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.
<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter/Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:25-11:50</td>
<td>The master validation plan: A vision of things to come!</td>
<td>Steven Mattos, ALKU Technologies, USA</td>
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<tr>
<td>11:50-12:15</td>
<td>Points to consider when managing regulatory submissions in Asia Pacific countries</td>
<td>Linda Yang, KleanGen, LLC., USA</td>
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<tr>
<td>13:00-13:25</td>
<td>Complaints handling and post marketing surveillance</td>
<td>Harshit Thakkar, Dekra Certification B.V., USA</td>
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<td>13:25-13:50</td>
<td>Regulations in the emerging market of nutraceuticals: From paradigms to practice</td>
<td>Karolina Bate, Cyton Biosciences Limited, UK</td>
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<td>14:15-14:40</td>
<td>Who does design control best? (Successful medical device manufacturers do)</td>
<td>Steve Jwanouskos, OptiMedica, USA</td>
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<tr>
<td>14:50-15:05</td>
<td>Combination products: Current regulations, challenges and global trends</td>
<td>Chitra Edwin, Cleveland HeartLab, Inc., USA</td>
</tr>
<tr>
<td>15:05-15:30</td>
<td>Overview and successful strategies for INDs and NDAs</td>
<td>Michelle Carpenter, Regulatory Consultant, USA</td>
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**Coffee Break 09:55-10:10 @ Sierra Foyer**

**Lunch Break 12:15-13:00 @ Tiburon/Sausalito**

**Coffee Break 15:30-15:45 @ Sierra Foyer**
Day 2  October 22, 2013

Redwood/Sequola

Track 5: Biologics and Other Special Categories
Track 6: Best Industry Practices
Track 7: Business, Law Enforcement, and Education

Session Chair: Netta Fulga, The Hospital for Sick Children, Canada
Session Co-Chair: Chitra Edwin, Cleveland HeartLab, Inc., USA

Session Introduction

09:00-09:25  Title: Current trends in computerized system validation-Challenges and solutions
Garikapati Pavan Kumar, Wipro Technologies, India

09:25-09:50  Title: Challenges in providing adequate high-level education in regulatory affairs, especially in view of small countries
Elvi Metsaranta, Crown CRO Oy, Finland

09:50-10:15  Title: Cleaning validation
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

10:15-10:40  Title: Liposome characterization required for regulatory approvals
Donald Kruppa, Azaya Therapeutics, Inc., USA

Coffee Break 10:40-10:55 @ Sierra Foyer

10:55-11:20  Title: Effective methods for software and systems integration
Boyd L. Summers, BL Summers Consulting LLC., USA

11:20-11:45  Title: Australian pharmaceutical patent system under review-To ‘balance’ the interests of pharmaceutical product innovators and the generics industry?
Gint Silins, Cullens Patent and Trade Mark Attorneys, Australia

11:45-12:10  Title: Medicines regulation in Australia and New Zealand-Unique and changing. An industry perspective
John L. Miller, John Miller Consulting (Aust) Pty. Ltd., Australia

Lunch Break 12:10-12:55 @ Tiburon/Sausalito

12:55-13:20  Title: Best industry practices-Audits and inspection
Kahl Melodie, QA/RA Independent Consultant, Switzerland

13:20-13:45  Title: External price referencing system - Implementation in Albania and consequences
Ledia Cikopana, Tirana University, Albania

13:45-14:10  Title: Good distribution practices (cGDP) and related regulatory affairs at the Brazilian supply chain
Frederico Rapussi, Pfizer, Brazil

14:10-14:35  Title: The quality journey: from the Stone Age to modern times, and the lessons learned
Mohammed R Khan, SynergeX Consulting, Canada

14:35-15:00  Title: Analytical test method validation (AMV) of finished pharmaceutical products (FPP) & system suitability requirements
Rober Remon Saad Habashy, Amoun Pharmaceutical Company, Egypt

15:00-15:25  Title: Regulatory roadmap for initiating a gene therapy drug into clinical trials in the US
William Lee, Cato Research, USA

15:25-15:50  Title: Regulatory submissions for blood products at Saudi FDA
Ali Mohammed Alsamii, Saudi Food And Drug Authority, KSA

Coffee Break 15:50-16:05 @ Sierra Foyer

16:05-16:30  Title: In vivo anti-diarrheal and ex-vivo spasmolytic activities of the aqueous extract of the roots of Echinops kebericho Mesfin in rodents and isolated guinea-pig ileum
Fisseha Shiferie, Mekelle University, Ethiopia

16:30-16:55  Title: Quality management and accreditation in a mixed research and clinical laboratory setting
Netta Fulga, The Hospital for Sick Children, Canada

16:55-17:20  Title: Remote internal quality audits-Effective and efficient
Garikapati Pavan Kumar, Wipro Technologies, India

17:20-17:45  Title: Biosimilars and non-innovator biotherapeutics in MENA region: Opportunities and challenges
Ibrahim AlJuffali, King Saud University, Saudi Arabia

17:45-18:10  Title: EUROPE-New regulations-What impact will the proposed new regulations in Europe have for medical device manufacturer?
Toni Kennet Jorgensen, Sorin Group, Switzerland

16:10-17:30  Poster Presentations @ Monterey
18:50-19:50  Cocktails Sponsored by Pharmaceutical Regulatory Affairs: Open Access

Day 3  October 23, 2013

Redwood/Sequola

Track 8: Intellectual Property Management
Track 9: Novel Strategies for Growth in the Pharma and Regulatory Environment

Session Chair: Linda Yang, KleanGen, LLC., USA

Session Introduction

09:00-09:25  Title: Electronic compliance monitoring and return on investment
Allan Wilson, Information Mediary Corporation, Canada

09:25-09:50  Title: Strategic management of global post approval regulatory activities
Linda Yang, KleanGen, LLC., USA

09:50-10:15  Title: Regulatory strategy should be business strategy
Rama K Pidaparti, Wipro Technologies, India

10:15-10:40  Title: Pricing policy for a patent medicine? Need for changing the frame work of rewarding an Innovation
Anantha Naik Nagappa, Manipal University, India
Coffee Break 10:40-10:55 @ Sierra Foyer

10:55-11:20  
Title: Quality risk management system  
Rashid Mahmood, Surge and Stancos Private Limited, Pakistan

11:20-11:45  
Title: Management of IP in a multi-collaborative framework: DST/Mintek nanotechnology innovation centre as a case study  
Makhapa Makafola, Mintek, South Africa

11:45-12:10  
Title: Problems encountered by third world countries especially Pakistan in pharmaceutical regulatory affairs and their remedies  
Shoaib Ahmed, Drug Regulatory Authority, Pakistan

12:10-12:35  
Title: Asia and ASEAN, what will be the result of all the harmonization effort going on in the Asian markets, and how should we as manufacturer deal with all these new regulations?  
Toni Kennet Jorgensen, Sorin Group, Switzerland

2nd International Summit on  
GMP, GCP & Quality Control  
November 12-14, 2013  DoubleTree by Hilton Hotel Chicago-North Shore USA

2nd International Conference and Exhibition on  
Pharmacovigilance & Clinical Trials  
November 18-19, 2013  Hilton San Antonio Airport, USA

Bookmark your dates

4th International Conference on  
Pharmaceutical Regulatory Affairs  
September 08-10, 2014  Philadelphia, USA