



**San Diego
Chapter**
ENGINEERING
PHARMACEUTICAL
INNOVATION

FULL DAY EXTENDED EDUCATION CLASS

PROCESS AND BUILDING AUTOMATION IN GMP/GLP ENVIRONMENTS

WEDNESDAY, MARCH 24, 2010

7:30 AM - 5:00 PM

LOCATION:

Biogen Idec Nobel Facility

5200 Research Place (UTC Area), San Diego, CA 92122

REGISTER ONLINE:

http://event-confirmation.com/ispesd_meetings.htm

Speakers:

Joe Hohn, Controls Engineer, Dynalectric

Vince Sebald, Owner, Sebald Consulting

Marcus Webb, Vice President of Manufacturing and Engineering, Suneva Medical

Program Managers:

Steven Chung, Control Systems Engineer, Dynalectric

Ed Domanico, PE, Sr. Director Engineering, Vical Incorporated

Hosted by:

Jerry Yaddgo, PE, Facilities Engineer, Biogen Idec

Sponsors:
**Calibration Consultants
Siemens Building Technologies**

Course Description:

The purpose of this course is to give participants an overview of process and building automation systems used in GMP/GLP Environments. Engineers and Technicians will get a primary understanding of terminology and project execution for automation projects. The course will also cover the concepts of control, instrumentation, measurement and system maintenance for validated environments.

Rates:

\$225 ISPE Members

\$315 Non-Members

\$100 ISPE Student Members

Free for Biogen Idec Employees

Rate Includes Continental Breakfast and Lunch

To Join ISPE: www.ispe.org



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This Course Will Cover the Following Topics:

Getting Started: Initial Steps in an Automation Project

- Requirements Definition – New Facility, Facility Expansion or Retrofit
- Consulting Engineer Selection and Scope
- Validation Consultant Selection and Scope
- Vendor Selection and Scope
- Contractor Selection and Scope
- Estimating Project Costs
- Exercise: User Requirements Specification – Defining Scope

Overview: Introduction to Control Systems

- Nomenclature and Acronyms
- Components Common to Control Systems
- Design Elements and Design Documents
- System Architectures: Host to Node, Peer to Peer, SCADA
- Field Buses: Bacnet, DeviceNet, Foundation Fieldbus, Lonworks, Profibus
- Control System Platforms: DCS, DDC and PLC Systems
- Integration Technologies
- Common Specials: Batch Control, Remote Access Standards and Standard Practices
- Data Acquisition and Reporting

Commissioning, Validation and Maintenance

- Commissioning Protocols
- Validation Protocols
- Validation Reports
- Change Control
- Maintenance
- Calibration and Metrology

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Speaker Bios:

Joe Hohn is a controls engineer with Dynalectric. He has designed and implemented instrumentation and control systems for pharmaceutical, power generation and mineral extraction and processing plants. Joe is also an instructor for both the Control Systems PE Review Course and the local International Society for Automation training classes. He has been with Dynalectric since 2000 and was Dyna's I&C engineering lead for the Idec/Genentech Oceanside plant.

Vince Sebald is owner of Sebald Consulting since 2005. He providing as-needed support to small to mid-sized companies in the areas of: Industrial Automation in compliance, GAMP 5 Implementation, 21CFR Pt11, Root Cause Analysis, Process Development, Statistical Analysis Support, Computerized System Validation Support and Gap Analysis and Facility/cGMP Equipment Design/Specification Support.

Prior to starting his own consulting company, he was Associate Director of Facilities Engineering for Amylin Pharmaceuticals where he was responsible for management of calibration and facilities maintenance groups. Also provided engineering and automation support for construction of facilities including Ohio manufacturing facility for new drug product. Automation of plant is based on ISA S-88 Batch Standard model for the process portion and an integrated PLC based building management system.

Marcus C. Webb has served as Vice President of Manufacturing and Engineering since joining Suneva Medical in June 2009. In this position, Mr. Webb is responsible for overseeing the manufacturing, engineering, facilities and environmental health and safety departments. He has over twenty two years experience in the engineering, pharmaceutical and biotechnology industries. Prior to joining Suneva Medical, Mr. Webb served as Sr. Director responsible for the engineering, facilities, validation and environmental health and safety departments for Pacira Pharmaceuticals. Previously, he served as Director, Technical Development for Biogen Idec. From 1996 to 2007, he filled various management positions of increasing responsibility in engineering, systems development, strategic projects and CMC program management at Biogen Idec. Prior to Biogen Idec, he worked as a Lead Engineer for Genzyme.

Mr. Webb received a B.S. in Chemical Engineering from the University of Kent at Canterbury, and an M.S. in Control Engineering from the University of Bradford, both in the UK. He is also a registered Chartered Engineer in the UK and registered European Engineer with FEANI.



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Continental Breakfast and Lunch Provided

REGISTRATION PROCESS & BUILDING AUTOMATION CLASS - March 24, 2010

Register Online at: http://event-confirmation.com/ispesd_meetings.htm

Or complete this form with credit card payment and fax it to 949-266-8461 or 949-387-9047. If paying by check, first fax your registration form then mail your check made payable to: ISPE SAN DIEGO CHAPTER, 5319 University Dr., Suite 641, Irvine, CA 92612. Chapter Hotline (800) 869-9621 or (949) 387-9046. Cancellations must be received in writing by March 17, 2010 for refund. After the cancellation date if you have reserved a space but do not attend, your payment MUST be remitted, however, an alternate person may attend in your place. If the alternate is not a member, they will need to join. Sponsors receive a 6' display table, recognition at the event and one admission to the meeting. Receipts for payment and Name Badges will be given at the on-site registration desk. Registration Rates:

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\$315 Non-Members

\$100 ISPE Student Members

\$500 Meeting Sponsor

First Name: _____

Last Name: _____

Title: _____

Company: _____

E-Mail: _____

Address: _____

City: _____

State: _____ Zip: _____

Tel Number: _____

Fax Number: _____

ISPE Member: _____

Chapter Affiliation: _____

CREDIT CARD PAYMENT

Type of Credit Card
Circle One



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