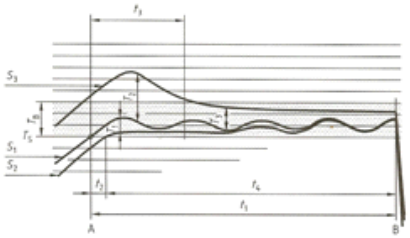
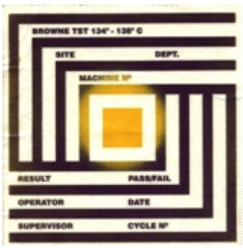
EU Sterilization Explained

The EU approach to sterilization is complex and is based on a variety of standards and guidance. This course provides attendees with the context and understanding essential for any US company that needs to comply with EU regulations.





Keith Shuttleworth is the Senior Consultant at KS & A, which provides a range of specialist products, consultancy and training services associated with sterilization processes and steam quality testing to an international market. He has over 25 years of practical experience in the procurement, commissioning, validation and maintenance of sterilizers. Keith was registered as an Authorized Person (Sterilizers) in October 1994 and is currently a member of the British Standards Institute Committee CH/198 (Sterilization of Medical Devices), has been the Chair of the P&HSS Sterilization Special Interest Group and has been a member of the PDA Taskforces for Sterilizer Validation and SIP Technical Reports. Keith has provided a wide range of presentations for ISPE, PDA and P&HSS, in addition to providing numerous in house training sessions throughout the world (including the UK's MRHA Inspectors).

All you need to know about EU Sterilization

One day course This course provides a detailed insight in how to satisfy all the EU requirements for moist heat sterilization. Topics include:

- History & Regulatory background
- Cycle design criteria
- Equilibration times and other measures
- Bowie Dick/DART tests - theory and practice
- Steam quality and steam quality testing
- Leak rate tests and test specifications
- Test frequencies
- Load configurations for validation/revalidation.
- Choice of biological indicators
- Long hold times
- Air detectors

For info and to reserve space:

Carltex Inc
PO Box 770, Nyack, NY 10960
Tel 845-535-3406 **Fax** 845-535-3407
info@carltex.com
www.carltex.com

The Background

There are some fundamental differences between the approaches to sterilization utilized in the US and Europe. These differences became more emphasized in the mid 1990's with the publication of HTM 2010 (replaced by CFPP 01-01, and replaced again in July 2016 by HTM 01-01) and EN 285 (which was updated in late 2015 with significant changes). The EU approach is not clearly codified and reference to high level documents such as Rules & Guidance for Pharmaceutical Manufacturers & Distributors 2015 (Orange Guide) provide little guidance to Production, QA, Validation and other professionals.

The EMA has a consistent approach to their audits and may cite a number of sources of guidance. These often relate to the medical devices industry and only some sections of these are relevant to the pharma and biotech industries. Furthermore, many of the requirements are not universal, being applied to the equipment sterilization process and not terminal product sterilization, or vice versa.

The Course Objectives

The objective of the one day course is to provide attendees with explicitly clear guidance as to the regulatory expectations, to detail common regulatory failures and highlight frequent errors in interpretation.

This will be done by dealing with each of the high level requirements and drilling down to a specific reference (or references) that will be explained in detail, using US terminology, where possible. Where corresponding requirements exist in PDA Technical Reports, for example, these references will also be provided.

The detailed course notes will contain all the necessary references and provide relevant extracts.

However, the course is not intended to be a simple progression through the various regulations but is meant to provide an in depth understanding of the EU approach that will include the history/derivation of the various requirements and the acceptance criteria utilized. Understanding the EU approach will enhance understanding of the sterilization process and will allow attendees to deal with any regulatory concerns or issues with a knowledgeable and confident approach.

Every Question Answered

Attendees are very welcome to pre-submit any questions to info@carltex.com and these will be dealt with anonymously during the course. In addition to ample opportunities to ask questions during the course, Keith Shuttleworth will also be available on the evening of the course to deal with additional questions on a one-to-one basis. A private LinkedIn Group has also been specifically established for delegates to ask any follow up questions they may have.

Carltex Inc, PO Box 770, Nyack, NY 10960
Tel 845-535-3406 **Fax** 845-535-3407 info@carltex.com www.carltex.com