Overview

Delivering Value and Resilience using Quality Risk Management.

The COVID Pandemic saw an unprecedented scale of risk management across public health and the pharmaceutical sector. In late 2021, the International Council for Harmonization of Technical Requirements for Pharmaceuticals, (ICH), released a draft revision to its guideline on **Quality Risk Management (ICH Q9).** Key areas addressed in the revision include risk-based decision making, formality, subjectivity and supply chain management.

PRST TUDublin and PDA Ireland are hosting a joint one-day seminar on **Sept 8th 2022** at TUDublin, Ireland exploring advances in Risk Management theory and practice related to pharmaceutical manufacture and supply. Academic, regulatory and industry leaders will share experiences, current concepts, opportunities and challenges, thus advancing research and sustainable enhancements to QRM practices for the benefit of patients.

Learning Benefits

- Gain a deeper understanding of research, interpretation and application of QRM from a Process, Quality, Operations and Supply Chain Perspective.
- Explore the impact of ICH Q9 R1 on QRM approaches across the product lifecycle and supply chain
- Hear from public health, regulatory, academic and industry experts regarding Q9 R1 key changes.
- Participate in working sessions with invited experts on application of Q9 (R1) to real-world scenarios.

Who should attend?

The following individuals or disciplines will benefit from attending this event:

· Quality Unit (QA & QC) personnel
· Qualified Persons
· Operations personnel (Late Phase to Commercial)
· Technical Services, Engineering & Pharmaceutical Scientists
Quality Risk Management Experts
Management with responsibility for risk management

Agenda

Session 1: Advancing Quality Risk Management for patient benefit through research, experience and ICH Q9 revision. Public Health, Regulatory Authority, Industry and Academic leaders will share experiences, current concepts, opportunities and challenges of risk management, drawing on experience during the pandemic and from Q9 revision.

Session 2: Current and Emerging Practices: Insights, Experiences and Future State. Experts will share their insights on the areas of Q9 revision including formality, subjectivity and

supply chain during this session, and attendees will participate in Q&A exploring the open points of discussion.

Session 3: Four Concurrent working sessions on interpretation and application to example scenarios. Attendees will discuss the interpretation and application of the four new elements to real-world scenarios such as operation reliability, quality release and supply chain.

Session 4: Close out Cafe. The event will conclude with a networking session, collating the discussions and identifying areas of best practice and future research.