**A Practical Introduction to Sterile Manufacturing**
**October 2022**
**Date & Venue TBC**
**One-Day Meeting**

Designed for those people who are new to industry this interactive 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 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

## Presenter: David Keen – Pharmig Chair & Director, Pharmaceutical Microbiology - Ecolab

### PROGRAMME OUTLINE

08.30 – 09.00 **Registration with tea/coffee**

09.00 – 09.45 **Introduction to sterile manufacturing**

- What does sterile mean?
- Why do we need sterile products?
- Sterile vs aseptic – are they the same?

09.45 – 10.30 **Introduction to microbiology**

- What is microbiology?
- The bacteria, moulds and yeasts, virology, parasites and TSEs

- Controlling and understanding microbial growth

10.30 – 11.00 **Morning break with tea/coffee**

11.00 – 11.45 **Introduction to cleanrooms**

- What is a cleanroom
- Cleanroom grades and controls
- Design and equipment
- Cleanrooms as a contamination control system
- Cleanroom behaviours

11.45 – 12.30 **Methods of sterilisation**

- Moist and dry heat
- Filtration
- Irradiation and e-beam
- Chemical

12.30 – 13.30 **Lunch**

13.30 – 14.15 **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

14.15 – 15.00 **Sterility assurance**

- What is sterility assurance?
- Risk based manufacturing
- Determination of sterility

15.00 – 15.30 **Afternoon break with tea/coffee**

15.00 – 15.45 **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?

15.45 – 16.00 **Closing remarks**

*Please note: all information addressed by the speakers are 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.*

## Your Presenters

## David Keen - Pharmig Chair & Director, Pharmaceutical Microbiology - Ecolab

David is a microbiologist working for Ecolab as a the Director of Pharmaceutical Microbiology for their Lifesciences division. David got his first taste of Pharmig quite a depressing number of years ago. In 2007 he became a committee member of Pharmig. 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 needless 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.

# BOOKING FORM

Please reserve……place(s) for **A Practical Introduction to Sterile Manufacturing**
being held (Venue TBC) Date (TBC in October)

Company: _____

Address: _____

**Contact name if different from the delegate:** _____

Tel: _____ Email: _____

**DELEGATE 1**
**Surname**: _____ First Name: _____

Job Title: _____ Email: _____

Dietary requirements: _____ Please tick to allow Pharmig to contact you ☐

**DELEGATE 2**

**Surname**: _____ First Name: _____

Job Title: _____ Email: _____

Dietary requirements: _____ Please tick to allow Pharmig to contact you ☐

**Email or fax your completed booking form for a provisional confirmed place**
Email: info@pharmig.org.uk Fax: +44 (0) 1920 871 156

**Member Fees ***
**Day Delegate £495/€614**
**NHS RATES £200**
(**Euro fee is higher to cover conversion rates)

**Non Members***
**Day Delegate £695/ €854**
**NHS RATES £300**

***Please Note:*** Fees include attendance to the meeting, an attendance certificate, refreshments and lunch, and links to download presentations in advance of the meeting. Pharmig no longer prints documentation folders.
Fees do not include accommodation which has to be booked directly with the hotel.

## Payment

☐ Cheque for £_____ / €_____euro to cover the fee per delegate(s) enclosed

☐ Cheque for £_____ / €_____euro to follow

☐ Total of £_____/ €_____euro transferred electronically

☐ Please supply invoice

☐ Please quote purchase order number _____

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

**Hotel Information and Accommodation**

TBC