



**ISPE Engineering Regulatory Compliance Conference  
Arlington, Virginia, USA**

E07: FDA Co-Sponsored Event: Regulatory perspectives on hot topics, Regulatory Trends, and Observations

Wednesday, 4 June 2008 (09.00-17.00) and Thursday, 5 June (08.00-17.00)

**Wednesday, 4 June**

07.30-09.00	Breakfast in Exhibit Hall
09.00-09.30	<b>Update on Implementation of Quality by Design</b> (Nasr)
09.30-10.00	<b>Implementation of QbD, Case Study</b> (Simmons)
10.00-10.30	<b>Implementation of QbD, Case Study</b> (Thurau)
10.30-11.00	Networking Break
11.00-11.45	<b>Update on Process Validation and Impacts on ICH Guidance</b> (Hasselbalch, McNally <i>invited</i> )
11.45-12.00	<b>Q&amp;A</b> (Morning Speakers)
12.00-13.00	Lunch
13.00-14.00	<b>Case Study on Continuous Processing/PAT</b> (Nosal, Spavins)
14.00-15.00	<b>Quality Systems</b> (Rodriguez <i>invited</i> )
15.00-15.30	Networking Break in Exhibit Hall
15.30-16.15	<b>Quality Systems: The Industry Point of View</b> (Kauffman)
16.15-17.00	Q&A
17.00	Seminar Adjourns for the Day, Reception

**Thursday, 5 June (Note that this day starts earlier!)**

07.00-08.00	Breakfast
08.00-08.30	<b>Regulatory GMP Trends Domestic and Worldwide</b>
08.30-09.15	<b>Update on Preapproval Inspections (PAI) Field Center Role</b> (Hasselbalch, Rivera <i>invited</i> )
09.15-10.00	<b>Case Study: How a PAI Inspection Went Bad</b> (Horan)
10.00-10.30	Networking Break
10.30-11.15	<b>Risk-based Approach to Post Approval Changes</b> (Smith)
11.15-12.00	<b>QbD for Legacy Products</b>
12.00-13.00	Lunch
13.00-13.45	<b>QbD Biopharmaceutical</b> (Kozlowski)
13.45-14.30	<b>QbD for Generics</b> (Holcombe)
14.30-15.00	Networking Break
15.00-15.15	<b>Update from the ICH Meeting</b>
15.15-17.00	<i>Ask the FDA - Bring Your Own Issue *</i> (D'Eramo, Moderator)
17.00	Adjourn