

Event: WASHINGTON 2010 CONFERENCE
 Session: E03 Science and Risk-Based C&Q: Transitioning and Transforming



Session Leader: Steve Wisniewski, Scott Hamm
 Dates: Monday and Tuesday 7-8 June 2010
 Location: Washington, DC

Monday, 7 June

Start Time	End Time	Presentation Title	Speakers
		(7:00 Speaker / Leader Breakfast)	
7:30	9:00	Breakfast	
9:00	10:00	Introduction, BG 12 - Background, Overview of the Process and Content This introduction presents the background rationale for adopting a Quality Risk Management approach for C&Q, an overview of the ASTM/ICH Q9 QRM process for an efficient C&Q Compliance process, and a review of structure and content of the soon to be published ISPE Baseline Guide 12 - Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment in support on implementation of ASTM E2500-07	Wisniewski
10:00	10:30	Networking Break	
10:30	12:00	Risk Assessment Methodologies and Workshop ASTM E2500-07 defines a risk-based lifecycle for equipment and systems, but how can you approach applying risk tools to verification? This workshop helps understand two powerful tools, Cause and Effect Diagrams and Fault Tree Analysis, and teaches application to the verification process through a progressive series of hands-on examples. Other methods such as Failure Modes and Effects Analysis and use of a Boston Matrix will also be discussed.	Howard Ruklic
12:00	13:00	Lunch	
13:00	14:15	Application of Quality Risk Management (QRM) Principles to Assure Equipment Fitness for Use and Process Sustainability for Manufacturing Operations This presentation will explain how QRM concepts (e.g., product/process knowledge, QbD, CQA, control strategies, risk assessment) form the foundation for a science and risk-based verification approach that results in more efficient equipment delivery and streamlined process operations. The focus will be on risk-based approaches to project delivery activities such as requirements definition, design review, change management, verification of fitness for use, and acceptance/release, as well as associated challenges. In addition, equipment and product/process life cycles will be addressed to explain how to maintain a validated state during operations, based on product/process knowledge that began in development and knowledge gained during the Verification and Validation processes.	Barrick Renton Weseli
14:15	15:00	Risk Based approaches to HVAC System Qualification Examples of different approaches that may be used for risk based qualification of HVAC systems	Haycocks Goldschmidt
15:00	15:30	Networking Break	

15:30	16:45	J&J Packaging Line Case Study and Workshop This presentation will describe how to apply process knowledge to determine the critical aspects of a liquid dose packaging line. Participants will learn the importance of developing product attributes, process parameters and control mechanisms early in the project lifecycle with the intention of influencing equipment design. The presentation will culminate in the demonstration of lean verification deliverables that confirm equipment's fitness for use. Participants will have the opportunity to apply these principles during an interactive activity.	Dollard Wojnarowicz
16:45	17:00	Q&A	All Speakers
17:00		Seminar Adjourns, Reception/Exhibit Hall Opening	

Tuesday, 8 June

Start Time	End Time	Presentation Title	Speaker
7:30	9:00	Breakfast	
9:00	9:10	Welcome to Day Two	Wisniewski
9:10	9:50	FDA Regulatory Perspective on Risk-Based C&Q	Gooen, FDA, <i>Invited</i>
9:50	10:30	EU Regulatory Perspective on Risk-Based C&Q (Presenting Online)	
10:30	11:00	Networking Break	
11:00	12:00	Coating Pan ASTM E2500 Case Study (Pfizer) This presentation focuses on saving paper, time and money by applying ASTM E2500-based verification and includes challenges and lessons learned.	Andreopoulos Dalby
12:00	13:00	Lunch	
13:00	13:45	Partnering with Vendors Optimize internal strategies and external terms and conditions with vendors / contractors in order to: <ul style="list-style-type: none"> • Focus on value added testing and data • Leverage data throughout C & Q • Set commercial terms that position you for C & Q success 	Larkin
13:45	14:30	Round Table Discussions: The Ideal FAT (Factory Acceptance Testing) Join in discussions with your peers to compare ideas and strategies for how to conduct the ideal FAT using a risk-based approach. Brainstorm on methods and practices that are being implemented in today's project environments and address issues such as the following: <ul style="list-style-type: none"> • What front-end loading activities should performed to ensure successful FAT? • What type of content should be included in Verification Plan? vendor specification? • What activities should be performed during FAT to maximize efficiency? • What vendor documents can be used to meet verification? • What are the potential issues associated with using vendor documents? Results will be shared with the entire group and general discussion will follow.	Hamm
14:30	15:00	Networking Break	
15:00	15:30	Report back from the Roundtables	
15:30	16:15	Round Table Discussions: Risk-based Roles & Responsibilities During this session participants will be provided with an overview of key organizational considerations when deploying a science and risk based C&Q program. The session will offer participants an opportunity to discuss challenges faced related to organizational restructuring, the new role of Quality and C&Q process ownership. Industry experts will be available to provide insights into effective solutions to overcome these organizational hurdles. <ul style="list-style-type: none"> • Organizational Restructuring • Quality's Role • Process ownership 	Dollard
16:15	16:45	Report back from the Roundtables	Hamm Wisniewski
16:45	17:00	Wrap-up/Q&A	Hamm Wisniewski
17:00		Seminar Adjourns	

****Please Note that Agendas are Subject to Change****