Program Outline
PV Workshop: Life Cycle Management Risk Based Approaches

Date: 18/19 Oct 2018

DAY 1		
0900-0915	Introductions	
0915-1030	**Session 1**: Science and Risk Based Approaches and Trends	• ICH Regulatory Drivers (QbD)
		• FDA, EMA, EU and others PV guidance and recent FDA and EU observations on PV
		• ISPE PQLI® Initiative
		• Implementation challenges
		• Detail of ISPE PV Discussion Papers
		– Determining & Justifying the Number of PPQ Batches
		– Applying CPV Expectations to New and Existing Products
		– Impact of Statistical Tools on PPQ Outcomes
		– Lifecycle Approach to Biotech Process Validation
1030-1100	**Session 2**: Product and Process Design and Quality Risk Management	• ICH Regulatory Requirements, CQAs, CPPs and Science and Risk Based Approaches
	(Process Validation Stage 1)	• Stage 1 QbD Deliverables
1100-1130	Morning Tea	
1130-1215	**Session 2**: Product and Process Design and Quality Risk Management	• Criticality and Risk Assessment
	(Process Validation Stage 1)	• Control Strategy Definition
1215-1300	Workshop 1: Control Strategy Development	• Participants will collaborate in small work groups to develop Control Strategy for a product.
1300-1400	Lunch Break	
1400-1500	Workshop 1: Control Strategy Development	• Participants will collaborate in small work groups to develop Control Strategy for a product.
1500-1530		• Review and discuss results with the other participants/groups
		• Lessons learned
1530-1600	Afternoon Tea	
1600-1700	**Session 3:** Facility/Equipment Qualification and PPQ	• Equipment Qualification (Stage 2.1)
	(Process Validation Stage 2)	• Qualification and Verification
		• PPQ / Process Validation Criteria (Stage 2.2) and approached to number of batches
		• PPQ/PV Protocol requirements

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DAY 2		
0900-0930	Recap Day 1	
0930-1100	**Session 4**: Continued Process Verification for New & Legacy Products	• Concept of Continued/Ongoing PV
	(Process Validation Stage 3)	• Regulatory requirements for 3a and 3b
		• Planning for Stage 3
		• Statistical tools
		• Approaches for legacy products
1100-1130	Morning Tea	
1130-1230	**Session 5**: Process Performance and Product Quality Monitoring Systems	• PPPQMS as part of the Pharmaceutical Quality System
	(Lifecycle Controls)	• Implementation of PPPQMS
		• Statistical considerations
		• CAPA
		• Management of Change
1230-1300	Workshop 2: Practical Application of Process Capability and Control Charts	• Examples and discussions on example datasets
1300-1400	Lunch	
1400-1445	Workshop 2: Practical Application of Process Capability and Control Charts	• Statistical assumptions and biopharm processes
		• Workgroup discussion
1445-1530	**Session 6**: Tech Transfers and CMOs	• PV with Tech Transfer and CMOs
		• Phase specific planning and considerations
1530-1600	Afternoon Tea	
1600-1645	**Session 7**: Future Trends	• ICH Q12 & Clinical Relevance
		• PV for Continuous Manufacturing, Cleaning and Accelerated Development products
		• Quality Metrics / Capability Maturity
1645-1700	Q & A and Workshop Close	