



Delivering Value and Resilience using Quality Risk Management



A joint seminar and workshop hosted by PDA Ireland and PRST TUDublin



Thursday 8th September 2022

09:00 – 17:30 (Irish Standard Time)

TUDublin Grangegorman

09:00 – 10:00	Networking and Breakfast. Registration	St. Lawrence Hall
10:00 -12:15	Session 1. Advancing Quality Risk Management (QRM) for patient benefit through research, experience and ICH Q9	Central Quad
Welcome and Opening		TUDublin & PDA Ireland
Risk management in the public health context – the Covid experience of risk-based decision-making during time of uncertainty and rapid research		Prof. Philip Nolan. Science Foundation Ireland
ICH Q9: Background to Revision 1, key concepts and implementation		Kevin O'Donnell., HPRA
Leveraging QRM to assure medicine supply during the pandemic		Barbara Allen, International Quality Expert
Clarifying the Diamonds - Decision Making in QRM and the PQS		Valerie Mulholland, PRST/GMP Services
Panel Discussion and Q&A		Speakers and Grainne Power, HPRA
12:15- 13:00	Lunch	St. Lawrence Hall
13:00 – 14:15	Session 2. Current and Emerging Practices: Insights, Experiences and Future State.	Central Quad
Quality Risk Management Formality - Not necessarily a Black-Tie Affair		Jim Cashman, Eli Lilly
Subjectivity – The behavioural science of risk management		Nuala Calnan PRST TUDublin / QRM Institute
The inter-relationship of Knowledge Management and Quality Risk Management		Marty Lipa Ph.D. PRST TUDublin/ MSD
Panel Discussion and Q&A		
14:15 – 14:30	Coffee Break	Central Quad
14:30 – 16:15	Session 3 Four Concurrent working sessions on interpretation and application to example scenarios	Central Quad
A	Integrating QRM & Reliability to enhance our P's - (Prevention, Prediction, Proactivity, imProvement, within Projects/Programs and oPerations)	Gary Power, MSD Marcus O'Mahony, UL
B	Batch Release Acceleration – Using Quality Risk Management to enable “warp speed” batch release	Richard Falcon, Pfizer Brendan Griffin, UCC
C	From Development to Commercialisation and during Accelerated conditions - How do we apply QRM?	Donna Leamy, Regeneron Marty Lipa, MSD
D	Quality Risk Management in Global Supply Chains	Ann McGee, MIAS Pharma Nuala Calnan, TUDublin /QRM Institute
16:30 – 17:00	Close Out café	Central Quad
Collation of the outputs from the working session, discussions and identification of best practice and areas for future research		

Thank you to our sponsors



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or contact deirdre.tobin@merck.com

PDA Members: €250 Non-Members: €300
Fee includes Lunch & Refreshments