Walk Away with Practical Solutions for Your Company

- Participate in group application exercises.
- Benchmark approaches and discuss problem solving.
- Discuss case studies for enhancing lifecycle process understanding.
- Address expectations for application of statistics in Process Validation.
- Compare and contrast application of Process Validation lifecycle approach for brand name and generic products.
- Hear from industry experts and regulators instrumental in developing FDA Process Validation Guidance.
- Practice applying compliant approaches in small group exercises.
- Discuss pressing issues such as application of the lifecycle approach for breakthrough therapies, quality metrics and various dosage types.

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2nd Annual
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Conference

9 – 10 October 2013

Hyatt Regency New Brunswick
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Developing the Lifecycle Approach

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2nd Annual Conference: Practical Application of the Lifecycle Approach

FDA's Grace McNally and Karthik Iyer to participate throughout the conference.

Speakers

Joanne Barrick
Advisor, Global Validation, Eli Lilly & Co., USA

James Bergum
President, BergumSTATS, LLC, USA

David Dolgin
Senior Quality Program Manager, AbbVie, Inc., USA

Gary Gamboa
Senior Research Scientist, Eli Lilly & Co., USA

Declan Greally
Pharma Specialist, Novartis, UK

Karthik Iyer
Senior Policy Analyst, FDA, USA

Mark D. Johnson, CMQ/OE & CQE
Principal Research Statistician AbbVie Operations Quality Assurance, AbbVie Inc., USA

Grace McNally
Consumer Safety Officer, FDA/CDER/Office of Compliance, USA

Dr. Tara Scherder
Senior Consultant, Arlenda, Inc., USA

Stephen Tyler
Director Quality Assurance, AbbVie Inc., USA

Jennifer Walsh
Associate Director of Manufacturing Technology, Bristol-Myers Squibb, USA

Be prepared to address the new expectations for Process Validation.

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Schedule

Wednesday, 9 October

08.30 – 09.00 Introduction: Objectives and Structure of Conference; PV Lifecycle Basics and the Importance of Variability; ISPE PQLI PV Team Activities; Interactive Benchmarking
Joanne Barrick, *Advisor, Global Validation, Eli Lilly & Co., USA*

09.00 – 10.00 FDA View of Lifecycle Approach to PV Implementation
Grace McNally, *Consumer Safety Officer, FDA/CDER/Office of Compliance, USA*

10.00 – 10.30 Networking Break

10.30 – 11.15 Expectations/Deliverables from PV Stage 1 — Process Understanding, Control Strategy, Variability — Case Study

11.15 – 12.15 Statistically Determined Acceptance Criteria and Sampling Plans for PPQ
Mark D. Johnson, CMQ/OE & CQE, *Principal Research Statistician, AbbVie Operations, Quality Assurance, AbbVie Inc., USA*

12.15 – 13.15 Lunch

13.15 – 14.00 Group Exercise: Determining PPQ Criteria and Sampling Plans

14.00 – 15.00 Case Study: Application of Lifecycle Approach to PV to Large Molecule Parenteral Product
Gary Gamboa, *Senior Research Scientist, Eli Lilly, USA*

15.00 – 15.30 Statistical/Risk Based Means to Determine the Number of PPQ Batches — ISPE PQLI PV Team Discussion Paper Approaches
ISPE Implementation Team Representative

15.30 – 16.00 Networking Break

16.00 – 16.45 Exercise: Determining the Number of PPQ Batches

16.45 – 17.30 PV Expectations Outside USA
Stephen Tyler, *Director Quality Assurance, AbbVie Inc., USA*

17.30 – 19.00 Networking Reception

Thursday, 10 October

08.00 – 08.30 FDA Inspector's View of PV Lifecycle Approach to Implementation
Invited FDA Leaders from District Office

08.30 – 09.00 Impact of Lifecycle Approach on Legacy Products — Case Study
Declan Greally, *Pharma Specialist, Novartis, UK*

09.00 – 09.45 Case Study: Applying Different Statistical Approaches for Same Data Set — Impact on PV Results (ISPE Discussion Paper)
Dr. Tara Scherder, *Managing Director, Arlenda Inc., USA*

09.45 – 10.15 Application of Lifecycle Approach to PV to Large Molecule/Biologics Processes (ISPE Discussion Paper)
David Dolgin, *Senior Quality Program Manager, AbbVie Inc., USA*

10.15 – 10.45 Networking Break

10.45 – 11.30 Challenges in Implementing the Lifecycle Approach to PV for Generic Manufacturing
Markus Kiefer, *Head of Global Product Allocation, Sandoz, Switzerland*

11.30 – 12.15 Panel Discussion — Most Difficult Challenges to Lifecycle Approach Implementation
All speakers including FDA will be participating on panel.

12.15 – 13.15 Lunch

13.15 – 14.00 Using ASTM E2709/E2810 Within Batch Variability Assessment During Process Validation and/or Batch Release
James Bergum, *President, BergumSTATS, LLC, USA*

14.00 – 14.45 Exercise: Applying USP Limits and ASTM Standards to a Data Set
James Bergum, *President, BergumSTATS, LLC, USA*

14.45 – 15.15 Networking Break

15.15 – 16.00 PV Stage 3 — Making PV Stage 3a Decisions
Joanne Barrick, *Advisor, Global Validation, Eli Lilly & Co., USA*

16.00 – 16.30 Business Benefits of Using a PV Lifecycle Approach — Return of Investment Model
Jennifer Walsh, *Associate Director of Manufacturing Technology, Bristol-Myers Squibb, USA*

16.30 – 17.00 Next Actions, Benchmarking Opportunity, Remaining Issues and Challenges, Future Discussion Topics

Conference Fees

REGULAR / ONSITE (AFTER 9 SEPTEMBER)			
❑ Member	$ 1,745	❑ Nonmember	$ 2,115
❑ New Member	$ 2,014	❑ Committee	$ 1,005
❑ Government	$ 500	❑ Student Members	$ 200
❑ Academia/Emerging Economy Members	$ 1,135		

How to Register

Online: www.ISPE.org/ProcessValidation

Via Fax: Complete the registration form online and fax it to: +1-813-264-2816

Via Mail: Complete the registration form online and mail it with payment to:
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Tampa, Florida 33609 USA

Questions? Call ISPE at tel: +1-813-960-2105, or email: ask@ispe.org
For more information visit the event website.

Written confirmation will be sent to you after your registration is processed (time permitting).

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3 – 5 participants	SAVE 10%
6 – 10 participants	SAVE 15%
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Cancellations must be made in writing. If cancellations are received by 16 September 2013, a full refund, minus a 10% handling fee (maximum of $100), will be issued. After that time, no refunds will be granted. If you are unable to attend, substitutions will be accepted. However, nonmembers substituting for a Member must pay difference in fees prior to the start of the event. ISPE is not responsible for lost airfare due to cancellations.

Hotel Information

Hyatt Regency New Brunswick
Two Albany Street
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newbrunswick.hyatt.com

For room reservations at the Conference venue, Hyatt Regency New Brunswick, New Brunswick, New Jersey, USA call tel: +1-732-873-1234 or +1-1-888-421-1442. When making your reservation by phone, mention ISPE for a discounted rate of $155 single/double. This rate is good until 15 September 2013, or until the room block is full, whichever comes first. Please contact the hotel as early as possible to make your reservations to ensure you are in the headquarters hotel. We thank you for staying at the Hyatt Regency New Brunswick as this enables ISPE to meet contract requirements.

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