

08:30-09:30 Registrations

Sciphol



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

Session Introduction

- 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

Sciphol

Keynote

10:00-10:30 **Title: Scientific definitions and computerized algorithms for advancement of medical and pharmaceutical regulatory affairs**
Ting-Chao Chou, PD Science LLC, USA

Workshop

10:30-11:15 **Title: Commercializing disruptive medical technologies in an evolutionary world**
Michael Drues, Vascular Sciences, USA

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

11:30-11:55 **Title: Toward better and efficient equilibrium dynamics of research, development, and regulation**
Ting-Chao Chou, PD Science LLC, USA

11:55-12:20 **Title: Urolithiasis-anti urolithic activity of extracts of roots of Ricinus communis**
Juhi Tiwari, Jayoti Vidya Peeth Womens' University, India

12:20-12:45 **Title: The practice of Regulatory Intelligence: Case studies**
Mariam Aslam, PAREXEL International, UK

Lunch Break 12:45-13:45 @ Lobby North

13:45-14:10 **Title: Prospects and challenges of providing pharmacovigilance services in resource limited countries**
Avong, Institute of Human Virology, Nigeria

14:10-14:35 **Title: Enabling, people and businesses to improve the quality of life, to do so faster and better**
Demet Sag, ClearRoadMap, USA

14:35-15:00 **Title: Anti-oxidant intake in antenatal cases high-risk for pregnancy induced hypertension and intrauterine growth restriction**
Rajiv Mahendru, B.P.S. Government Medical College for Women, India

15:00-15:25 **Title: Poisoning lightening creams in Morocco: Epidemiological profile**
Bellaje R, University Ibn Tofail, Morocco

Networking & Refreshment Break 15:25-15:40 @ Foyer

15:40-16:05 **Title: Challenges & latest regulations have to know about medical devices in Middle East region**
Sara Hegazi, Philips Healthcare, UAE

16:05-16:30 **Title: Poisoning by hydrogen peroxide hair bleaching: Moroccan Poison Control Center data**
Bellaje R, University Ibn Tofail, Morocco

16:30-16:35 **Title: SWOT analysis of the Addis Ababa City administration food, medicine and health care administration and control authority**
Solomon Getnet Meshesha, Addis Ababa University, Ethiopia

14:00 - 15:00 **Poster Presentations @ Lobby North Foyer**

Day 3 August 05, 2015

Sciphol

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

10:00-10:25 **Title: A review on autism**
Juhi Tiwari, Jayoti Vidya Peeth Womens' University, India

10:25-10:50 **Title: The effectiveness of the spontaneous reporting system**
Avong, Institute of Human Virology, Nigeria

10:50-11:15 **Title: Understanding your supply chain**
Brian Hill, Brian Hill Consulting, USA

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
- 11:55-12:20 **Title: Want to eliminate events & predict quality near misses; reduce deviation rate by >90% & gain >25% production efficiency simultaneously?**
Amy Peterson, Quality Systems, USA
- 12:20-12:45 **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

Lunch Break 12:45-13:45 @ Lobby North

- 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
- 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

Networking & Refreshment Break 15:00-15:15 @ Foyer

- 15:15-15:40 **Title: Quality assessment and *in vitro* dissolution profile: Comparison of different brands of amoxicillin**
Lantider Kassaye Bekele, GlaxoSmithKline Ltd., Ethiopia
- 15:40-16:05 **Title: Quality risk management system**
Rashid Mahmood, Surge Laboratories Private Limited, Pakistan
- 16:05-16:30 **Title: Pharmaceuticals & novel drug delivery systems**
Tariq Jamshaid, Surge Laboratories Private Limited, Pakistan

Award Ceremony

