



Delivering Value and Resilience using Quality Risk Management



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

Thursday 8th September 2022 Time: 09:00 – 17:30 (Irish Standard Time) TUDublin Grangegorman

09:00 Networking and Breakfast. Registration (60 min)

10:00 **Welcome and Opening**

TUDublin & PDA Ireland

Session 1 Advancing Quality Risk Management (QRM) for patient benefit through research, experience and ICH revision

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, *Industry Expert*

Clarifying the Diamonds - Decision Making in QRM and the PQS

Valerie Mulholland, *PRST/GMP Services*

Panel Discussion and Q&A

12:00 Lunch (45 min)

Session 2 Current and Emerging Practices: Insights, Experiences and Future State

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*

Risk management across manufacturing operations networks

Invited *BMS*

Panel Discussion and Q&A

Session 3 Four Concurrent working sessions on interpretation and application to example scenarios

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*



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Session 4

Close Out cafe

The event will conclude with a networking session, including the collation of the outputs from the working session discussions and identification of best practice and areas for future research.

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or contact deirdre.tobin@merck.com

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