MARKTHOMPSON
LIFESCIENCES

Quality Risk Management (QRM)

Overview

Every Quality Critical aspect of Pharmaceutical manufacture has to be associated with and justified by a documented assessment of Risk. One of the most frequent regulatory findings is associated with failures of a site QMS and QRM.

This course provides training in Risk Assessment techniques and how they should be applied to your site. Regulators are keen for you to tailor the QRM system to suit your specific site needs and therefore this course delivers a range of approaches with countless examples as to how they applied on different sites.

This course is exclusively delivered as a tailored on site course and generally as part of a package of work we are undertaking to develop site QRM procedures.

Following QRM approaches presented, the second half of the course presents how the data is to be used and leveraged across site. Annex 15 requires that as new information is made available during commercial manufacture, risk assessments shall be updated. This effectively means that risk assessments have to be maintained as live documents. Mechanisms for developing and maintaining live risk assessments are presented together with how the data is used for process improvement, maintenance, qualification, requalification and ongoing monitoring / review.

Target audience

QA and everyone involved in QRM. Which is nearly everyone on site! For this reason this training is often summarised following the initial 2 day course and cascade trained as short modules. MTL has recently got the facility to produce professional video modules so that the training can be cascaded in a consistent and still engaging manner.

About the Lecturers

This course is generally delivered by Mark Thompson. Mark has led the way in many companies with the introduction of risk based approache3s to qualification as well as Process Risk Assessments for overall process Improvement, Sterility Assurance etc. Over 18 years ago Mark was involved in developing Sterility Assurance Risk assessments for Sterility Assurance on parametric release facilities, this early experience has developed.

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Course Programme

DAY 1:

- Regulatory Requirements and Guidance for QRM
- ICH Q9 and Risk Analysis tools
- Regulatory feedback on different Risk analysis tools
- HACCP and applications of CCP's
- FMEA (Traditional and Developed examples)
- Application examples and Case studies
- Hybrid approaches CCP's and FMEA
- The Risk Statement
- Boundary definition
- Data input sources (Push and Pull of data).
- Prospective and Retrospective Risk Assessments
- Evidence based analysis

DAY 2:

- Examples of Regulatory feedback and concerns over application.
- QRM for Process Improvement
- QRM for Deviation and Change Control
- QRM for Contamination Control
- QRM for Qualification and Requalification
- System Impact assessment for new Equipment
- Defining CQA's and CPP's for processes.
- Application Problems
- Maintaining live Risk Assessments
- Application examples and Payback
- Inspection readiness, presentation and ongoing review.