



Joint Event

9th International Conference on

Pharmaceutical GMP, GCP & Regulatory Affairs

&

2nd International Conference on

Pharmaceutical Analysis & Analytical Chemistry

August 02-03, 2019 | Chicago, USA

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| Day 1 August 02, 2019 | |
| 09:30-10:00 Registrations | |
| 10:00-10:15 Opening Ceremony | |
| KEYNOTE FORUM | |
| 10:15-10:20 | Introduction |
| 10:20-11:00 | Title: Is your machine learning algorithm worth its application in the healthcare industry? |
| | Ewa J. Kleczyk, PHD, Symphony Health, USA |
| GROUP PHOTO 11:00-11:05 | |
| NETWORKING & REFRESHMENT BREAK 11:05-11:20 | |
| 11:20-12:00 | Title: Challenges for testing finished pharmaceutical products; one possible solution: Solventless sample preparation combined with HRAM mass spectrometry |
| | Gyorgy Vas, Ph.D., Intertek Pharmaceutical Services, USA |
| 12:00-12:40 | Title: Quality tolerance limits – Implementation of this ICH E6 R2 concept will transform the the way we handle and report quality in clinical truals and submissions |
| | William Andrew Lawton, Risk Based Approach Ltd, UK |
| Sessions: Biologics and Biosimilars Analytic method development and validation Regulatory Affairs | |
| Session Chair: William Andrew Lawton, Risk Based Approach Ltd, UK | |
| Session Co-Chair: Nermeen Abuelsoud, The British University in Egypt, Egypt | |
| Session Introduction | |
| 12:40-13:05 | Title: Similar biologics in India – Opportunities and challenges |
| | Milind Antani, Nishith Desai Associates, India |
| PANEL DISCUSSION | |
| LUNCH BREAK 13:05-14:05 | |
| 14:05-14:30 | Title: Regulatory direction in clinical development – The path to quality by design |
| | William Andrew Lawton, Risk Based Approach Ltd, UK |

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| 14:30-14:55 | Title: The impact of inter partes review and post grant review on biologic and biosimilar development |
| | Ha Kung Wong, Venable Fitzpatrick, USA |
| 14:55-15:20 | Title: Inspection findings against ICH E6 R2 – what can you expect |
| | William Andrew Lawton, Risk Based Approach Ltd, UK |
| 15:20-15:45 | Title: Dyslipidemia in young age population _ An experience from Egypt |
| | Nermeen Abuelsoud , The British University in Egypt, Egypt |
| PANEL DISCUSSION | |
| NETWORKING & REFRESHMENT BREAK 15:45-16:05 | |
| 16:05-16:30 | Title: The new 510 (K) in US? and what about EU-Brexit procedures? |
| | Maria Agustina Duguine, RQMIS INC., UK |
| 16:30-16:55 | Title: Small-angle X-Ray scattering: An emerging tool for pharmaceutical industry |
| | Archan Dey, Dr Reddys Lab, India |
| Day 2 August 03, 2019 | |
| KEYNOTE FORUM | |
| 10:00-10:40 | Title: Fabric phase sorptive extraction: A new generation sample preparation technology to meet the growing demands of twenty first century modern analytical laboratories |
| | Abuzar Kabir, Florida International University, USA |
| PANEL DISCUSSION | |
| NETWORKING & REFRESHMENT BREAK 10:40-11:00 | |
| 11:00-11:40 | Title: Measurement and applications of biomimetic HPLC to obtain protein and phospholipid binding data at the early stages of drug discovery to reduce attrition |
| | Klara Valko, Bio-Mimetic Chromatography Ltd, UK |
| 11:40-12:20 | Title: Rapidly evolving expectations and supporting data for characterization of polymeric process equipment related leachables (PeRLs) |
| | James Hathcock, Pall Biotech, USA |
| Sessions: Clinical Affairs & Regulatory Strategies Quality Assurance and Quality Control Regulatory Challenges for Medical Devices | |
| Session Chair: Gyorgy Vas, Ph.D., Intertek Pharmaceutical Services, USA | |

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| 12:20-12:45 | Title: Analytical method development and validation by HPLC in pharmaceutical development |
| | Hua Liu, PTC Therapeutics, USA |
| 12:45-13:10 | Title: Studying calcineurin inhibitors metabolic complications and the associated single nucleotide polymorphisms in Egyptian liver transplant patients |
| | Nermeen Abuelsoud , The British University in Egypt, Egypt |
| PANEL DISCUSSION | |
| LUNCH BREAK 13:10-14:10 | |
| 14:10-14:35 | Title: ABEE-labeled oligosaccharide-marker approach to qualitative and quantitative analysis of specific polysaccharides in herbal formulas by LC-qTOF-MS: Danggui Buxue Tang, a case study |
| | Lifeng Li, Hong Kong Baptist University, China |
| POSTER PRESENTATIONS 14:35-15:35 | |
| ETEC 01 | Title: Isolation of lupeol from <i>Grewia lasiocarpa</i> E. Mey. ex Harv. Stem bark: Antibacterial, antioxidant and cytotoxicity activities |
| | Nneka Augustina Akwu, University of KwaZulu-Natal, South Africa |
| ETEC 02 | Title: Measurement of collagen cross-links from tissue samples by mass spectrometry |
| | Amar Joshi, Pharmaxis, Australia |
| ETEC 03 | Title: Oligosaccharide markers approach for the quality control of polysaccharide-rich chinese medicine: <i>Dendrobium officinale</i> , a case study |
| | Tin Long Wong, Hong Kong Baptist University, China |
| Panel Discussions | |
| Networking Break 15:35-15:55 | |
| Awards and Closing Ceremony | |

