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
             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
## Keynote Forum

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-08:35</td>
<td>Introduction</td>
</tr>
</tbody>
</table>
| 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 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: 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 |
| 11:45-12:05  | **Title: Continuous reactions and the FDA**  
James R Bruno, Chemical and Pharmaceutical Solutions, Inc., USA |
| 12:05-12:30  | **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 12:30-12:40

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 13:45-14:05  | **Title: Medical device**  
Syed Abid Hassan, Jamjoom Pharmaceuticals Company, Kingdom of Saudi Arabia |
| 14:05-14:30  | **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 |

### Video Presentations

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 14:40-15:05  | **Title: Develop a practical quality risk management scheme in accordance with vial’s dimension deviations in aseptic filling process**  
Nasim Rahmani, Pasteur Institute of Iran, Iran |
| 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**