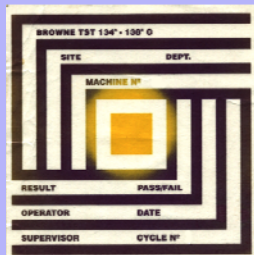
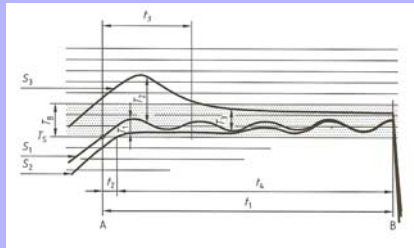




Keith Shuttleworth  
& Associates

# EU Sterilization Explained

The EU approach to sterilization is complex and is based on a variety of standards and guidance. This course provides delegates 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 some 25 years practical experience in the procurement, commissioning, validation and maintenance of sterilizers. Keith was registered as an Authorised Person (Sterilizers) in October 1994 and is currently a member of the British Standards Institute Committee CH/198 (Sterilization of Medical Devices), is 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** – Courses provide 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 frequency's
- Load configurations for validation/revalidation.
- Choice of biological indicators
- Long hold times
- Air detectors

## Steam Quality Training Master Class

**On site - One day course** – Courses will provide delegates with a detailed theoretical and practical knowledge of all aspects of steam quality testing. Topics include:

- Steam quality theory
- Test point installation
- Health & Safety
- Testing techniques
- Hands on training
- Troubleshooting

For both courses delegates will receive comprehensive notes and Certificates of Attendance. Formal assessments and Certification of Competence available on request.

## For info and to reserve space:

**Keith Shuttleworth & Associates Ltd**

D5 Basepoint Business Centre,  
110 Butterfield, Luton LU29HE UK

**Tel** +44(0)1582 433723 **Fax** +44(0)207 1173251

info@ksapharma.com

www.ksapharma.com