



MARKTHOMPSON
L I F E S C I E N C E S

Qualification of Thermal Systems

Overview

There are many thermal environments which have a critical impact on product quality:-

- Autoclaves, ovens and tunnels for sterilisation and depyrogenation
- SIP Systems, bulk sterilisation
- Cold rooms, WIP stores, warehouses
- Laboratory incubators, fridges and freezers
- Transit / shipping controls and shipping studies
- Process; fermentation and biotech

This course will start by introducing a methodical approach to assessing the quality critical impact of any thermal systems. Linking to the VMP for the site this approach will help to define the qualification and requalification requirements. This is the basis for justifying the whole approach, as described in Annex 15.

The course then goes into the detail of thermal measurement systems, options (pros and cons) for different technologies and different data logging options. The course programme opposite describes the sections covered. This two day course covers the qualification of thermal systems in considerable detail from initial assessment to ongoing requalification trending and data review.

It is possible through careful design and initial qualification to establish some thermal systems that are continuously verified by the installed monitoring, therefore requalification becomes a documented review rather than physical thermal placement.

As with all of our courses, the course ends with a presentation on current regulatory feedback and inspection trends.

Target Audience

The course is designed for validation technicians and engineers who need to establish and execute qualification programmes for thermal systems. QA representation from people involved in review and approval of the protocols and presented data would also benefit from this training.

About the Lecturers

This course is delivered by Mark Thompson and Chris Maughan. Chris is the Managing Director of Thermal Compliance Ltd, a company specialising in the execution of thermal qualification. Thermal Compliance Ltd are on our resources page as a recommended company for the execution of thermal Qualification and the company we work with if we need to deliver a full turn key project. Chris has over 15 years of direct hands on experience of Thermal Qualification, this practical experience and troubleshooting case studies adds considerably to the value of this course.

Course Programme

DAY 1:

- Regulatory Framework and requirements
- Identifying Direct Impact Systems
- Process Risk Assessment Based upon Operation.
- Temperature Measurement Principles.
- Data Logging options and Data Integrity.
- Calibration, Verification and Recalibration.
- Validating The Validation System.
- Understanding the Thermal environment to be Qualified.

DAY 2:

- Defining Challenge locations based upon Risk Assessment
- Defining Challenge conditions, events, interventions
- Commissioning phase for Thermal Systems
- The Performance Qualification Protocol
- Execution; Set up, Calibration, placement, data collection.
- Data review and Reporting
- Handling deviations.
- How to maintain the Qualified State.
- Requalification options
- Current inspection trends and regulatory feedback

| Consultancy & training in sterile product manufacture |

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