Updated: 2/22/2013

Event: Aseptic Conference
Track: Cleaning & Sterilization
Leader: Gordon Leichter and Becky Brewer
Dates: 4 & 5 March, 2013
Location: Baltimore, Maryland

Monday, 4 March 2013

Start Time	End Time	Presentation Titles	Speaker Full Name	Speaker's Company	Total min.
7.30	8.30	**Breakfast**			60
8.30	8.45	Welcome and Introduction	Charlotte Enghave Fruergaard, PhD	NNE Pharmaplan	15
8.45	9.45	FDA Perspectives on Aseptic Processing w/Q&A	Rick Friedman	FDA	60
9.45	10.30	**Networking Break**			45
10.30	11.15	Applying QbD Principles for Robust and Efficient Cleaning Processes	Laura Klewer	Amgen	45
11.15	12.00	Automating a Manual System	John Spohn, CPIP	Hargrove Life Sciences, LLC	45
12.00	13.00	**Lunch**			60
13.00	13.45	Cleaning Inactivated Compounds	Chris Moore, Invited	Diosynth	45
13.45	14.30	Equipment Cleaning and Sterilization in a sterile powder process operation	Carl Hospach	Merck	45
14.30	15.00	**Networking Break**			60
15.00	15.45	Cleaning-(Detergent sciences)	Rebecca Brewer	Dober Group	45
15.45	16.30	Serilization of Radio Active Products	Sumit Verma	Covidien	45
16.30	17.00	Q&A Session			30
Track Adjourns					

Tuesday, 5 March 2013

Start Time	End Time	Presentation Titles	Speaker Full Name	Speaker's Company	Total min.
7.30	8.30	**Breakfast**			60
8.30	9.15	Sterilization of Parenteral Drug Containers with Nitrogen Dioxide	Evan Goulet, PhD	Noxilizer	45
9.15	10.00	Utilizing a Hybrid Approach to Terminally Sterilize Combination Products	John Logar	Johnson & Johnson	45
10.00	10.30	**Break**			30
10.30	11.15	Autoclave Cycle Optimization	Todd Ditmore	Valsource	45
11.15	12.00	Energy Saving Trends and Concepts for Steam Sterilizers	Thomas Ofenböck	Bosch	45
12.00	13.00	**Lunch**			60
13.00	14.30	Cleaning Validation Limits based upon New Risk Mapp Guidelines	Rebecca Brewer	Dober Group	90
13.00	14.30	Workshop - The Mathematics of Sterilization D-Value, Z-Value and the determination of Fo	Jerry Dalfors	JD Technologies, LLC	90
14.30	15.00	**Break**			30
15.00	15.30	Feedback from working groups			30
15.30	17.00	**Regulatory Q&A Panel:** •Rick Friedman, Associate Director for Risk-Science Intelligence and Prioritization, OMPQ, OC, CDER, FDA, Confirmed •Destry Sillivan, Senior Regulatory Review Officer, FDA, USA, Confirmed •Robert Sausville, Director, Division of Case Management (DCM) Office of Compliance and Biologics Quality, at FDA's Center for Biologics Evaluation and Research, FDA, USA, Confirmed •Dave Doleski, Acting Director, Division of Good Manufacturing Practice Assessment, OMPQ, OC, CDER •Thomas J. Arista, Field Investigator, National Expert Pharmaceutical/Biotechnology, Office of Regulatory Affairs, Drug Inspection Branch, FDA, Invited			90
Track Adjourns					