



Berlin Conference
17-20 September 2007
Hilton Hotel - Berlin, Germany

Product Quality Lifecycle Implementation (PQLI): Practical Approach to Quality by Design 19 September, ISPE 2007 Berlin Conference

What's PQLI?

The Product Quality Implementation Lifecycle (PQLI) initiative was launched in June 2007, and born from the need to help industry find global solutions to the challenges in implementing ICH guidances. Through PQLI, ISPE is spearheading the effort to help industry begin to define areas where they will be able to provide the technical framework for the implementation of QbD in regulatory submissions, and to turn Q8, Q9, and the imminent Q10 (Pharmaceutical Quality Systems), into a cross-functional and practical reality.

This is the first European session of Product Quality Lifecycle Implementation (PQLI): Practical Approach to Quality by Design and will be held 19 September at ISPE's Berlin Conference. This is a critical opportunity for industry leaders from science, manufacturing, quality, and engineering to begin to define areas where industry will be able to provide the technical framework for the implementation of Quality by Design (QbD) in regulatory submissions.

What's In It For You?

EU regulators will be contributing to the conference and there will be a Q&A session to enable attendees to pose questions to all participants. Input will be sought from Berlin attendees to plan a highly-interactive workshop scheduled for April 2008 in Copenhagen. If your organization was involved in Washington – or more importantly, if you missed that meeting – this is your chance to get in on the ground level in Europe.

Three critical areas of discussion will be addressed in Berlin:

- Design Space
- Critical vs. Non-Critical
- Control Strategy

Berlin attendees will:

- Learn about the global PQLI initiative and hear updates regarding progress made thus far
- Hear EU regulators' views on these critical issues
- Receive a draft overview of the White Paper generated from output of the highly-interactive inaugural PQLI session in Washington
- Play an active role in determining the areas of focus and workshops for the two-day PQLI Copenhagen working session in April 2008

How Can You Get Involved?

Get in on the "ground floor" of PQLI in Europe by registering for the PQLI session at Berlin Conference, and take advantage of this unique opportunity to directly and significantly affect your future.

Subsequent PQLI sessions to follow Berlin are 2007 ISPE Annual Meeting (5-6 November, Las Vegas, Nevada, USA) and Copenhagen Conference in April 2008.

Working groups will continue to monitor progress between sessions, collect and process information, and develop output into white papers and technical documents that will be produced by ISPE for industry worldwide.

For more information about PQLI, visit www.ISPE.org/pqli. To register for Berlin Conference, please call ISPE Customer Service at Tel: +1-813-960-2105 or visit www.ISPE.org/BerlinConference.

Exhibit and sponsorship opportunities available