

Tuesday, 15 January 2013

9:00 Welcome and Workshop Overview

Georg Roessling, *PDA Europe*

Session 1: The PDA Technical Report on Single Use Systems
in the Pharmaceutical Industry

Moderator: Georg Roessling, *PDA Europe*

9:05 The PDA Technical Report: Concept, Purpose and Scope
- General Introduction
- Manufacturing Strategy
- Implementation
- Technology Choice
- Business Models
- Qualification

Jerold Martin, *Pall*
Stephen Brown, *Vivalis*
(Members of the PDA Task
Force)

10:30 Coffee Break & Exhibition

Session 2: Single Use Systems in Clinical Trials

Moderator: Walter de Matteo, *IBSA*

11:00 Full Disposable Processes in Formulation & Filling to Support NPI in
GSK Commercial Facility and R&D Clinical Manufacture GSK Pilot Plant

Massimo Rastelli &
Fabrizio Gaboardi, *GSK*

11:45 Scale-up Study of Single Use Bioprocessing for Influenza Virus

Jakob Liderfelt, *GE Healthcare*

12:15 Filling Systems for the Future

Carole Langlois, *Sartorius Stedim*
Klaus Ullherr, *Bosch*

13:00 Lunch Break

Session 3: Case Studies: Applications of Single Use Systems –
R&D in Manufacturing

Moderator: Massimo Golia, *Pall*

14:00 Scale Up of Single Use Clarification Process
for Mammalian Cell Cultures

Amir Goudarzi, *DSM Biologics*

14:30 Single Use System – The Right Choice
for a Biotech Multiproduct Manufacturing Site

Federico Sanvito &
Manuela Camisa, *Adienne*

15:15 Single-Use Technology for a Bacterial Vaccine Production

Marco Restelli, *Novartis*

15:45 Coffee Break & Exhibition

16:15 Why to use Single Use Systems in the Biopharmaceutical Production?
The Kedrion Experience in Plasma Fractionation Area

Franco Capannacci &
Sara Mondini, *Kedrion*

16:45 Integration of a Disposable System
in a Traditional Manufacturing Process

Angela Molaschi &
Antonella Uboldi, *Actavis*

17:15 Single Use Systems – Regulatory Aspects and Considerations

Luisa Stoppa, *AIFA*

17:45 Panel Discussion: Questions by the End Users
Topics: Supplier Agreements, Transportation, Leak Testing, Integrity
Testing, Extractables & Leachables
Panelists: Suppliers, Industry and Regulatory Representatives

Moderator:
Walter de Matteo, *IBSA*

18:15 End of Day 1 Transfer back to COSMOHOTEL TORRI, Milano
Networking Dinner

Wednesday, 16 January 2013

Session 4: The Suppliers' Solutions

Moderator: Massimo Golia, *Pall*

Presentations about the Latest Technological Innovations in the Meeting Room:

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| 9:00 | Discover Next Generation Disposable Bioreactors for Efficient Cell, Virus and Protein Production | Pascale Berthet,
<i>ATMI LifeSciences</i> |
| 9:15 | Robust & Innovative Single Use Solutions from Formulation to Filling | Anissa Boumlic,
<i>Merck Millipore</i> |
| 9:30 | Secure Investments in Single Use Technology | Dirk Tillich, <i>Finesse</i> |
| 9:45 | Automated Aseptic Sampling into Single Use Materials – 2 Case Studies (R&D and Production) | Ronald den Uil,
<i>Alfa Wassermann</i> |
| 10:00 | Performance Tested Single Use Technology | Daniel Nelson,
<i>Thermo Fisher Scientific</i> |
| 10:15 | Single Use Technology for Formulation and Filling: Considerations and Solutions | James Barry,
<i>Pall Life Sciences</i> |
| 10:30 | Practical Demonstrations on Latest Technology at the Exhibitors' Booths to small groups – Part I | |
| 13:00 | Lunch Break | |
| 13:00 | Practical Demonstrations on Latest Technology at the Exhibitors' Booths to small groups – Part II | |
| 15:00 | Site Visit at Adienne | |
| 16:00 | Closing Remarks and End of Workshop | Georg Roessling, <i>PDA Europe</i> |