



Training Course Agenda

547 – Technical Report No. 54-5: Quality Risk Management for the Design, Qualification and Operation of Manufacturing Systems

DAY 1

8:30 Welcome and Introductions

Training Course Overview

8:45

- Review of regulatory requirements
- Review of business benefits
- Review of day's agenda

QRM for the Design Phase of a Manufacturing System

9:00

- Goals of QRM application in Design phase
- How to apply QRM to the Design phase

10:00 Coffee/Tea Break

QRM for the Qualification Phase of a Manufacturing System

10:15

- Goals of QRM application in the Qualification phase
- How to apply QRM to the Qualification phase
 - QRM for carry-forward of supplier information/commissioning
 - QRM to support qualification plans and protocol design (what to test and how much to test; SIA, process FMEA, and Design FMEA)

12:00 Lunch

13:00

Review of morning content and discussion of sticking points

QRM for the Operation and Maintenance Phases of a Manufacturing System

13:30

- Goals of QRM application in the Operations and Maintenance phases
- How to apply QRM to the Operation and Maintenance phases

14:30 Coffee/Tea Break

QRM for the Quality System of a Manufacturing System

14:45

- Goals of QRM application in the quality system (for manufacturing systems)
- How to apply QRM in the quality system for a manufacturing system
 - Deviations
 - CAPA
 - Change control

15:45

Summary and Assessment
Evaluations

16:00 End of Training Course