

ICH Q9(R1): The Next Frontier

An audience with international thought leaders exploring how the effective use of knowledge can enhance QRM outcomes to benefit the patient

1st June 2023 TU Dublin, Grangegorman

Welcome and Opening

Room CQ006

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| 9:00 – 9:15 | Welcome Address | Prof. Declan McCormack Head of School, TU Dublin |
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Keynote Presentations – Chair Dr Marty Lipa

Room CQ006

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| 9:15 – 10:00 | Smart Missions that Enable Innovation in High-risk Environments | Dr Ed Hoffman, Columbia University, NASA (retired) |
| 10:00 – 10:30 | Balancing Quality & Innovation in Pharmaceutical Manufacturing | Dr Emma Ramnarine PRST |

Plenary Session – Chair Dr Colin Hughes

Room CQ006

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| 10:50 – 11:10 | Fireside Chat on RBDM with Dr Gregg Claycamp, US FDA (retired) <i>Hosted by: Valerie Mulholland, PRST & GMP Services</i> | |
| 11:10 – 11:30 | ICH Q9(R1) Overview | Dr Kevin O'Donnell HPRA, ICH Q9(R1) Rapporteur |
| 11:30 – 11:50 | Quality Reborn – The Role of Quality in Innovation | Dr Anders Vinther Kronos Bio |
| 11:50 – 12:10 | Fostering Innovation in Manufacturing & Clinical Trials from a Regulatory Perspective | Peter Twomey EMA |
| 12:10 – 13:00 | Panel Discussion with Keynote & Plenary Speakers, joined by Dr Grainne Power, HPRA Moderators: Dr Aidan Harrington, PDA Ireland & Alice Redmond, ISPE Ireland | |

Parallel Sessions (see p.2)

Rooms noted on p.2

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|---------------|------------------------------------------------------------|---------------------------------|---------------------------------------------------|
| 14:00 – 15:40 | Track A: Innovation & Digital Transformation | Track B: QRM and RBDM | Track C: Pharma Workplace of the Future |
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Closing Session – Chair Dr Marty Lipa

Room CQ006

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|---------------|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| 16:00 – 16:15 | Continuous Improvement in Pharma – Contradict or Complement to Compliance | Prof. Thomas Friedli University of St Gallen |
| 16:15 – 16:45 | Advantages of Modern Manufacturing for Patients, Industry, and Regulators | Rick Friedman US FDA |
| 16:45 – 17:15 | Panel Discussion with representatives from Afternoon Sessions Moderators: Prof Anne Greene & Jim Vesper | |
| 17:15 – 17:30 | Closing remarks | Dr Marty Lipa PRST & MSD |

This seminar will explore **Knowledge Application** in three key areas:

1. Advancing the effectiveness of **QRM & Risk Based Decision Making**
2. Enabling innovation in the **Pharma Workplace of the Future**
3. Supporting **Digital Transformation**

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Parallel Session Details (from p.1)

| | Track A (Room CQ010): Innovation & Digital Transformation Chair: Dr Marcus O'Mahony | Track B (Room CQ009): QRM and RBDM Chair: Dr Ghada Haddad | Track C (Room CQ008): Pharma Workplace of the Future |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14:00 - 14:25 | Data-driven risk management – a practical approach to minimize subjectivity Pedro Ferreira ValGenesis | Risk Based Decision Making – using knowledge of risk throughout the lifecycle Dr Michael Schousboe Novo Nordisk & ICH Q9(R1) EWG | Smart Missions need Smart Workplaces! <i>Introduction by Dr Ed Hoffman</i> Workshop I: Interactive session exploring: |
| 14:25 - 14:50 | Leveraging Advanced Analytics in the Pharmaceutical Industry Patrick O'Sullivan PRST & EY | Improving RBDM Effectiveness Valerie Mulholland PRST & GMP Services | <ul style="list-style-type: none"> The role of knowledge in the Pharma Workplace of the Future Nurturing a Smart Culture: What does "Good" look like to cultivate learning & growth? |
| 14:50 - 15:15 | The Practicalities of Digitalizing KM to Enable Data-driven QRM David Twohig Accenture | The Long Road to ICH Q12 Dr Jean Louis Robert ICH Q12 IWG | Workshop II: Interactive session exploring: |
| 15:15 - 15:40 | Initiatives of Research Collaboration and GMP Human Resource Development at Three Universities with GMP Laboratories in Japan Prof Shingo Sakurai Tokyo University of Science Prof Ryoko Naruse University of Toyama Dr Osamu Hiruta Kumamoto Health Science University | Achieving Warranted Public Acceptance of Biopharma Innovations Prof Baruch Fischhoff Dr Emily Grayek Carnegie Mellon University | <ul style="list-style-type: none"> "The How": Leveraging the approaches and tools available within your workplace for excellence Ready for the Future: Reflections and Learnings from the workshops <p><u>Workshop Facilitators</u> Stephanie Friedrichsen Eli Lilly & Dr Nuala Calnan PRST & QRMI</p> |

Organising Committee

Anne Greene (Co-Chair) | Marty Lipa (Co-Chair) | Kevin O'Donnell | Valerie Mulholland | Adrienne Fleming

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Space is limited – Please register your interest by emailing anne.greene@tudublin.ie

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