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1234th Conference

Scientific Program

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

Sponsor & Exhibitor

GMP Trends

Abbott

Conference Series - America

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Conference Series - UK

Kemp House, 152 City Road, London EC1V 2NX Toll Free: +1-800-216-6499

Day 1 September 25, 2017

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

Zurich

conferenceseries.com 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 @ 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

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: Regualtory 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 Room

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 Remirez 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

14:50-15:10	**Title: Traditional plant drugs as potential immunomodulators** **P Brindha,** Sastra University, India
15:10-15:30	**Title: Cleaning validation in pharmaceuticals** **Rashid Mahmood,** Surge Laboratories Private Limited., Pakistan
	Networking Break 15:30-15:50 @ Athens Room
15:50-16:10	**Title: Roadmap to pharmaceutical regulatory harmonization in Pakistan** **Muhammad Naeem,** Indus Pharma (Pvt.) Ltd, Pakistan
16:10-16:30	**Title: Early access to unapproved medicines in EU** **Parminder Kaur,** RegPak BioPharma Consulting, Netherlands
	Video Presentation
16:30-16:50	**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
	Panel Discussion

Day 2 September 26, 2017

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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
10:50-11:10	**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 @ Athens Room
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 Room
13:30-14:30	**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

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: 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
15:30-15:50	**Title: Formulation and evaluation of herbal tablets and capsules containing Urtica dioica extract** **Farah Khalil Yousef,** Damascus University, Syria

Poster Presentations 15:50-16:10 @ Cannes

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

RAGMP 001	**Title: GMP deficiencies found by ANVISA in foreign inspections** **Andrea Geyer,** Universidade de Brasilia, 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,** The University of Manchester, UK

Networking Break 16:10-16:30 @ Athens Room

Video Presentations

16:30-16:50	**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
16:50-17:10	**Title: Biochemical diagnosis of acute pancreatitis** **Anil Batta,** GGS Medical College, India
17:10-17:30	**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