



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

# Steam Quality Testing (Theory & Practical Assessment)

## Overview

The Quality of Steam used for Sterilisation of Equipment, Vessels and Processes is one of many Critical Process Parameters that needs to be controlled on a Sterilisation process. The European inspectorate apply European Standard EN285 (2015) to Autoclaves and Equipment Sterilisation. The new Annex 1 references Steam Quality also. EU Inspectorates are frequently finding problems with Steam Quality and Steam Quality testing at sites around the world in their compliance with these requirements.

The expectation is that all equipment / porous load autoclaves and SIP systems shall have Steam Quality Tested at the user point.

This course will address the purity of the steam (Condensate testing) as well as the Physical properties of Non Condensable gases, Dryness value and Superheat of the Steam. This one day course is generally delivered on site with 2.5 hours classroom based and 4.5 hours practical 'hand-on' training so that people who attend are signed off as being competency assessed in the testing not just understanding the standards.

There are many examples of bad practice in the industry when it comes to Steam Quality Testing including getting the testing wrong. Switched on regulators often spot these errors!

## Target audience

Steam Quality Testing is usually the responsibility and performed by Engineering, the people that perform the testing will attend the whole day of training; theory and practical. It can be beneficial for QA or others to attend the first part of the day so that they have an appreciation of the requirements and the data presented.

## About the Lecturers

This course is delivered by Mark Thompson who has been performing Steam Quality Testing on Pharmaceutical applications for nearly 28 years now. Mark has been training in Steam Quality and Steam Quality Testing for the last 19 years. Mark is regularly auditing steam systems and troubleshooting Steam Quality Issues.

| Consultancy & training in sterile product manufacture |

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## Course Programme

### DAY 1:

- Regulatory Requirements for Steam Quality Testing
- The Properties of Steam Condensate (wfi, EN285 etc)
- The Physical Properties of Steam and how they can impact Sterilisation
  - NCG Non Condensable Gases
  - DV Dryness Value
  - Superheat
- Engineering best practice for Steam Generation and Distribution
- Steam Test Points Installation
- Failure modes in Steam Generation and Distribution systems linked to the Physical Properties of steam.
- PRACTICAL
- Steam Isolation and installation of test equipment
- Set up for each of the physical tests
  - Every test demonstrated
  - Every test 'hands on' experienced by Trainee
  - Data recording and calculation

NOTE : Access to a Steam Quality test location is required for the practical training. This can be in the plant room, steam generator or at user point whichever is most convenient and with the best access.

## Recent Comment

"We thought we had a failure on Dryness Value and wet steam even though no wet autoclave loads have been observed. This days training has identified that actually our contractor has been using the incorrect set up and giving us false failures in Steam Dryness Value! Pleased we are taking control of this testing"

Fintan, Site Engineering Manager