# Sterilisation and Depyrogenation

The new Annex 1 requires definition and control of the Critical Control Points (CCP's) of a process. For Sterile Product Manufacture, many of these CCP's are associated with the sterilisation and depyrogenation Processes.

The 5 modules that make up Sterilisation and Depyrogenation cover the topic from first principles through to current best practice, benchmarking with industry, compliant approach to CQV and requalification as well as several real world case studies.

GxP Training, The Compliance Group and Mark Thompson Lifesciences have worked together in training delivery for many years and provide a complete overview from Engineering, CQV and the Regulatory inspectors perspective.

## about the course

This Sterilisation and Depyrogenation Training course has been delivered by Mark Thompson to industry and regulators for over 20 years. The course is constantly developing based upon current technology, regulatory requirements and industry best practice. Benchmarking with industry is one of the most valuable deliverables of these modules.

The course has recently been adapted to a modular format of 5 one day modules.

- Module 1 is recommended for everyone as it covers the first principles of bioburden and endotoxin control as well as Sterilisation definitions, Sterility Assurance Levels and requirements. This module will also include an overview of all sterilisation technology options.
- Modules 2 to 5 cover each specific topic; Science, Technology, Regulatory Requirements and CQV for each.

These courses benchmark with industry best practice and are ladened with case studies and troubleshooting advice.

## who should attend

This course will benefit all involved in Sterilisation and Depyrogenation. The course is designed to develop Subject Matter Experts (SME's) and to expand SME knowledge.

## sterilisation and depyrogenation course:

**MODULE 1**
**Sterilisation and Bioburden Control Technologies**

**MODULE 2**
**Equipment Load Steam Sterilisation**

**MODULE 3**
**Steam in Place Systems**

**MODULE 4**
**Fluids Sterilisation**

**MODULE 5**
**Dry Heat Sterilisation and Depyrogenation**

## course content - course preparation material

In advance of the course you will be sent some course preparation material. This information will be reviewed during the course also, but the preparation will ensure that you are able to consider key aspects of your site requirements.

## what else should I know

It is recommended that every participant does Module 1 with 1 or more of the other 4 modules to get the most out of their training and a background to each of the different modules.
The cost of Module 1 is €800. Thereafter, the cost of each additional module is €600 per module, or €3,000 for the full course. The course fee includes all course material.

## how to apply

Applications can be made online at **www.gxp.ie**

## location and date

Location : Individual modules will be delivered in a live online environment.

For upcoming course dates see **www.gxp.ie/training**

## about the presenters

**Mark Thompson** is a Chartered Engineer with over 30 years' experience in the Life Science industries. Mark has been delivering Training and Consultancy in Sterilisation and Depyrogenation for the past 23 years. Throughout this period Mark has worked all over the world with hundreds of organisations, delivering training to thousands of people. This has included delivering training courses for regulatory inspectors from China, Saudi, UK, Ireland, Italy, Denmark and the Netherlands.

**Stan O'Neill** After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (QP) and then joined the Irish Medicines Board (now the HPRA) for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, represented Ireland at European level for negotiation of standards of inspection for medicinal products (including Annex 1) and trained Inspectors at Irish, European and International levels.