

## **An Introduction to Sterile Manufacturing**

**Split over two afternoon virtual Zoom sessions**

**Wednesday 21<sup>st</sup> April & Thursday 22<sup>nd</sup> April 2021**

Designed for those people who are new to industry this virtual training course will help you understand what sterile manufacturing is and will cover topics which include: microbiology, clean room design, sterilisation processes, sterility assurance, manufacturing methods and regulatory oversight.

**Target audience (those new to industry):** Microbiologists, cleanroom operators, production, quality, engineers, and sales & marketing

### ***It is designed to:***

- Get you to think about the risks associated with sterile manufacturing
- Understand the basic elements of sterility assurance

### ***The course will support:***

- Building greater people capability and consistency in your sterile operations
- Reducing quality issues, waste, defects and accidents
- Being better able to meet your regulators expectations
- Releasing batches more consistently → get products to the patient more reliably
- Better management of individual performance

### ***At the end of this virtual training programme, you will:***

- Have an underpinning awareness of sterile manufacturing and associated risks.
- Attain an introductory understanding and knowledge of key sterile processes and controls

### ***The Trainer***

**David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair**

David is a microbiologist working for Ecolab as Director, Pharmaceutical Microbiology in their Lifesciences division. With reference to Pharmig – David became a Committee member in 2007 and in November 2013 he had the honor of being elected as Pharmig Chair.

David started life at GSK Barnard Castle. Here he performed environmental monitoring and clean room qualification before moving on to sterile finished product testing. He then moved to a small startup company called SCM Pharma. Here he set up a new microbiology lab and developed a new microbiology team. He helped design and qualify the new clean rooms. He then moved from microbiology to project management and became the technical manager.

David then moved to Reckitt Benckiser at their Hull site where he discovered the magic and pain of working in an FMCG environment. His role was to improve microbiological awareness on the site and a large amount of time was spent investigating significant microbial contamination events with suppliers and products. He was lucky enough to be sent across the world investigating microbiological issues on behalf of the company. If you get caught by him at the bar, he can bore you to death on the wonders of seaweed.

In 2012 David moved back to GSK at the Ulverston site in the Lake District. This is a large-scale primary API manufacturing site makes bulk sterile antibiotics. It uses isolator technology in a primary environment, which was a bit of a steep learning curve.

David started a new role as a microbiological consultant for Ecolab in March 2018. In this role David utilizes his experience to help Ecolab's clients with microbiological and manufacturing issues, across the globe.

He is experienced in most drug dose forms from sterile needled injection systems, explosive aseptic ampoules to inhalation devices, oral doses of microbial sensitive products and sticky capsules. Plus, a great deal of primary manufacturing to boot. He is now dipping his toe into the world of disinfectants and contamination control – a microbiologist's best friend.



**PROGRAMME OUTLINE**  
**RUNNING AS 2 HALF-DAY VIRTUAL MEETINGS (AFTERNOONS)**

**WEDNESDAY 21<sup>st</sup> APRIL 2021 (13.00 – 16.00 BST)**

- |                      |  |
|----------------------|--|
| <b>13.00 – 13.10</b> | <b>Welcome and quick tour around Zoom</b><br><b>David Keen – Director Pharmaceutical Microbiology, Ecolab &amp; Pharmig Chair</b>  |
| <b>13.10 – 13.55</b> | <b>Introduction to sterile manufacturing</b> <ul style="list-style-type: none"><li>• What does sterile mean?</li><li>• Why do we need sterile products?</li><li>• Sterile vs aseptic – are they the same?</li></ul>  |
| <b>13.55 – 14.00</b> | <b>Q&amp;A session</b>   |
| <b>14.00 – 14.45</b> | <b>Introduction to microbiology</b> <ul style="list-style-type: none"><li>• What is microbiology?</li><li>• The bacteria, moulds and yeasts, virology, parasites and TSEs</li><li>• Controlling and understanding microbial growth</li></ul>                         |
| <b>14.45 – 15.00</b> | <b>Q&amp;A session and virtual break</b>   |
| <b>15.00 – 15.45</b> | <b>Introduction to cleanrooms</b> <ul style="list-style-type: none"><li>• What is a cleanroom</li><li>• Cleanroom grades and controls</li><li>• Design and equipment</li><li>• Cleanrooms as a contamination control system</li><li>• Cleanroom behaviours</li></ul> |
| <b>15.45 – 16.00</b> | <b>Q&amp;A session and close of virtual day one</b>  |

Cont....

**THURSDAY 22<sup>nd</sup> APRIL 2021 (13.00 – 16.45 BST)**

- 13.00 – 13.10**      **Welcome back:**  
**David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair**
- 13.10 – 13.55**      **Methods of sterilisation**
- Moist and dry heat
  - Filtration
  - Irradiation and e-beam
  - Chemical
- 13.55 – 14.00**      **Q&A session**
- 14.00 – 14.45**      **Process manufacturing**
- Common product dose forms
  - How to manufacture these dose forms
  - Isolators RABS and open filling
  - Blow fill seal, freeze drying
  - Process simulations, media fills and broth trials
- 14.45 – 15.00**      **Q&A session and virtual break**
- 15.00 – 15.45**      **Sterility assurance**
- What is sterility assurance?
  - Risk based manufacturing
  - Determination of sterility
- 15.45 – 15.50**      **Q&A session**
- 15.50 – 16.30**      **Sterile manufacturing and the regulations and compliance to GMP**
- Why is there a need for regulations?
  - Who regulates the pharmaceutical industry?
  - Are you inspection ready?
- 16.30 – 16.45**      **Questions and closing remarks of virtual day two**

*Please note: all information addressed by the speaker is of their own/ their company opinions and viewpoints. Pharmig is not responsible for any content presented at the meeting.*

*Pharmig also has the right to change the programme at any time due to unforeseen circumstances.*

## BOOKING FORM

### An Introduction to Sterile Manufacturing via Zoom Afternoons of the 21<sup>st</sup> & 22<sup>nd</sup> April 2021

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

Address: \_\_\_\_\_

Contact name if different from the delegate: \_\_\_\_\_

Tel: \_\_\_\_\_ Email: \_\_\_\_\_

**DELEGATE 1**

Surname: \_\_\_\_\_ First Name: \_\_\_\_\_

Job Title: \_\_\_\_\_ Email: \_\_\_\_\_

**DELEGATE 2**

Surname: \_\_\_\_\_ First Name: \_\_\_\_\_

Job Title: \_\_\_\_\_ Email: \_\_\_\_\_

### VIRTUAL Introduction to Sterile Manufacturing (2 half-day events on the 21<sup>st</sup> & 22<sup>nd</sup> April 2021)

**Member Fees**

Member Delegate - £200 / €245

**Non-Member Fees**

Non-Member Delegate - £400 / €470

**NHS Member Fees**

Member Delegate - £100

**NHS Non-Member Fees**

Non-Member Delegate - £200

NOTE: \*Euro fee is higher to cover conversion rates

### PAYMENT

Cheque for £\_\_\_\_\_ / €\_\_\_\_\_ euro to cover the fee per delegate(s) enclosed

Total of £\_\_\_\_\_ / €\_\_\_\_\_ euro transferred electronically

Please quote company approved purchase order number \_\_\_\_\_

I wish to pay by credit card (Pharmig will contact you for details)

**Please note:** Due to these unusual times, and the need for Pharmig to ensure fees are received in a timely manner before the event, it will have the right to cancel a delegate's attendance unless alternative arrangements have been agreed in advance of the event(s) by both parties

Email or fax your completed booking form for a provisional confirmed place

Email: [info@pharmig.org.uk](mailto:info@pharmig.org.uk)

Fax: +44 (0) 1920 871 156

### INFORMATION ON FEES & PAYMENTS

- The fees advertised cover 2 half-days on the afternoons of the 21<sup>st</sup> & 22<sup>nd</sup> April 2021.
- Pharmig **cannot reduce this fee** if you can only attend one of the morning sessions.
- **Fees must be paid in advance** in order to attend the virtual conference. This can be done via credit card payment OR by an approved company purchase order number

### INFORMATION ON ZOOM SET UP

Once you have sent back your registration form and payment (please see info of fees and payments above), Pharmig will add you to the Zoom list and will send out an email which will include **TWO SEPARATE ZOOM LINKS** (one for each day) for you to click onto for the 21<sup>st</sup> & 22<sup>nd</sup> April.

For those not familiar with Zoom – we will do a quick tour around the screen (it's all very straightforward) before starting the session on the afternoon of the 21<sup>st</sup> April.