08:30-09:30 Registrations

09:30-09:55 Opening Ceremony

Keynote Forum

09:55-10:00 Introduction

10:00-10:30 Essential consensus and scientific definitions for advancement in pharmaceutical regulatory affairs
Ting-Chao Chou, PD Science LLC, USA

10:30-11:00 Regulatory issues for validation and qualification for new human-on-a-chip systems
James J Hickman, University of Central Florida, USA

Networking and Refreshment Break: 11:00-11:15 @ Foyer

11:15-11:45 Commercializing disruptive medical technologies in an evolutionary world
Michael Drues, Vascular Sciences, USA

Track 1: Regulatory Affairs for Healthcare Products
Track 2: Best Industry Practices
Track 3: Novel Strategies for Growth in the Pharma and Regulatory Affairs

Session Chair: Ting-Chao Chou, PD Science LLC, USA
Session Co-Chair: Hudson Nakamura, Goias Eye Bank Foundation, Brazil

11:45-12:10 Title: The life cycle approach to cleaning validation
Elizabeth Rivera, STERIS Corporation, USA

12:10-12:35 Title: The premarket notification a.k.a. 510k: Using substantial equivalence to your advantage!
Michael Drues, Vascular Sciences, USA

12:35-13:00 Title: Regulatory intelligence: Industry’s best practice
Mariam Aslam, PAREXEL International, UK

Lunch Break 13:00-14:00 @ Lobby North

14:00-14:25 Title: Mexico: Lessons learned from the “external review process” and the “recognition schemes” on the reduction of timelines for the approval of marketing authorizations
Antonio Trejo Diaz, Teva Pharmaceuticals, Mexico

14:25-14:50 Title: Combined scleral buckle and pars plana vitrectomy as a primary procedure for pseudophakic retinal detachments
Hudson Nakamura, Goias Eye Bank Foundation, Brazil

14:50-15:15 Title: First to file (FTF) regulatory challenge to QbD adoption
Kishor K Chakraborty, Riyadh Pharma, Saudi Arabia

Networking & Refreshment Break 15:15-15:30 @ Foyer

15:30-15:55 Title: Pharmacogenomics: The future of clinical trials, new product development and the practice of medicine
Michael Drues, Vascular Sciences, USA

15:55-16:20 Title: Cosmetics regulations in Saudi Arabia
Mishal A Altamimi, SFDA, Saudi Arabia
### Day 2  
#### August 04, 2015

**Sciphel**

#### Keynote

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
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<tbody>
<tr>
<td>10:00-10:30</td>
<td>Scientific definitions and computerized algorithms for advancement of medical and pharmaceutical regulatory affairs</td>
<td>Ting-Chao Chou, PD Science LLC, USA</td>
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#### Workshop

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<td>Michael Drues, Vascular Sciences, USA</td>
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| Networking & Refreshment Break 11:15-11:30 @ Foyer |

**Track 4: Regulatory Requirements for Pharmaceuticals**

**Track 5: Requirements for Medical Devices**

**Track 6: Biologics and Other Novel Therapies**

**Session Chair:** Michael Drues, Vascular Sciences, USA  
**Session Co-Chair:** Antonio Trejo Diaz, Teva Pharmaceuticals, Mexico

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<tr>
<td>11:30-11:55</td>
<td>Toward better and efficient equilibrium dynamics of research, development, and regulation</td>
<td>Ting-Chao Chou, PD Science LLC, USA</td>
<td></td>
</tr>
<tr>
<td>11:55-12:20</td>
<td>Urolithiasis-anti urolithic activity of extracts of roots of Ricinus communis</td>
<td>Juhi Tiwari, Jayoti Vidya Peeth Womens’ University, India</td>
<td></td>
</tr>
<tr>
<td>12:20-12:45</td>
<td>The practice of Regulatory Intelligence: Case studies</td>
<td>Mariam Aslam, PAREXEL International, UK</td>
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**Lunch Break 12:45-13:45 @ Lobby North**

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<tbody>
<tr>
<td>13:45-14:10</td>
<td>Prospects and challenges of providing pharmacovigilance services in resource limited countries</td>
<td>Avong, Institute of Human Virology, Nigeria</td>
<td></td>
</tr>
<tr>
<td>14:10-14:35</td>
<td>Enabling, people and businesses to improve the quality of life, to do so faster and better</td>
<td>Demet Sag, ClearRoadMap, USA</td>
<td></td>
</tr>
<tr>
<td>14:35-15:00</td>
<td>Anti-oxidant intake in antenatal cases high-risk for pregnancy induced hypertension and intrauterine growth restriction</td>
<td>Rajiv Mahendru, B.P.S. Government Medical College for Women, India</td>
<td></td>
</tr>
<tr>
<td>15:00-15:25</td>
<td>Poisoning lightening creams in Morocco: Epidemiological profile</td>
<td>Bellaje R, University Ibn ToFAIL, Morocco</td>
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**Networking & Refreshment Break 15:25-15:40 @ Foyer**

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<tbody>
<tr>
<td>15:40-16:05</td>
<td>Challenges &amp; latest regulations have to know about medical devices in Middle East region</td>
<td>Sara Hegazi, Philips Healthcare, UAE</td>
<td></td>
</tr>
<tr>
<td>16:05-16:30</td>
<td>Poisoning by hydrogen peroxide hair bleaching: Moroccan Poison Control Center data</td>
<td>Bellaje R, University Ibn ToFAIL, Morocco</td>
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</tr>
<tr>
<td>16:30-16:35</td>
<td>SWOT analysis of the Addis Ababa City administration food, medicine and health care administration and control authority</td>
<td>Solomon Getnet Meshesha, Addis Ababa University, Ethiopia</td>
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**14:00 - 15:00**  
**Poster Presentations @ Lobby North Foyer**

### Day 3  
#### August 05, 2015

**Sciphel**

**Track 6: Intellectual Property Management**

**Track 7: Marketing Authorizations, Advertising and Marketing Practices**

**Track 8: Drug Designing and Development**

**Session Chair:** Rajiv Mahendru, B.P.S. Government Medical College for Women, India  
**Session Co-Chair:** Brian Hill, Brian Hill Consulting, USA

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<tr>
<td>10:00-10:25</td>
<td>A review on autism</td>
<td>Juhi Tiwari, Jayoti Vidya Peeth Womens’ University, India</td>
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<tr>
<td>10:25-10:50</td>
<td>The effectiveness of the spontaneous reporting system</td>
<td>Avong, Institute of Human Virology, Nigeria</td>
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<tr>
<td>10:50-11:15</td>
<td>Understanding your supply chain</td>
<td>Brian Hill, Brian Hill Consulting, USA</td>
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**Networking & Refreshment Break 11:15-11:30 @ Foyer**
11:30-11:55  Title: Stem cells and its basic use in medicinal field  
Sai Sankar Prabhu Kella, K. J. R. College of Pharmacy, India  
Title: Want to eliminate events & predict quality near misses; reduce deviation rate by >90% & gain >25% production efficiency simultaneously?  
Amy Peterson, Quality Systems, USA  
Title: New perspective on how to discover drugs from herbal medicines: Simulating wild animals self medication by human diseased-animal models to screen new therapeutics  
Wael Ebied, SQA Services Inc., USA

13:45-14:10  Title: Formation of nucleation and coalescence of bubbles in different benzene and liquid solutions by liquid - liquid extraction using partial miscible mixtures  
Nadeem Ahmad, Advanced product design services, Canada  
Title: Sharing regulatory data as tools for strengthening health systems in the region of the Americas  
Damaris Silveira, University of Brasilia, Brazil  
Title: Facial cosmetics & role of pharmacist in client education  
Mamoona Firdous Naqvi, Gulf Pharmaceutical Industries, UAE

14:10-14:35  Title: Sharing regulatory data as tools for strengthening health systems in the region of the Americas  
Damaris Silveira, University of Brasilia, Brazil

14:35-15:00  Title: Facial cosmetics & role of pharmacist in client education  
Mamoona Firdous Naqvi, Gulf Pharmaceutical Industries, UAE

15:15-15:40  Title: Quality assessment and in vitro dissolution profile: Comparison of different brands of amoxicillin  
Lantider Kassaye Bekele, GlaxoSmithKline Ltd., Ethiopia  
Title: Quality risk management system  
Rashid Mahmood, Surge Laboratories Private Limited, Pakistan  
Title: Pharmaceutics & novel drug delivery systems  
Tariq Jamshaid, Surge Laboratories Private Limited, Pakistan  

Award Ceremony