“Organize your Events at OMICS Group Conferences”
Proposals are invited for organizing Symposia/Workshops at OMICS Group Conferences or OMICS Group will sponsor small events at your universities in related areas under the title of your own. These proposals can be sent to respective conference mail ids or to symposia@omicsonline.org

OMICS Group Conferences
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Email: gmpsummit2014@omicsgroup.us
Day 1  
September 25, 2014

Committee Room 5

09:00-09:25  
Opening Ceremony

Keynote Forum

09:25-09:30  Introduction
Victor Sanchez  
Pharma-Bio Serv S.L., Spain

09:30-09:55  Sundar Chellamani  
SysComm Project Management Limited, Ireland

09:55-10:20  Maria Pellin Amoros  
Laboratoires Quinton International S.L., Spain

Coffee Break 10:45-11:00 @ Auditorium 3 Foyer

11:00-11:25  Rama K Pidaparti  
Wipro Technologies, USA

Track 1: Good Manufacturing Practices: The Gap within  
Track 2: Current Regulations and Quality Standards  
Track 3: Current GMP Guidelines  
Track 5: Good Clinical Practices & Good Laboratory Practices

Session Chair: Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden  
Session Co-Chair: Rama K Pidaparti, Wipro Technologies, USA

11:25-12:25  Workshop on Natural Health Products site licensing in Canada: How to meet the GMPs regulations  
Jalal Mokhalalati, Quality Medical Regulations Services, Canada

12:25-12:45  Regulatory requirements and benefits converting to continued process verification  
Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden

12:45-13:05  Greening the pharmaceutical industry to afford Good Laboratory Practice  
Salwa Elmeligie, Cairo University, Egypt

Lunch Break 13:05-14:00 @ Multi Purpose Hall 2

14:00-14:20  Effective methods for software and systems integration for software companies and institutions  
Boyd L Summers, BL Summers Consulting, LLC., USA

14:20-14:40  Reflections about quality control and quality assurance in clinical trials  
Fernando Geijo, Telstar, Spain

14:40-15:00  Role of Good Laboratory Practice in Good Clinical Practice  
Salwa Elmeligie, Cairo University, Egypt

15:00-15:20  Quality excellence through benchmarking quality improvement models  
Kamran Atif, Arwan Pharmaceuticals Industries, Lebanon

Track 6: Quality Assurance  
Track 7: Quality Control

Session Chairs: Dharmi Trivedi, University of Phoenix, USA  
Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden

15:20-15:40  Ensure quality assurance for software companies and institutions  
Boyd L Summers, BL Summers Consulting, LLC., USA
15:40-16:00 Effective CAPA program, A valuable tool in quality improvement
Dharmi Trivedi, University of Phoenix, USA

Coffee Break 16:00-16:15 @ Auditorium 3 Foyer

16:15-16:35 Evaluation of bacterial contamination of clean room clothing
Noelle H O Driscoll, Robert Gordon University, Scotland
Optimization solutions for validation procedures in the quality control of enantiomers; Chirality tests for antidepressants Citalopram and Venlafaxine
Ivanka Pencheva, Sofia Medical University, Bulgaria

16:35-16:55 How to improve quality and consistency of legacy products applying QbD/Six Sigma methodology
Alicia Tebar, Telstar, Spain

16:55-17:15 Maintain the effectiveness of a QMS by using Lean Six Sigma approach
Peter Jehander, AF Technology AB, Sweden

17:15-17:35 Analytical method lifecycle management
Gerald de Fontenay, Amatsi Group, France

Panel Discussion
B2B Meetings

Day 2 September 26, 2014 Committee Room 5

Keynote Forum

10:00-10:25 David L Chesney
Parexel International, USA

10:25-10:50 Wael Ebied
SEDICO Pharmaceuticals-Merck & Co., Egypt

10:50-11:15 Aziz Chraibi
Pharma Bio Expert Inc., Canada

Coffee Break 11:15-11:30 @ Auditorium 3 Foyer

11:30-12:30 Workshop on Best practices for internal and supplier auditing
David L Chesney, Parexel International, USA

Track 8: Validation
Track 9: Contract Manufacturing, Sterile/Aseptic Manufacturing
Track 11: Medical Devices

Session Chair: Aziz Chraibi, Pharma Bio Expert Inc., Canada
Session Co-Chair: Jixing Wang, Dalton Pharma Services, Canada

12:30-12:50 Managing equipment validation using ASTM approach for optimum cost and aggressive schedule
Sundar Chellamani, SysComm Project Management Limited, Ireland

Industrial process validation of metformin tablets to facilitate the scale up of commercial production: A GMP and validation perspective
Gannu Praveen Kumar, Sahasra Institute of Pharmaceutical Sciences, India

Lunch Break 13:10-14:00 @ Multi Purpose Hall 2

Workshop on ICH Q9 risk management applied to the compliance challenges between cGMP & safety design issues in manufacturing pharmaceutical & biotechnology facilities

14:00-15:00 3 Case Studies: High Potent (HP1@5) Plants, Bio-safety containment (BSL1@4) facilities and explosive environment (ATEX 1@3)
Aziz Chraibi, Pharma Bio Expert Inc., Canada
<table>
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| 15:00-15:20 | GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality  
Maria Pellin Amoros, Laboratoires Quinton International S.L., Spain |
| 15:20-15:40 | DHF, DMR and DHR - The three Ds of Medical devices  
Rama K Pidaparti, Wipro Technologies, USA |
| 15:40-16:00 | Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)  
Mootaz El Halawani, Pharmaceutical Quality Expert, Egypt |
| 16:00-16:15 | Coffee Break 16:00-16:15 @ Auditorium 3 Foyer |
| 16:15-16:35 | Challenges of cGMP implementation at different CMO's - role of quality agreements  
Rivka Zaibel, Advanced Regulatory Services Ltd. (ADRES), Israel |
| 16:35-16:55 | CMO’s challenges and strategies in sterile manufacturing  
Jixing Wang, Dalton Pharma Services, Canada |
| 16:55-17:15 | Production of biosimilars in developing countries: Challenges and opportunities: SEDICO case Study  
Wael Ebied, SEDICO Pharmaceuticals - Merck & Co., Egypt |
| 17:15-17:35 | The relevance of training in supply chain management of pharmaceutical products  
Ibelema Emeh, Setax Training & Consultancy Limited, United Kingdom |
|           | Closing Ceremony |
|           | B2B |

Bookmark your dates

4th International Summit on GMP, GCP & Quality Control
October 26-28, 2015 Hyderabad, India