

# “Current Moist Heat Sterilization and Validation Seminar”

**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.



4<sup>th</sup> - 6<sup>th</sup> March 2019

**Scantago A/S**  
Skulbjerg 9  
Gevninge  
DK-4000 Roskilde





## 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, personnel involved with the design and validation of sterilization cycles and those involved in maintaining moist heat sterilizers.

## Program - 4<sup>th</sup> March 2019

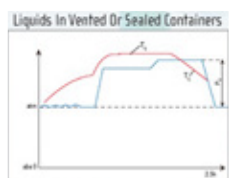
### Part I: Understanding Moist Heat Sterilization

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 understanding of what processes are available and when they should be used.



- Downwards displacement processes
- Equipment/solid good sterilization
- Standard fluid sterilization
- Overpressure fluid sterilization
- Recirculating water fluid sterilization
- Discard processes for hard goods
- Discard processes for liquid products
- Steam/sterilize in place



### 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. Challenges associated with:

- EMEA
- FDA
- EN 285:2015
- Revision draft of Annex 1 “Manufacture of Sterile Medicinal Products” of the EU Guideline for good manufacturing practice for drug products and drug substances: 20 December 2017”
- EN ISO 17665-1:2006
- PDA Technical Report No. 1
- Other relevant standards and guidance

## Program - 5<sup>th</sup> March 2019

### Part IV: Common Validation Challenges

Background information that relates specifically to the challenges associated with validation of steam sterilization.

Participants will amongst others gain knowledge on:

- The appropriate validation protocol
- Cycle development
- Worst caseloads
- Air removal & Leakage
- Superheat
- Wet loads
- Loading techniques

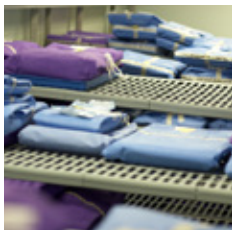




### **Part V: Calibration, Maintenance and Ongoing Management & Controls**

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

## Program - 6<sup>th</sup> March 2019



### **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.

- PQ 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
- Superheat testing
- Non-condensable gas testing
- Testing techniques and tips
- Troubleshooting



## About the speaker Keith Shuttleworth

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 over thirty 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 and Associated Equipment and Processes) has been 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.



## Venue

**Pharmakon**  
Milnersvej 42  
3400 Hillerød

**Pharmakon** is a modern conference and training center. All efforts are focused on creating the best possible environment for teaching and to ensure efficiency from arrival to departure. More information can be found on [www.pharmakon.dk](http://www.pharmakon.dk)

Please direct all questions regarding the seminar or accommodation to [mail@scantago.com](mailto:mail@scantago.com) or +45 59 470 600

### **Practical information**

The seminar will be held in English language

The seminar begins at 08.00 and finishes at 16.30

Included in the seminar:

- **Light breakfast buffet**
- **Midmorning break with healthy snacks**
- **Large lunch buffet in the restaurant**
- **Afternoon break with coffee/tea and homemade cake and healthy snacks**

## Registration Form

Please register to Scantago before February 4<sup>th</sup>, 2019

by e-mail mail@scantago.com

Last Name: Mr./Mrs. \_\_\_\_\_ First Name: \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Street: \_\_\_\_\_

Area code: \_\_\_\_\_ City: \_\_\_\_\_ Country: \_\_\_\_\_

Tel.: \_\_\_\_\_ Fax: \_\_\_\_\_ VAT: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Fees excl. VAT (payable in DKK or Euro)** please select:

- |  |                   |                      |
|--|-------------------|----------------------|
| <input type="checkbox"/> Two days incl. accommodation (4-5 March):       | <b>10,103 DKK</b> | <b>(1,347- Euro)</b> |
| <input type="checkbox"/> Two days excl. accommodation (4-5 March):       | <b>8,800 DKK</b>  | <b>(1,173- Euro)</b> |
| <input type="checkbox"/> One day incl. accommodation (6 March):          | <b>4,400 DKK</b>  | <b>(586- Euro)</b>   |
| <input type="checkbox"/> All three days incl. accommodation (4-6 March): | <b>15,806 DKK</b> | <b>(2,107- Euro)</b> |
| <input type="checkbox"/> All three days excl. accommodation (4-6 March): | <b>13,200 DKK</b> | <b>(1,760- Euro)</b> |

Accommodation includes 3 course dinner and breakfast.

**Please note**, that your registration for participation is binding. Delegate substitutions may be made at any time up to the start of the course.

### Payment by

- An invoice will be submitted approx. 2 weeks before the seminar.

Please inform about order reference if needed

### Cancellation policy:

Scantago A/S reserve the right to cancel the seminar, for want of attendees.