Keith Shuttleworth on:

“Current Moist Heat Sterilization and Validation Seminar”

At Comwell in Roskilde, Denmark
25-27 May 2010
Key Objectives

At the completion of this interactive course, participants will be able to:

- Understand the key principles of moist heat sterilization
- Be aware of best practices in moist heat sterilization processes
- Know current regulatory thinking with regard to moist heat sterilization
- Be familiar with suitable approaches to validating a moist heat sterilization process
- Ensure that ongoing process effectiveness is maintained and controlled

Who should attend?

The course will benefit all individuals associated with sterilization. In particular, personnel responsible for developing a company’s sterilization policies, Quality Assurance staff, and personnel involved with the design and validation of sterilization cycles and those involved in maintaining moist heat sterilizers.

Part I: Understanding moist heat sterilization

A truly comprehensive insight into the principles of sterilization:
Participants will learn the properties of different processes and how they relate to sterilization.

- The difference between dry and moist heat processes.
- How bacteria and spores are killed, their resistance to sterilization and the impact that different temperatures have upon them.
- The fundamental differences between liquid and equipment cycles.
- What is $F_0$ and when/how is it used.
- Different approaches to overkill and bio burden designed cycles.
- How to design sterilization cycles from first principles.
- The selection and the educated use of biological indicators.

Part II: The different sterilization processes

A complete overview of all the different moist heat sterilization processes:
Participants will gain an appreciation of what processes are available and when they should be used.
Part III: The Regulatory Environment

An up to date review of all the standards that apply to the sterilization process in the EU and US.
Delegates will understand which standards to apply and gain knowledge of current best practices.

- EMEA
- FDA
- EN 285:2006
- EN ISO 17665-1:2006
- PDA Technical Report No. 1
- Other relevant standards and guidance
- The world approach

Part IV: Validation principles

Background information that relates specifically to the validation of steam sterilization.
Delegates will be able to establish the key aspects necessary for the effective validation/re-validation of their steam sterilizers, to assist them in the purchase of new equipment and to avoid common mistakes.

- User Requirement Specifications
- Design Qualification
- Factory Acceptance Testing
- Installation Qualification
- Operation Qualification
- Performance Qualification
  - Load configurations and validation approaches
- Revalidation
Part V: Calibration, Maintenance and Ongoing Management & Controls

- Calibration and practical issues arising
- Maintenance
- Leak rate tests
- Bowie Dick tests
- Cycle scrutiny
- Operator SOP’s

Part I: Master class
- PQ Testing and techniques (optional)

A comprehensive practical session covering the different aspects of PQ testing in detail.
Participants will understand all the practical and logistical issues associated with PQ testing and be able to develop their own protocols and program.

- OQ Prerequisites
- Acceptance criteria
- Logging equipment, sensors and set up
- BI types and handling techniques
- Load definition/configuration
- Probe/BI location
- Data analysis and reporting
- Troubleshooting

Part II: Master class
- Steam Quality Testing (optional)

A detailed practical session covering all aspects of steam quality testing.
Delegates will gain the knowledge to confidently undertake steam quality testing and obtain accurate and repeatable results.

- Steam theory
- Test point location and installation
- Chemistry/Endotoxin sampling
- Dryness testing
Place

Comwell
Vester Kirkevej 12
4000 Roskilde

Comwell Roskilde is located in Roskilde, with a view of Roskilde fjord. The hotel offers all rooms and facilities necessary to conduct the whole seminar in one location. More information can be found at the [hotel website](#):

Practical information

The seminar will be held in English language.
The Seminar begins at 08.00 and finishes at 16.30

About the speaker

Keith Shuttleworth is the Senior Consultant at Keith Shuttleworth & Associates Ltd, which provides a range of specialist products, consultancy and training services associated with steam quality testing and sterilization processes to the international market.

Following a career as an Engineering Officer in the Merchant Navy, he has worked as an engineering manager in the UK’s National Health Service, the pharmaceutical industry and the sterilizer supply and service sector.

He has some twenty-five years practical experience in the procurement, commissioning, validation and maintenance of sterilizers. Mr Shuttleworth 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 responsible for Sterilizer Validation and SIP Technical Reports.
Registration Form

Please register to Scantago before 23rd April 2010

by e-mail seminar@scantago.com or fax +45 59 470 670

Last Name: Mr./Mrs.____________________________ First Name:_________________________________

Title:____________________________________________________________________________________

Company:__________________________________________________________________________________

Street: ___________________________________________________________________________________

Area code: ___________________ City: __________________________ Country: ____________________

Tel.:___________________________ Fax:___________________________ VAT: _____________________

E-mail:_____________________________________________________________________________________

Fees (payable in DKK) please tick:

☐ Two days incl. accommodation (25-26 May): 9,400 DKK (1,260.- Euro)
☐ Two days excl. accommodation (25-26 May): 8,200 DKK (1,100.- Euro)
☐ One day incl. accommodation (27 May): 5,300 DKK (710.- Euro)
☐ One day excl. accommodation (27 May): 4,100 DKK (550.- Euro)
☐ All three days incl. accommodation (25-27 May): 14,700 DKK (1,971.- Euro)
☐ All three days excl. Accommodation (25-27 May): 12,300 DKK (1,650.- Euro)

Written cancellations with a full refund will be accepted up to 20 working days before the start date of the course. A cancellation fee of 50 % will be payable for cancellations received between 14 and 20 working days before the start of the seminar. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.

Payment by

☐ An invoice for payment on participation approx 3 weeks before the seminar.
   Please inform about order reference if is needed.

An invoice will be submitted (or provided) by us approximately 3 weeks before the seminar.

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Cancellation policy: Scantago ApS reserve the right to cancel the seminar, for want of attendees.