Updated: 2/22/2013

Event: Aseptic Conference
Track: Aseptic & Disposables
Leader: Joerg Zimmermann
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	Benefit of emerging techniques for subvisible particle and aggregate analysis for product development	Angelika Freitag, PhD	Coriolis, Martinsried	45
11.15	12.00	Considerations and Challenges in Clinical Supplies Manufacture Compared to Commercial Production	Christine Martin, PhD	AbbVie (formerly Abbott), Ludwigshafen	45
12.00	13.00	**Lunch**			60
13.00	13.45	Setting up a clinical operation based on disposable technology	Claudia Roth, PhD	Vetter, Skokie, IL	45
13.45	14.30	Current status of disposables in aspetic manufacturing	Michael Moussurakis	Pall	45
14.30	15.00	**Networking Break**			30
15.00	15.45	Control of Particles for Manufacture of Single Use Systems used for Critical Processes	Eric Isberg	ATMI	45
15.45	16.30	The disposable facility of the future	Rob Roy Timothy Hanrahan	IPS	45
16.30	17.00	Closing Remarks and Discussion			
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	Innovations in Lyophilisation Technology	Frank DeMarco	IMA Life North America, Inc.	45
9.15	10.00	Aseptic Spraydrying or Disposables	Sam da Costa	NovaLabs	45
10.00	10.30	**Networking Break**			30
10.30	11.15	Minimizing glass stress in aseptic manufacturing	Mathias Kreher	Robert Bosch GmbH	45
11.15	12.00	Workshop: Discussion in small groups on current topics	All		45
12.00	13.00	**Lunch**			60
13.00	13.40	Groups report back to the full audience	All		40
13.45	14.30	Future challenges in biologics drug delivery	Carl Hitscherich, Jr., PhD	Biogen Idec	45
14.30	15.00	**Networking Break**			30
15.00	15.30	Afternoon Debrief			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					