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: gmp2013@omicsonline.us
Day 1  November 12, 2013  
09:00-10:00  Registrations  

Opening Ceremony  

Keynote Forum  

10:25-10:30  Introduction  
Gerard Pearce  
SQA Services, Inc., USA  
10:30-10:55  Gerard Pearce  
SQA Services, Inc., USA  
10:55-11:20  Ashraf Youssef  
AYPharma Safety Consulting, USA  

Coffee Break 11:20-11:35 @ Foyer  

11:35-12:00  Patricia Henley  
London School of Hygiene & Tropical Medicine, UK  
12:00-12:25  James Huang  
Forest Laboratories, Inc., USA  

Track 1: Current Regulations and Quality Standards  
Track 2: Current GMP Guidelines for Pharmaceuticals  
Track 7: Quality Control, Quality Assurance and Validation  

Session Chair: James Huang, Forest Laboratories, Inc., USA  
Session Co-Chair: M. S. Lourdes Sanchez, Sintenovo SA de CV, Mexico  

12:25-12:45  Maintaining your laboratory in a state of Control - The data integrity challenge  
Jacqueline McCulloch, Clarkston Consulting, USA  
12:45-13:05  Case study: Quality assurance and quality control partnering to drive compliance, science, and innovation  
Jason Ruckert, Advanced Testing Laboratory, USA  
13:05-13:25  Quality assurance on a budget from a non-commercial perspective  
Lucy H H Parker, St George's Healthcare NHS Trust, UK  

Lunch Break 13:25-14:10 @ Athens  

14:10-14:30  Automation in validated environments  
Abitha Sundararajan, Med Manage Systems, USA  
14:30-14:50  Quality accreditation for medical research at Universities?  
Brigitte von Rechenberg, University of Zurich, Switzerland  
14:50-15:10  Risk assessment  
M.S. Lourdes Sanchez, Sintenovo SA de CV, Mexico  
15:10-15:30  Modern quality systems & Risk management approaches  
Naveen Kumar Venkatesham, Laurus Labs Private Limited, India  
15:30-15:50  Diverting from traditional validation approaches - Beefing up and speeding up validation, while minimizing vulnerabilities to new regulatory inspection foci  
Constance E. Curts, FDA and EU Regulatory Validation Consultant, USA  

Coffee Break 15:50-16:05 @ Foyer
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>16:05-16:25</td>
<td>Data integrity issues</td>
<td>Mohammad Iqbal Hossain</td>
<td>Novartis Ltd., Bangladesh</td>
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<tr>
<td>16:25-16:45</td>
<td>Challenges in benefit-risk evaluations during co-development among partnerships and alliances</td>
<td>Ashraf Youssef</td>
<td>AYPharma Safety Consulting, LLC, USA</td>
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<tr>
<td>16:45-17:05</td>
<td>Is your company in a state of control?</td>
<td>Brian Hill</td>
<td>Brian Hill &amp; Associates, USA</td>
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<tr>
<td>17:05-17:25</td>
<td>Prior knowledge assessments: A knowledge compilation process that can be used to bring about more focused process characterization and development studies for platform products</td>
<td>Jim Seely</td>
<td>Bioprocessing Consultant, USA</td>
</tr>
<tr>
<td>17:25-17:45</td>
<td>Mitigating the environmental impact of cleaning processes in GMP regulated facilities</td>
<td>Elizabeth Rivera</td>
<td>STERIS Corporation, USA</td>
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**Day 2**  
**November 13, 2013**  
**Berlin**  

**Track 3: The role of “C” in cGMP**  
**Track 8: Legal Requirements for Medical Devices**  
**Track 10: Computational Strategies in GMP/GCP**  

**Session Chair:** Pejman Parhami, Hyland’s, Inc., USA  
**Session Co-Chair:** Brian Hill, Brian Hill & Associates, USA

<table>
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<tr>
<td>09:30-09:50</td>
<td>The role of “C” in cGMP</td>
<td>Naveen Kumar Venkatesham</td>
<td>Laurus Labs Private Limited, India</td>
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<tr>
<td>09:50-10:10</td>
<td>The evolution of the medical device 510 (k) process and impending changes</td>
<td>Jacqueline McCulloch</td>
<td>Clarkston Consulting, USA</td>
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<tr>
<td>10:10-10:30</td>
<td>Supplier management-Key components of managing suppliers in a cGMP environment</td>
<td>Pejman Parhami</td>
<td>Hyland’s, Inc., USA</td>
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<tr>
<td>10:30-10:50</td>
<td>Bridging the cultural divide: Supplier auditing in a global economy</td>
<td>Jennifer Leny</td>
<td>American Society for Quality, USA</td>
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<tr>
<td>10:50-11:05</td>
<td>Coffee Break</td>
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<tr>
<td>11:05-11:25</td>
<td>A risk based scientific approach to analytical method development and validation activities for regulated laboratories</td>
<td>Shib Mookherjea</td>
<td>ValQual International, USA</td>
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<tr>
<td>11:25-11:45</td>
<td>Moving beyond part 11; Quality assurance considerations for translating cGMP compliance into electronic batch record initiatives</td>
<td>Heather Schwalje</td>
<td>Emerson Life Sciences Industry Solutions Group, USA</td>
</tr>
<tr>
<td>11:45-12:05</td>
<td>Leadership’s role in change management</td>
<td>Myriam Ochart</td>
<td>Lean Compliance Partners, USA</td>
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<tr>
<td>12:05-12:50</td>
<td>Lunch Break</td>
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**Workshops**  
**Zippy Lean Workshop (Production Line Simulation) by**  
**Myriam Ochart,** Lean Compliance Partners, USA & **Jennifer Leny,** American Society for Quality, USA

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<tr>
<td>15:35-18:05</td>
<td>Cocktail Presentations</td>
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<tr>
<td>16:20-17:20</td>
<td>Poster Presentations</td>
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<td>18:30-19:30</td>
<td>Cocktails Sponsored by Advances in Pharmacoepidemiology &amp; Drug Safety</td>
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</table>
Track 4: Good Clinical Practice
Track 5: Good Laboratory Practices and Clinical Trials
Track 6: Quality Inspections and Auditing
Track 9: Contract Manufacturing
Track 12: Microbiology, Food and Nutraceuticals

Session Chair: Anthony Grilli, Focus Scientific Solutions, USA

10:00-10:20 Performing microbial risk analysis on a standard compounding pharmacy aseptic fill process
Anthony Grilli, Focus Scientific Solutions, USA

10:20-10:40 The effect of L-arginine on mice placenta
Mohanad AbdulSattar Ali Al-Bayati, University of Baghdad, Iraq

10:40-11:00 Cleaning challenges in the dietary supplement industry
Elizabeth Rivera, STERIS Corporation, USA

Coffee Break 11:00-11:15 @ Foyer

11:15-11:35 Myrica rubra fruit drink sub-chronic toxicity and hepatoprotective effect in rats
Mohamed AIAjmi, King Saud University, Saudi Arabia

11:35-11:55 The informed consent form process: A basic contemporary standpoint for medical research professionals
Peter Odeh, SNBL Clinical Pharmacology Center, USA

11:55-12:15 DHF, DMR and DHR-The three Ds of medical devices
Rama K. Pidaparti, Wipro Technologies, USA

12:15-12:35 Immunosuppressive effects of mesenchymal stem cells versus corticosteroid in experimental model of arthritis
Marwa Elhussiny Youniss, Cairo University, Egypt

12:35-12:55 Comparative pharmacokinetics and compliance issues to optimize art- The Indian scenario
Prince Louis Palatty, Father Muller Medical College, India

12:55-13:15 A new cGMP bioassay involving electrophysiological recordings of CFTR currents
Antonio Lacerda, ChanTest Corporation, USA

Lunch Break 13:15-14:00 @ Athens