Scientific Program

International Conference and Expo on

Parenterals & Injectables

August 17-19, 2015 Chicago, USA

Day 1 August 17, 2015

09:00-09:30 Registrations

Conference Hall-1

OMICS International conferenceseries.com

09:30-09:45 **Opening Ceremony**

Keynote Forum

09:45-10:00	**Introduction**
10:00-10:35	**Diane Paskiet** West Pharmaceutical Services, USA
10:35-11:05	**Bill Hartzel** Catalent Pharma Solutions, USA

Networking & Refreshments 11:05-11:20 @ Foyer

Track 1: Novelties in Pre-filled Syringe products
Track 5: Trends and Challenges in Formulation and Development
Track 9: Global Market Trends in Injectables and Parenterals
Track 10: Technical and Regulatory Challenges of Parenterals and Autoinjectors

Session Chair: Maik W Jornitz, G-CON Manufacturing Inc., USA
Session Co-Chair: Jim Polarine, Steris Corporation, USA

Session Introduction

11:20-12:20	**Workshop on** **Challenges in parenteral formulation development studies and an evaluation from QbD point of view** **Gulay Yelken Demirel,** Sanovel Pharmaceuticals, Turkey
12:20-12:50	**Qualification of extractables & leachables from container closure systems in drug products- Introduction to the Product Quality Institute (PQRI) recommendations** **Diane Paskiet,** West Pharmaceutical Services, USA

Lunch Break 12:50-13:50 @ Athens

13:50-14:20	**Case studies of human flora and spore contamination in clean rooms** **Jim Polarine,** Steris Corporation, USA
14:20-14:50	**The review of flexible production platforms for pharma/biopharmaceutical processing** **Maik W Jornitz,** G-CON Manufacturing Inc., USA
14:50-15:20	**The value of the "Simulated study" as a tool to predict actual leachables in parenteral drug products** **Carsten Worsoe,** Novo Nordisk, Denmark

Networking & Refreshments 15:20-15:35 @Foyer

15:35-16:05	**Global implementation of system-based microbial control for Parenteral manufacture** **Edward C Tidswell,** Baxter Healthcare Corporation, USA
16:05-16:35	**Purity, endotoxin level, and trace metal comparison of different grades of trehalose** **Ben Nelson,** Pfanstiehl, USA
16:35-17:05	**Formation of inherent protein aggregates in the visible and sub-visible size range by excessive and inhomogenious lubrication in syringes and cartridges** **Oliver K Valet,** rap.ID Inc., Germany

Panel Discussions

Day 2 August 18, 2015

Conference Hall-1

Keynote Forum

09:30-10:05 **Panayiotis P Constantinides**
Biopharmaceutical & Drug Delivery Consulting, LLC, USA

Track 3: Safeguard of Injectables and Leachables
Track 4: Manufacturing Considerations in Delivery devices
Track 13: Drug Development and Designing
Track 6: Impact on Product Behavior in Delivery Systems

Session Chair: Neervalur V Raghavan, Rags Pharma Consulting LLC., USA
Session Co-Chair: Jianfeng Hong, Fresenius Kabi, USA

10:05-11:05 **Workshop on**
Contract research and development and/or manufacturing of Parenteral products-Steps for building a successful and mutually beneficial partnership
Neervalur V Raghavan, Rags Pharma Consultlng LLC., USA

Networking & Refreshments 11:05-11:20 @Foyer

11:20-11:50 **Extractable and leachable studies of Parenteral infusion and transfusion products**
Jianfeng Hong, Fresenius Kabi, USA

11:50-12:20 **Systematic approach to development of aqueous drug formulation and drug device combination injectable products and challenges**
Neervalur V Raghavan, Rags Pharma Consulting LLC., USA

12:20-12:50 **Development of co-formulations of monoclonal antibodies and recombinant human hyaluronidase (rHuPH20)**
Claudia Mueller, FHoffmann La Roche, Switzerland

Lunch Break 12:50-13:50 @ Athens

13:50-14:20 **Adapting drug product manufacturing strategy and processes for pre-sterilized, ready-to-use (RTU) vials, syringes & cartridges**
Josh Russell, AST, USA

14:20-14:50 **Compatibility assessment of a model monoclonal antibody formulation in glass and in Blow-Fill-Seal (BFS) plastic vial delivery formats**
Dipesh Shah, Catalent Pharma Solutions, USA

14:50-15:20 **Drug delivery device strategy for patient centric therapies**
Li-Chun Tsou, AstraZeneca Pharmaceuticals, USA

15:20-15:50 **Disruption in the US machine tool industry: The role of in house users and pre-disruption component experience in firm response**
Raja Roy, Drexel University, USA

Networking & Refreshments 15:50-16:05 @ Foyer

16:05-17:05 **Workshop on**
Foreign Particulate Matter Control in Parenterals
Oliver K Valet, rap.ID Inc., Germany

Poster Presentation

PC-P01 **Plasma concentrations of copeptin, C-reactive protein and procalcitonin are positively correlated with APACHE II scores in patients with sepsis**
Li Jiang, DaLian Medical University, China

Panel Discussions

Day 3 August 19, 2015

Conference Hall-1

10:00-11:00 **Workshop on**
Human Factor Study for Cobination Products and Medical Devices
Li-Chun Tsou, AstraZeneca Pharmaceuticals, USA

Networking & Refreshments 11:00-11:15 @ Foyer

11:15-12:15 **Bussiness to Bussiness meeetings (B2B)**
12:15-13:00 **Acedamic and Research meetings**

Lunch Break 13:00-14:00 @ Athens

Awards & Closing Ceremony