

Sterilisation and Depyrogenation

Sterilisation and Depyrogenation processes are integral to many of the Critical Control Points associated with Sterile Product Manufacture; autoclaves, steaming in place systems, depyrogenation tunnels and ovens. In addition, EU GMP Annex 1 and EN285 have some very specific requirements related to these subjects.

about the course

This course has developed over many years and is constantly being updated as technology and regulatory expectations progress. Lectures include numerous case studies and relevant examples to help provide practical application of the subject. This course will form part of the broader SME Training Series being developed by GXP Training in conjunction with The Compliance Group and Mark Thompson Lifesciences.

who should attend

This course will benefit all involved in Sterilisation and Depyrogenation. The course goes to SME level with ongoing consultancy support following the training as required.

about gxp training

The Compliance Group is a specialised consultancy group consisting of ex-regulators. Consultancy Services are provided to Regulatory Agencies, NGOs, State Bodies and companies.

course content

course preparation material	day one Half day – 2pm start time on day 1	day two
<p>In advance of the course you will be sent some course preparation material including an online video lecture.</p> <p>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.</p>	<ul style="list-style-type: none"> • Course Introduction and Review of preparation material • The Spectrum of Sterilisation and Depyrogenation • Regulatory Standards, Guidelines and Inspection requirements. • Steam properties and Quality testing 	<ul style="list-style-type: none"> • Principles of an Autoclave • Porous Load and Equipment Sterilisation • Air Detectors and specific EU Requirements • Porous Loads Air removal problems solved • Wet loads problems solved • Fluids Load Sterilisation

what else should I know

Course Fee: €2,000 for 3 days. The course fee includes all course material, lunches and refreshments. Please note that this course may also be organised in an in-house basis. Please contact us for further information. Sterilisation and Depyrogenation Training delivered on your site is generally tailored to the specific loads, sterilisation processes, autoclaves, tunnels and any current issues.

how to apply

Applications can be made online at www.gxp.ie or by emailing training@gxp.ie

location and date

For dates see www.gxp.ie

about the presenters

Mark Thompson



Mark is a Chartered Engineer with over 25 years' experience in the Life Science industries. Mark has been delivering Training and Consultancy in Sterilisation and Depyrogenation for the past 18 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.

about SME training series:



The SME Series is a series of advanced training courses being developed by GXP Training for professionals to deepen their knowledge and develop their understanding to a SME level.

The initial focus of this series will be on Validation and Engineering, providing insight into Sterilisation and Depyrogenation; High Purity Water Systems - Generation, Storage & Distribution; Pharmaceutical Engineering.

Sterilisation and Depyrogenation is the first of the series to be launched.

course content

day three	day four
<ul style="list-style-type: none"> • Porous Load Cycle Operations and Cycle Review. • Fluids Load Cycle Operations and Cycle Review. • Sterilisation in Place (SIP) • Depyrogenation Ovens and Tunnels • Air quality requirements and controls in Depyrogenation • Qualification of Depyrogenation Ovens and Tunnels 	<ul style="list-style-type: none"> • Qualification requirements unique to sterilisation and autoclaves • Autoclave Cycle and Load Development • Scoping the Qualification approach (Bracketing and justifications) • PQ; Thermal / Biological Challenges and Sterility Assurance Level • Defining and justifying the Requalification scope and frequency. • Current Inspection Trends and the Inspectors perspective