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
5716 Corsa Ave., Suite 110, Westlake Los Angeles, CA 91362-7354, USA
Phone: +1-650-268-9744, Fax: +1-650-618-1414, Toll free: +1-800-216-6499
Email: gmpsummit2014@omicsgroup.us
Day 1  
September 25, 2014

Committee Room 5

08:00-09:00  Registrations

09:00-09:25  Opening Ceremony

09:00-09:25  
Committee Room 5  
OMICS Group Conferences  
Opening Ceremony

09:25-09:30  Introduction
09:30-09:55  Victor Sanchez  
Pharma-Bio Serv S.L., Spain
09:55-10:20  Sundar Chellamani  
SysComm Project Management Limited, Ireland
10:20-10:45  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 Introduction

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  Title: Regulatory requirements and benefits converting to continued process verification
Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden

12:45-13:05  Title: 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  Title: Effective methods for software and systems integration for software companies and institutions
Boyd L Summers, BL Summers Consulting, LLC., USA

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

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

15:00-15:20  Title: 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  Title: Ensure quality assurance for software companies and institutions
Boyd L Summers, BL Summers Consulting, LLC., USA
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<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker/Institution</th>
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<tbody>
<tr>
<td>15:40-16:00</td>
<td>Title: Effective CAPA program, A valuable tool in quality improvement</td>
<td>Dharmi Trivedi, University of Phoenix, USA</td>
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<td>16:00-16:15</td>
<td>Coffee Break</td>
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<td>16:15-16:35</td>
<td>Title: Evaluation of bacterial contamination of clean room clothing</td>
<td>Noelle H O Driscoll, Robert Gordon University, Scotland</td>
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<td>16:35-16:55</td>
<td>Title: Optimization solutions for validation procedures in the quality control of enantiomers; Chirality tests for antidepressants Citalopram and Venlafaxine</td>
<td>Ivanka Pencheva, Sofia Medical University, Bulgaria</td>
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<td>16:55-17:15</td>
<td>Title: How to improve quality and consistency of legacy products applying QbD/Six Sigma methodology</td>
<td>Alicia Tebar, Telstar, Spain</td>
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<td>17:15-17:35</td>
<td>Title: Maintain the effectiveness of a QMS by using Lean Six Sigma approach</td>
<td>Peter Jehander, AF Technology AB, Sweden</td>
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<td>17:35-17:55</td>
<td>Title: Analytical method lifecycle management</td>
<td>Gerald de Fontenay, Amatsi Group, France</td>
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### Day 2  
**September 26, 2014**  
Committee Room 5

**Keynote Forum**

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<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker/Institution</th>
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| 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                                                                                   |
| 11:30-12:30| **Workshop on Best practices for internal and supplier auditing**  
David L Chesney, Parexel International, USA                                                                       |
| 12:30-12:50| **Sundar Chellamani**, SysComm Project Management Limited, Ireland  
**Title: Industrial process validation of metformin tablets to facilitate the scale up of commercial production:**  
Gannu Praveen Kumar, Sahasra Institute of Pharmaceutical Sciences, India |
| 12:50-13:10| **A GMP and validation perspective**  
Aziz Chraibi, Pharma Bio Expert Inc., Canada                                                                       |

**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**

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<tr>
<td>14:00-15:00</td>
<td><strong>3 Case Studies: High Potent (HP1@5) Plants, Bio-safety containment (BSL1@4) facilities and explosive environment (ATEX 1@3)</strong></td>
<td>Aziz Chraibi, Pharma Bio Expert Inc., Canada</td>
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### Panel Discussion

### B2B Meetings
Title: 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

Title: DHF, DMR and DHR - The three Ds of Medical devices
Rama K Pidaparti, Wipro Technologies, USA

Title: Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)
Mootaz El Halawani, Pharmaceutical Quality Expert, Egypt

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

16:15-16:35
Title: Challenges of cGMP implementation at different CMO’s - role of quality agreements
Rivka Zaibel, Advanced Regulatory Services Ltd. (ADRES), Israel

16:35-16:55
Title: CMO’s challenges and strategies in sterile manufacturing
Jixing Wang, Dalton Pharma Services, Canada

16:55-17:15
Title: Production of biosimilars in developing countries: Challenges and opportunities: SEDICO case study
Wael Ebied, SEDICO Pharmaceuticals - Merck & Co., Egypt

17:15-17:35
Title: The relevance of training in supply chain management of pharmaceutical products
Ibelema Emeh, Setax Training & Consultancy Limited, United Kingdom

Closing Ceremony