bark against human pathogenic microorganism in the absence and presence of Zn2+ cations
Jagessar R C , University of Guyana, Guyana

12:05-12:30 Title: Continuous reactions and the FDA
James R Bruno, Chemical and Pharmaceutical Solutions, Inc., USA

Panel Discussion 12:30-12:40

Lunch Break 12:40-13:40 @ Benjamin's

13:45-14:05 Title: Quality risk management in pharmaceuticals
Rashid Mahmood, SURGE Laboratories Private Limited, Pakistan

14:05-14:30 Title: Good manufacturing practices: The gap within (developing countries)
Bernice Brempong, Makhealth Pharmaceuticals Ltd., GHANA

Panel Discussion 14:30-14:40

Video Presentations

14:40-15:05 Title: Medical device
Syed Abid Hassan, Jamjoom Pharmaceuticals Company, Kingdom of Saudi Arabia

15:05-15:30 Title: Developing a practical quality risk management scheme in accordance with vial's dimension deviations in aseptic filling process
Nasim Rahmani, Pasteur Institute of Iran, Iran

Panel Discussion 15:30-15:40

Networking & Refreshment Break 15:40-16:00 @ Foyer

Award & Closing Ceremony