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
Day 1  September 25, 2017

08:00-09:00 Registrations

Zurich

09:00-09:25  Opening Ceremony

Keynote Forum

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: 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 @ Foyer

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

11:20-11:40  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
11:40-12:00  Title: Quality control in statistical programming under GCP
             Sharmeen Reza, Cytel Inc, USA
12:00-12:20  Title: Data integrity requirements for GxPs
             Chris Wubbolt, QACV Consulting LLC, USA
12:20-12:40  Title: Regulatory compliance & notified bodies inspection readiness
             Mayra Guzman-Kaslow, GK Regulatory, Compliance, & Engineering Consulting Corporation, USA
12:40-13:00  Title: Quality risk management system
             Rashid Mehmood, Surge Laboratories Private Limited, Pakistan

Lunch Break 13:00-13:50 @ Athens

13:50-14:10  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 Ramirez Figueredo, Devices and medical equipments (CECMED), Cuba

14:10-14:30  Title: Antimicrobial activity of the ethanolic and aqueous extract of Vicia faba L. (Fabaceae)
             R C Jagessar, University of Guyana, Guyana
14:30-14:50  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 15:30-15:50 @ Foyer

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

09:25-09:30 Introduction

09:30-10:00 Title: Global regulatory challenges and implications
Eliana Silva de Moraes, ABPVS, Brazil

10:00-10:30 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

10:30-10:50 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 11:10-11:30 @ Foyer

11:30-12:00 Title: Quality control and validation
Chintan V Pandya, HVHP Institute, India

12:00-12:20 Title: GMP deficiencies found by ANVISA in foreign inspections
Andrea Geyer, Universidade de Brasilia, Brazil

12:20-12:40 Title: Pharmacogenetic: Regulatory considerations, cuban guidance
Remirez Diadelis, Devices and medical equipments (CECMED), Cuba

Lunch Break 12:40-13:30 @ Athens

13:30-14:30 Title: GxP/GMP and its consequences for documentation and information technology systems
Eleonora Babayants, Galaxy Consulting, USA
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<th>Time</th>
<th>Title</th>
<th>Presenter</th>
<th>Institution</th>
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<tr>
<td>14:30-14:50</td>
<td>Development of the molecular diagnostics considering the quality of damaged nucleic acids from formalin-fixed paraffin-embedded tissue samples</td>
<td>Young Kee Shin</td>
<td>Seoul National University, Korea</td>
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<tr>
<td>14:50-15:10</td>
<td>Prevalence of anemia in pregnancy among women visiting antenatal clinic in Bingham university teaching hospital</td>
<td>Olorunfunmi</td>
<td>Bingham University, Nigeria</td>
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<td>15:10-15:30</td>
<td>Antimicrobial activity of the ethanolic and aqueous extract of passion fruit (<em>Passiflora edulis</em> Sims) in the absence and presence of transition metal salts</td>
<td>R C Jagessar</td>
<td>University of Guyana, Guyana</td>
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<td>15:30-15:50</td>
<td>Formulation and evaluation of herbal tablets and capsules containing <em>Urtica dioica</em> extract</td>
<td>Farah Khalil Yousef</td>
<td>Damascus University, Syria</td>
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**Poster Presentations 15:50-16:10 @ Foyer**

**Poster Judge: Paul J Cummings, PJC Pharma Consulting Ltd, UK**

| RAGMP 001   | GMP deficiencies found by ANVISA in foreign inspections | Andrea Geyer                      | Universidade de Brasília, Brazil  |
| RAGMP 002   | 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**

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<tr>
<td>16:30-16:50</td>
<td>Antibacterial activity of lawsonia inermis (<em>Sudanese Henna</em>) leaves extracts against staphylococcus aureus, <em>Escherichia coli</em> and <em>Pseudomonas aeruginosa</em> among recurrent urinary tract infection patients</td>
<td>Hanaa A M Elgailany</td>
<td>Sudan University of Science and Technology, Sudan</td>
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<td>16:50-17:10</td>
<td>Biochemical diagnosis of acute pancreatitis</td>
<td>Anil Batta</td>
<td>GGS Medical College, India</td>
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<td>17:10-17:30</td>
<td>Strengthening health regulation in the Americas: The experience of the national regulatory authorities of regional reference</td>
<td>Lisette Pérez Ojeda</td>
<td>CECMED, Cuba</td>
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**Panel Discussion**

**Award and Closing Ceremony**