

Agenda

Quality Management Systems
Training for professionals of the vaccine industry - Rio de Janeiro 6-10 July 2015

Day 1

Monday

Train the trainer approach – the multiplier effect

08:00	10:00	The training process: current knowledge and skill person with potential company's vision, mission and goals department and individual goals
10:00	10:15	Coffee break
10:15	12:30	Knowledge and skills requirements. Gap analysis and prioritization.
12:30	13:30	Lunch break
13:30	16:00	Objectives plan. Qualified trainer
16:00	16:15	Coffee break
16:15	17:30	Actual training : exercise. Evaluation knowledge vs skills.

Day 2

Tuesday

08:00	10:00	Overview of ICH Q 10: <ul style="list-style-type: none"> • Purpose • Responsibilities of Senior Management Exercise: How does your senior management exercise their responsibilities?
		<ul style="list-style-type: none"> • Enablers • System Elements • Metrics • Suppliers • Continuous Improvement
10:00	10:15	Coffee break
10:15	12:30	“Deficiencies” in ICH Q 10: <ul style="list-style-type: none"> • Evaluation of changes by expert teams • Definition of a system, the components of the PQS, how to create the PQS. Exercise: What are the most important processes? Which are the weakest? (a Risk Analysis)
		<ul style="list-style-type: none"> • Process - interlinkage, thinking and management • Management processes • Efficiency and waste reduction - costs Exercise: Do you measure waste and what are you doing to reduce it?
		<ul style="list-style-type: none"> • World Class and Operational Excellence
12:30	13:30	Lunch break

13:30	16:00	Implementation Issues	
		The Quality Policy:	
		• Customer (external and internal) focus	
		• Quality is everyone's responsibility	
		Exercise: How are you implementing your quality policy?	
		System:	
		• Definition	
• Components of the PQS			
• Management of the system			
16:00	16:15	Coffee break	
16:15	18:00	Process:	
		• Interlinkage and integration - examples validation and supply chain	
		• Process thinking and management	
		• Process and human error	
		Exercise - What is the connection between process quality and human error?	
		Culture	
		Change - Benefits/Barrier Analysis	
		Exercise: Develop a strategy to improve your compliance with ICH Q10.	
		Optional:	
		Operational Excellence and World Class	
		• ISO 9004 maturity scale	
		• Malcolm Baldrige scale	
• Oliver Wight checklist for Operational Excellence			
• Cobit 5 Process Capability model			
Day 3			
Wednesday parallel sessions			
08:00	09:00	Introduction tutor and objectives for programme	Importance of culture - The Pharmaceutical Quality System
09:00	10:00	International perspectives on GMP and Quality Management	Components of a quality culture: Exercise - What are the 5 most important components of the quality culture for your organization?
10:00	10:15	Coffee break	
10:15	11:00	QMS, what should it do, what can it not do	Analysis of your organization's culture
11:00	11:30	Inspectors: how they judge organizations	Exercise - What is your organization's culture?
11:30	12:30	Dis-approved, how to recover (what to consider, plan of attack)	
12:30	13:30	Lunch break	
13:30	14:15	Case-study: GMP-issues in a European facility	Measurement of culture
14:15	15:00	Management of Knowledge	Exercise - How do you measure your company's quality culture today?
		Management: examples of	
15:00	16:00	Toolbox to help improving your organization	
16:00	16:15	coffee break	
16:15	17:30	Exercise on practical tools	Change/improvement of culture: Exercise - What improvements do you want to make in your culture? Develop a strategy to do

Day 4		
Thursday		
08:00	09:00	Yesterday's workshop: presentations and discussions
09:00	10:00	Principles concerning Validation and Qualification
10:00	10:15	Coffee break
10:15	11:00	A practical example: Qualification of Equipment
11:00	11:45	Risk Management, explanation,
11:45	12:30	practicing the tools as per ICH-Q9, examples
12:30	13:30	Lunch break
13:30	14:30	Aseptic Facilities: zoning, cleanroom-complexes, Media Fills, sterility tests on finished products.
14:30	15:15	Media Fills (I) Mind-mapping and design of Media Fills, including Personnel Qualification
15:15	16:00	Media Fills (II) examples of failures and consequences
16:00	16:15	Coffee break
16:15	17:30	Work-shop: design of a closed system for formulation and fill of an aseptic process
Day 5		
Friday		
08:00	10:00	Organizing building/upgrading your facility: how to do, what to consider
10:00	10:15	Coffee break
10:00	10:30	Consultants: what can they do, what can they not do, assignments
10:30	11:00	Clean construction management, a must to support qualification programs (how
11:00	12:00	Yesterday's workshop: presentations and discussions
12:00	12:30	Process Validation, the change in paradigm, background and how it will help your
12:30	13:30	Lunch break
13:30	14:15	Case studies: failures of qualifications and validations due to improper preparational
14:15	15:00	Environmental Monitoring Program, Out of Trend/Limits, Disinfectants Effectiveness
15:00	16:00	Organizing your documentation (e.g. Equipment Files), supporting oversight and a great help during inspections
16:00	16:15	Coffee break
16:15	17:30	How to prepare an inspection and how to perform/behave during an inspection.