



Quality Risk Management (QRM) 2-day Workshop

The DPS workshop on Quality Risk Management is a 2-day event which will allow the various facility/project stakeholders to move from an informal and qualitative assessment of risk to a more formal and quantitative assessment. This will allow for prioritization of risks that will give rise to an action plan and project schedule for an upcoming Regulatory Audit or for a Pre-Approval Inspection of a new manufacturing facility.

Day-1

Day-1 of the workshop straightforwardly and robustly introduces the following risk management tools and processes identified in ICH Q9 Guidelines:

1. Cause and Effect Diagrams
2. Fault Tree Analysis (FTA)
3. Failure Mode Effects (and Criticality) Analysis (FMEA/ FMEAC)
4. Preliminary Hazard Analysis (PHA)
5. Hazard and Operability Analysis (HAZOP)
6. Event Tree Analysis (ETA)
7. System and Component Impact Assessment (ISPE Baseline Guide 5 'Commissioning and Qualification)
8. GAMP5 Process for Categorizing Software Packages
9. ISO 14971 – Application of Risk Management to Medical Devices
10. Hazard Control and Critical Control Points (HACCP)

Participants are first introduced to each risk management tool/process and then partake in a practical exercise where they immediately apply the principles learned to real and relevant pharmaceutical specific examples.

Day-2

Using a relevant and specific example (adapted for the particular class/attendees), the workshop on day-2 will demonstrate how quality risk management, supporting a scientific and practical approach to decision-making, will identify and mitigate known and potential risks in line with the ICH Q9 Guidelines which form the basis of Regulatory Audits.

The day-2 workshop will take the following approach:

Step-1: Define the problem and/or risks, including pertinent assumptions identifying the potential for risk, to a successful regulatory audit.

Step-2: Identify the desired state/solution: *i.e.* how to protect patient health.

Step-3: Use and/or adapt the various quality risk management tools and processes from day-1 to show how to bridge the gap from the problem to the solution.

In the context of this scenario, quality risk management will allow the various facility stakeholders to move from an informal and qualitative assessment of risk to a more formal and quantitative assessment, allowing for prioritization of risks that will give rise to an action plan and schedule.