

ASTM E2500 Standard and Its Use in the Real World

Tuesday, February 17, 2009

Biogen Idec Cambridge

Building 8, 14 Cambridge Center, Cambridge, MA 02142



**Boston Area
Chapter**

ENGINEERING
PHARMACEUTICAL
INNOVATION

PRESENTATION: In the highly competitive Life Science market, product research, development, and manufacturing requires lighting fast commissioning and validation schedules to get products to market. Please join your Bio-Pharm colleagues this evening in understanding the major challenges integrating commissioning and validation requirements and what procedures and systems can be implemented to overcome these challenges.

SPEAKER:

Robert Chew, President, Commissioning Agents, Inc.

Mr. Chew is the current ISPE Man of the Year, and he served on ISPE's International Board of Directors from 2004 - 2007. He served on the task team that created ASTM E2500 to improve how the industry does qualification, and is a member of the task team updating ISPE's Commissioning and Qualification Baseline Guide. He is former chairman of ISPE's North American Education Committee, ISPE's International Education Executive Committee, and former President of the Great Lakes Chapter of ISPE. He is an official trainer for the ISPE Baseline Commissioning and Qualification Baseline Guide. Mr. Chew has a BS in Chemical Engineering from Case Western Reserve University, and is a registered Professional Engineer.

ABSTRACT:

ASTM E2500 was approved in August 2007. In November, 2008, FDA issued a draft update to its 1987 Process Validation Guidance document. This presentation will address several topics:

1. What are the key provisions of ASTM E2500 and how do they relate to US and EU GMP regulations?
2. Is ASTM E2500 consistent with FDA's draft guidance document? The answer is yes from a philosophical point of view. However, there are some prescriptive sections that go beyond GMP regulations, which we have commented on and hope will be modified.
3. In those areas where ASTM may not conform to FDA's draft guidance, what should be done to reconcile those differences?

SPEAKER:

Robert L. Smith, Sr. Commissioning Manager, Life Science Division, Parsons Corporation

Mr. Smith has eighteen years of experience in the pharmaceutical and biopharmaceutical industries. His previous responsibilities have included process engineering, commissioning, qualification and project management. He has been responsible for managing the design, construction, commissioning and qualifications for projects associated with biologics, sterile fill and finish including lyophilization and solid dosage products. Mr. Smith has recently completed a project where the ASTM E2500 standard was used to determine if equipment and systems were fit for intended use for the manufacturing of biological products. He is currently involved in a project where the standard is being applied. Mr. Smith holds a BS Biochemistry from Michigan State University.

ABSTRACT:

This presentation will review the lessons learned generated from applying the ASTM E 2500 Standard. It will explain how the standard was applied, examination the positive and negative experiences and discuss best practices for future applications. It will also analyze the team approached that was used during the application of the standard.

MEETING MANAGERS:

David Truex, Commissioning Agents, Inc
Jay Zaino, GxP Automation, LLC

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PROGRAM SCHEDULE:

Registration: 5:30 PM – 6:00 PM
Reception: 5:30 PM – 6:30 PM
Presentations: 6:30 PM – 8:30 PM

*A networking reception, with hors d'oeuvres, will be held **BEFORE** the presentations.*

REGISTRATION:

PRICE:	Registration by 2/10/2009	After 2/10/2009
<input type="checkbox"/> Members	\$20	\$25
<input type="checkbox"/> Non-members	\$40	\$50
<input type="checkbox"/> Student Members	\$5	\$10
<input type="checkbox"/> New Member Special –	\$30 **	

** \$20 meeting fee when you sign up for ISPE Membership (\$215) for a total of \$235
A completed membership application must be submitted with your New Member Special registration.

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Telephone: 781-647-ISPE (4773) ☒ Fax: 781-647-7222 ☒ Email: ispe@camihq.com

Directions to Biogen Idec, Cambridge:

<http://www.biogenidec.com/site/directions-to-cambridge.htm>

Parking is available at Biogen Idec for \$10.00