

# Biological Indicators:

How they can go wrong and how to put it right! (Includes case studies)

**TUESDAY 19<sup>TH</sup> OCTOBER 2021**  
**HALF-DAY DAY MEETING (VIA ZOOM)**



## Sessions at a glance include:

- **Control and use of biological indicators**  
Biological indicators are widely used in the pharmaceutical industry to demonstrate the effectiveness of sterilisation, fumigation/vapour disinfection, and depyrogenation processes.
- **Biological Indicators**  
Find out more about different types of BIs and how are they made.
- **Endotoxin indicators for depyrogenation**  
How to do a depyrogenation study.
- **Johanna Hemphälä presents a Case study on the impact of rubber stoppers on biological indicator D-values**  
*Impact of material on spore resistance and survival and the importance of choosing biological indicators with the appropriate properties to correctly challenge your sterilisation process*
- **Dr Tim Sandle presents a Case study on where can autoclaves go wrong & cause biological indicator failures?**

**For more information please contact Pharmig:**

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# BIOLOGICAL INDICATORS:

HOW THEY CAN GO WRONG AND HOW TO PUT IT RIGHT! 19<sup>TH</sup> OCTOBER (HALF DAY MEETING VIA ZOOM) **AGENDA (INCLUDES CASE STUDIES)**

## TUESDAY 19<sup>TH</sup> OCTOBER 2021

13.00 – 13.10

08.00 – 08.10

### Welcome

**Laura Guardi - Associate QA Director, AstraZeneca (& Pharmig Committee Member)**

13.10 – 13.50

08.10 – 08.50

### Control and use of biological indicators

Biological indicators are widely used in the pharmaceutical industry to demonstrate the effectiveness of sterilisation, fumigation/vapour disinfection, and depyrogenation processes. This session discusses the critical attributes of biological indicators that should be understood and appropriately controlled to ensure they are fit for their intended purpose. It will also review current regulatory guidance for the use of biological indicators, as well as practical tips for their storage, use, and culture.

**Laura Guardi - Associate QA Director, AstraZeneca (& Pharmig Committee Member)**

13.50 – 13.55

08.50 – 08.55

### Q&A session and changing over of speaker

13.55 – 14.35

08.55 – 09.35

### Biological Indicators

- Different types of BIs
- How are they made?
- Enzyme indicators
- How good are BIs anyway
- What are rogue BIs?

**David Keen – Director Pharmaceutical Microbiology & Consulting, Ecolab (& Pharmig Committee Chair)**

14.35 – 14.40

09.35 – 09.40

### Q&A session and changing over of speaker

14.40 – 15.20

09.40 – 10.20

### Endotoxin indicators for depyrogenation

- How to do a depyrogenation study
- Dr Tim Sandle – Head of Microbiology, Risk Management, & Sterility Assurance, BPL (& Pharmig Committee Member)**

15.20 – 15.35

10.20 – 10.35

### Q&A session, virtual break and changing over of speaker

## REAL-LIFE CASE STUDIES

15.35 – 16.05

10.35 – 11.05

### Case study: The impact of rubber stoppers on biological indicator D-values

*The presentation will cover: Impact of material on spore resistance and survival and the importance of choosing biological indicators with the appropriate properties to correctly challenge your sterilisation process*

**Johanna Hemphälä – QA Specialist in Microbiology, AstraZeneca**

16.05 – 16.10

11.05 – 11.10

### Q&A session and virtual break changing over of speaker

16.10 – 16.40

11.10 – 11.40

### Case study: Where can autoclaves go wrong & cause biological indicator failures?

**Dr Tim Sandle – Head of Microbiology, Risk Management, & Sterility Assurance, BPL**

16.40 – 17.00

11.40 – 12.00

### Q&A session / summary and close of virtual meeting

*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.*

### KEY RE: TIMES

BLUE – BST (British Summer Time)

GREEN – EST (Eastern Standard Time)

# BIOLOGICAL INDICATORS:

HOW THEY CAN GO WRONG AND HOW TO PUT IT RIGHT! 19<sup>TH</sup> OCTOBER (HALF DAY MEETING VIA ZOOM) **BOOKING FORM**

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

## CONTACT NAME IF DIFFERENT FROM DELEGATE:

Telephone: \_\_\_\_\_ Email: \_\_\_\_\_

### 1<sup>ST</sup> DELEGATE

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

Surname: \_\_\_\_\_

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

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

### 2<sup>ND</sup> DELEGATE

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

Surname: \_\_\_\_\_

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

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

## BIOLOGICAL INDICATORS: HOW THEY CAN GO WRONG & HOW TO PUT RIGHT! TUESDAY 19<sup>TH</sup> OCTOBER 2021

### PHARMIG MEMBER FEES

Member Delegate Euro / Dollar £270/ \*€330 /\*\$395

### NON-MEMBER FEES

Non-Member Delegate Euro / Dollar £470 / \*€561 /\*\$673

### NHS PHARMIG MEMBER FEES

Member Delegate £170

### NHS NON-MEMBER FEES

Non-Member Delegate £270

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

## PAYMENT METHODS (PLEASE TICK RELEVANT OPTION)

Please raise an invoice to cover the delegate fee(s) - £/€ \_\_\_\_\_

UK BACS Sort code 60 19 28 Account 80843867 \_\_\_\_\_

Wire Transfer Natwest Bank, 118 High Street, Slough, Berkshire SL1 1JH \_\_\_\_\_

SWIFT (BIC) NWB KGB2L Account 80843867

IBAN GB64 NWBK 6019 2880 843 867 \_\_\_\_\_

Please quote company approved purchase order no. \_\_\_\_\_ For £/€/€/\$ \_\_\_\_\_

I/we wish to pay by credit card (Pharmig will contact you for details) \_\_\_\_\_

**EMAIL: INFO@PHARMIG.ORG.UK**

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**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.

**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 the Zoom link and additional information.

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 19th October 2021

**PRIVACY POLICY:** By registering for these events, I accept the processing of my Personal Data. Pharmig will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Pharmig will only send information in relation to this order or similar events/publications/training courses etc. Pharmig may send your name and company only to other companies attending the same event in the form of an attendee list. Your full personal data will not be disclosed to third parties (see also privacy policy at <https://www.pharmig.org.uk/en/privacy-policy/>). You can ask for the modification, correction or deletion of my data at any time via an email to [maxine@pharmig.org.uk](mailto:maxine@pharmig.org.uk)

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