



cGMP Compliance and Operational Excellence from Lab to Plant

Thursday, May 12, 2011

- 8:15 - 8:45 IMACS Registration Desk Open & Continental Breakfast
- 8:45 - 9:00 Chairman's Introduction to IMACS 2011
- 9:00 - 10:00 Day 1 Keynote Presentation
Update – Business Challenges and Impact of a Global SmartLab Deployment
Chris Haviland, Manager, QA Global Quality Labs
Lukas Gogis, Manager, Global Lab Informatics
Eli Lilly & Company
- 10:00 - 10:30 ***Managing a Global Quality System Deployment in a Changing Environment***
Pascal Maes, Principal Engineer, Strategic Operations
Janssen Pharmaceuticals
- 10:30 - 11:00 Break
- 11:00 - 11:30 ***How “Procedure Execution” Automation is Fundamental to Forest’s Long Term Compliance and Productivity Plans***
Bhavna Aggarwal, Lab Director
Forest Laboratories
- 11:30 - 12:00 ***Automated Procedure Execution in the cGMP QC Lab: Productivity and Compliance Implications***
Adam Aldred, Technical Services Process Leader
McNeil Consumer Healthcare (a Johnson & Johnson Company)
- 12:00 – 1:00 Lunch

- 1:00 – 1:30 ***FDA Audit Experiences – Your SmartLab Inspection Curtain Call***
David Schultenover, Manager, Quality Data Systems
Meda Pharmaceuticals
- 1:30 – 3:00 ***Forum: Perspectives on Lab & IT/IS System Integration and Convergence Strategies*** (moderated by Bill Buote, Chief Technology Officer, VelQuest)
- Convergence of SAP and Lab Execution Systems in cGMP Quality Operations***
Clarkston Consulting
- MES Linkage to QC Lab Operations***
Werum Software & Systems
- Planning Issues and Answers for Enterprise cGMP Systems Integration***
LabAnswer
- Research & Development ELNs, Instrument Integration and Technology Transfer Opportunities to Commercial Operations***
Agilent Technologies
- 3:00 – 3:30 Break
- 3:30 - 4:00 ***Adding an Environmental Monitoring (EM) Management Application to Our Global eLab ELN/LIMS Implementation***
Mike Stroz, Global QC System Owner
Steve Zartarian, Business Analyst, Global Operations Information
AstraZeneca
- 4:00 – 4:45 **Panel Discussion** featuring lab and IT management from leading pharmaceutical companies engaged in procedure automation projects. Panelists will take questions and lead discussions concerning lab software automation projects.
- 4:45 – 5:55 Reception
- 6:00 Bus Departs for Spirit of Boston Dinner Cruise
- 6:30 – 9:00 **Spirit of Boston Dinner Cruise**

Friday, May 13, 2011

- 8:30 - 9:00 IMACS Registration Desk Open & Continental Breakfast
- 8:55 - 9:00 Chairman's Introduction to Day 2
- 9:00 - 10:00 Day 2 Keynote Presentation
A Business and Technical Perspective of the Use of an ELN in a CRO
Rob Petrie, VP IT and Mike Drewery, Associate Director, IT
PPD, Inc.
- 10:00 - 10:30 ***Rapid Realization of Benefits: The Rationale for a Staged Implementation of SmartLab LES in Generic Pharma***
Jennifer Stasio, Compliance Support
Perrigo Company
- 10:30 - 11:00 Break
- 11:00 - 11:30 ***Integrated Laboratory Execution System Architecture and Workflows***
Leonard Weiser, Amgen Information Systems, Quality Client Services
Bruce Grieshaber, Director Corporate Quality Control
Amgen Inc.
- 11:30 - 12:00 ***A Workstation-based Inventory Management System for Clinical Samples and Materials Management***
Al Correia, Executive Vice President, Operations
Cambridge Biomedical Inc.
- 12:00 - 12:30 ***Implementation of a Lab Execution System: 2 Years of Experience and Lessons Learned***
Michael Schofield, Informatics Specialist
Gerard Laboratories (Ireland), Mylan Pharmaceuticals
- 12:30 - 1:30 Lunch
- 1:15 - 1:30 ***IMACS 2011 Review and Closing Comments***
Ken Rapp, President and CEO, VelQuest Corporation
- 2:00 **Meeting Ends**

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