



ISPE New England Chapter Meeting



May 19, 2004

GAMP 4 Risk Based Approach, MES Case Study

Meeting Location: Holiday Inn, Suffern, NY
Virtual Tour of Novartis Pharmaceuticals Corporation
Manufacturing and Packaging Facility, Suffern, NY

Topic 1: ISPE GAMP Guide for Validation of Automated Systems

The presentation will focus on using the GAMP Concepts of Categorization and Risk Assessment Methodology in an efficient and effective manner. Utilizing these proven Good Automated Manufacturing Practices can minimize project costs and implementation time while maintaining a high level of compliance.

Topic 2: Automated Material Management with Manufacturing Execution System (MES)

Novartis Pharmaceutical Operations has implemented an MES system at its Suffern, NY manufacturing and packaging facility. Case Study will review how the system was qualified using GAMP risk based principals. The system ties in electronic signatures, electronic batch records, and manufacturing and packaging component requests from an automated warehouse.

Guest Directions will be sent to those who register.

Program Outline: 1:30 Vendor set-up and Registration 2:15 - 3:00 GAMP 4 – Risk Based Approach 3:00 – 3:30 Break 3:30 - 4:00 MES Case Study 4:00 - 4:30 Virtual Tour of MES 4:30 - 6:00 Round Table Discussion/ Networking/ Refreshments/Vendor Display	<p align="center">Speakers:</p> <p align="center">Dr. Arthur (Randy) Perez Executive Expert, QA, Novartis Pharma Corp Chairman, ISPE GAMP Americas Steering Committee</p> <p align="center">Mr. Richard Lemire Executive Director, Global Automation, Novartis Pharma Corp</p>	Pre-Registration - ISPE Members ONLY <input type="checkbox"/> ISPE Member \$50.00 On-site registration: <input type="checkbox"/> ISPE Member \$ 65.00 <input type="checkbox"/> New member special \$ 170.00 (includes ISPE membership and seminar) Charge to <input type="checkbox"/> Visa <input type="checkbox"/> MC <input type="checkbox"/> AMEX Card Number _____ Expiration Date _____
<input type="checkbox"/> Vendor Table Registration \$250 (includes seminar attendance for two attendees) Space is limited to 20 vendors. Checks must be received by 4-15-04.		Mail or fax completed form with check by May 14, 2004 to: ISPE New England Chapter PMB 190, 1643 Warwick Avenue Warwick, RI 02889 401-737-0959 Fax Questions: Alice Stanelun 401-739-6419 Dean Priebe 845-368-6412

Name _____ ISPE Membership# _____
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