Quality Risk Management (QRM)
How mature are you?

Full Day Seminar

Monday, 20th March 2017

NIBRT, UCD Campus, Fosters Avenue, Mount Merrion, Blackrock, Co Dublin

Time	Topic	Speakers
08.30	Registration	
	PRESENTATIONS	Chair: Anne Greene
09.00 – 9:15	Open and Welcome	PDA – Georg Röessling, PDA Europe PDA – Mike Morris, President PDA Ireland BPCI – Matt Moran, Director, BPCI
9.15 – 10.15	How Mature are you? QRM Maturity Benchmarking Model *Interactive audience survey based on Maturity Model*	Kelly Waldron, Manager, Global Quality Risk Management an Design Control, Sanofi, Boston US
10.15– 11:00	Regulatory Perspective The PIC/S Expert Circle on Quality Risk Management – Inspector Training Initiatives on Advanced QRM	Kevin O Donnell, Market Compliance Manage HPRA
11.00 – 11.30	COFFEE BREAK	NETWORKING
11.30 – 12:00	Process Understanding –Lifecycle Process Risk Assessment, a key basis for Verification	Alice Redmond, VP European Operations, CAI
12.00 – 12.30	Industry Case Study Title TBA	Merck
12.00 – 13.00	Industry Case Study QRM Process and Tools with worked example	Donna Leamy Quality Risk Process Owner, Amgen
13.00 -13:30	Q&A and Panel Discussion	All Presenters and Audience
13.30 – 14.00	LUNCH	NETWORKING
14:00 -15:00	Workshop 1 Using QRM to Determine Critical Process Parameters and the Process Control Stragey Facilitators: Kelly Waldron/Anthony Newcombe	Workshop 2 Formal vs Informal Risk Assessment Facilitators: Kevin O Donnell/Ann McGee
15:00 – 15:15	COFFEE BREAK	
15:15 – 16:15	Workshop 3 Risk Facilitator Training Facilitators: Alice Redmond/John Henchion	Workshop 4 PCI QRM Working Group Facilitator: Enda Dempsey
16:15 – 16:30	Workshop Feedback	Facilitators
16:30 – 17:00	Q&A / Discussion	Chair: Declan Quinlan

Cost : €200 per person   For further information contact: anne.greene@dit.ie or enda.dempsey@ibec.ie

Registration at:
http://www.biopharmachemireland.ie/IBEC/Events.nsf/wvPCIPages/Event~quality-risk-management---how-mature-are-you-20-03-2017?OpenDocument

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