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EXCELLENCE IN MICROBIOLOGY

THE VOICE OF MICROBIOLOGY
FOR 30 YEARS: 1991 - 2021

Cleaning & Disinfection:
A roadmap to compliance and how to make sense of it all

WEDNESDAY 20TH & THURSDAY 21ST OCTOBER 2021
2 X HALF-DAY VIRTUAL MEETINGS (VIA ZOOM)

Sessions at a glance include:

- Upcoming regulatory changes and their impact for cleaning & disinfection: EudraLex draft Annex 1 v.12 & USP draft chapter <1072>
- Update on current methods
- Disinfectant Workshop: Factors to consider when designing a disinfectant efficacy test and interpretation of results
- Final phase of disinfectant efficacy – the field trials
- Where can disinfectants go wrong and the consequences: life lessons!
- Implementing a new disinfectant regime: commissioning to first use

Attend and receive the latest updated:
Guide to Disinfectants & their use in the Pharmaceutical Industry 2021

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CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE AND HOW TO MAKE SENSE OF IT ALL

Programme outline running as 2 half-day meetings (via Zoom)

WEDNESDAY 20TH OCTOBER

09.50 – 10.00 **Welcome**
Rachel Kirkham – Director, Global Technical Consulting Contamination Control & Validation, Ecolab

10.00 - 10.40 **Upcoming regulatory changes and their impact for cleaning & disinfection: EudraLex draft Annex 1 v.12 & USP draft chapter <1072>**

- Brief summary of the history of these publications and their revisions to date
- Key changes in the proposed draft regulations relating to cleaning and disinfection, versus current industry practice

Laura Guardi – Associate QA Director, AstraZeneca

10.40 - 10.45 **Q&A session & speaker change-over**

10.45 - 11.25 **Update on current methods**
This presentation will cover key considerations when designing an efficacy study, including the selection of organisms and surface materials, alignment to in-house cleaning practices and pros and cons of the standard test methods available
Kim Morwood – MD, MGS Laboratories

11.25 - 11.40 **Q&A session and virtual break & speaker change-over**

11.40 - 12.20 **Disinfectant Efficacy Workshop:**
Delegates will be provided with a set of data and asked to develop a rationale for a disinfectant regime and interpretation of results
Laura Guardi – Associate QA Director, AstraZeneca & Rachel Kirkham – Director, Global Technical Consulting Contamination Control & Validation, Ecolab

12.20 - 12.30 **Q&A session round up and close of virtual day one**

THURSDAY 21ST OCTOBER

09.50 - 10.00 **Welcome**
Rachel Kirkham – Director, Global Technical Consulting Contamination Control & Validation, Ecolab

10.00 - 10.40 **Final phase of disinfectant efficacy – the field trials**
After completion of the laboratory studies, the final phase of introducing a new disinfectant is the field trial. This remains the only part of disinfectant qualification for which no standard has been written. This session will cover:

- The aims of the field trial
- Designing the study
- Selecting cleanrooms
- Setting acceptance criteria
- Interpreting microbial counts and statistical review
- Assessing recovered microorganisms
- When to repeat the trial
- This session includes case study data

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

10.40 - 10.45 **Q&A session & speaker change-over**

10.45 - 11.45 **Where can disinfectants go wrong and the consequences: life lessons!**
Delegates will be taken through 4 real-life scenarios from presenters who had to deal with them, followed by an open discussion session where you too can share your experiences: Lessons learnt

Lesson 1 - Disinfectant efficacy validation studies

Lesson 2 - Cleaning & disinfection: What happens when no-one is looking?

Lesson 3 - You think your operators are following the SOPs? Think again!

Lesson 4 - See no evil, hear no evil, speak no evil – when everyone collectively fails to see the obvious"

Continued on next page...

CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE AND HOW TO MAKE SENSE OF IT ALL

Programme outline running as 2 half-day meetings (via Zoom)

THURSDAY 21ST OCTOBER

11.45 - 12.00 **Q&A session, virtual break, & speaker change-over**

12.00 - 12.40 **Implementing a new disinfectant regime: commissioning to first use**

Introducing a new cleaning and disinfection regime can be a daunting step, with lots of elements to consider to ensure a compliant implementation. This presentation provides a detailed account taking you through the stages of a new cleaning and disinfection project.

- Planning the project and completing the change control
- Reviewing and approving the supplier
- Selecting the appropriate agents for your facility
- Planning and executing the relevant validation steps
- Introducing quality control measures for the new products
- Designing the rotational regime aligned to the contamination control risks
- The final stage where the cleaning and disinfection stage is implemented, including the additional cleaning steps for start-up of a new facility.

Helen Gates – Global Technical Consultant, Ecolab

12.40 - 13.00 **Q&A session, summary and close of virtual day two**

ADDITIONAL MEETINGS & WEBINARS

Please **click here** for a full list of current meetings and webinars that you, your colleagues may be interested in.

PUBLICATIONS / FACT SHEETS & PHARMIG'S ON-LINE INTERCATIVE TRAINING MODULE

Click here for more detailed information and links.

BOOKING FORM: FOR CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE AND HOW TO MAKE USE OF IT ALL

Click here to go to the registration pages

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.

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BOOKING FORM:

CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE AND HOW TO MAKE SENSE OF IT ALL

2 x half-day virtual meetings: 20TH & 21ST OCTOBER 2021

Attend and receive the latest updated: Guide to Disinfectants & their use in the Pharmaceutical Industry 2021

Company: _____ Address: _____

_____

Contact Name (if different from from the delegate) _____

Tel: _____ Email: _____

DELEGATE ONE

Surname: _____ First Name: _____

Job Title: _____ Email: _____

Fee (£/€/$) : _____

DELEGATE TWO

Surname: _____ First Name: _____

Job Title: _____ Email: _____

Fee (£/€/$) : _____

CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE

20th & 21st OCTOBER 2021 (2 x 1/2-day meetings via Zoom)

Attend and receive the updated: Guide to Disinfectants & their use in the Pharmaceutical Industry

MEMBER FEES	Euro / Dollar
Member Delegate	£450 / *€538/ *$688

**Fee is higher to cover conversion rates*

NON-MEMBER FEES	Euro / Dollar
Non-Member Delegate	£650 / *€768/ *$912

**Fee is higher to cover conversion rates*

NHS MEMBER FEES	
Member Delegate	£250

NHS NON-MEMBER FEES	
Non-Member Delegate	£350

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PAYMENT:

CLEANING & DISINFECTION: A ROADMAP TO COMPLIANCE AND HOW TO MAKE SENSE OF IT ALL

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.*

☐ 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)

INFORMATION ON FEES & PAYMENTS

Where possible 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 the Zoom link and additional information.

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**

CANCELLATION POLICY:

Written cancellation will be accepted up to 5 working days prior to the event, and all cancellations will incur a fee. No refunds are available 2 working days before the start date and full fees will be due for delegates who fail to attend. Substitutions may be made at any time, preferably in writing to Maxine Moorey. Please email: **maxine@pharmig.org.uk**

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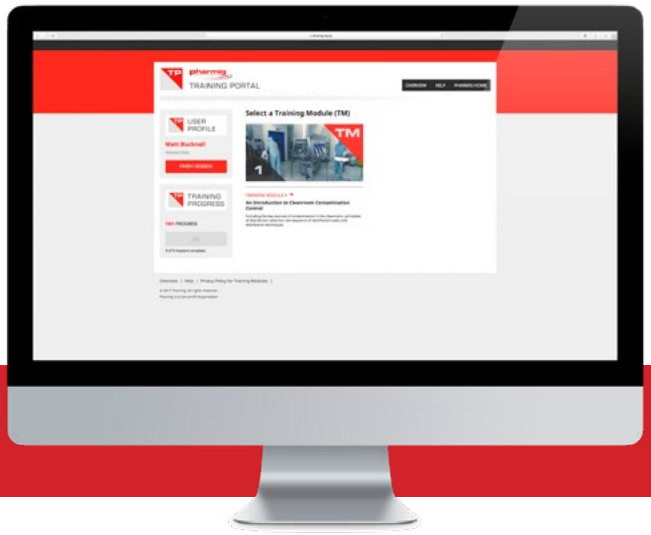
PHARMIG'S INTERACTIVE ON-LINE TRAINING MODULE ON: CLEANING AND DISINFECTION OF CLEANROOMS



DON'T LET COVID STOP YOUR VITAL STAFF TRAINING.

- Ensure your teams stay up-to-date on the crucial aspects of Cleaning and Disinfection of Cleanrooms by using our dynamic, interactive online training portal which will make:
  - **Personnel training easy**
  - **Convenient**
  - **Quantifiable**
- The Pharmig Training Portal (TP) features high quality demonstration footage for the training of cleanroom operatives in the Pharmaceutical, Healthcare, Cosmetics and Medical Device Industries.
- Each training video is followed by detailed multiple choice questions about the subjects covered in the video modules.
- Each user is issued with a personalised certificate upon successful completion of the module.
- The Pharmig Training Portal features full administrator control enabling you to:
  - **Set the required pass mark**
  - **Monitor and manage user activity**
- All of which results in better trained operatives working to best practice

Interested?

Then please do visit the Pharmig website for more information and a video of the on-line Training Portal capabilities **www.pharmig.org.uk.**

If you would like a more detailed 'virtual' demonstration led by a Pharmig Committee Member, please do email Pharmig at **info@pharmig.org.uk** and we will schedule in a time that suits you.

Pharmig Publications

Publication orders can be placed via the website - www.pharmig.org.uk

A series of 8 Major Objectionable Microorganisms Fact Sheets

One of the expectations of GMP regulators is that microbiology laboratories are knowledgeable about the main objectionable microorganisms that could be found in pharmaceutical products or in the manufacturing environment. The identification, characterisation and interpretation of these microorganisms can be challenging. To act as a training aid and information resource, Pharmig has produced eight new fact sheets (Fact Sheet Pack 2). Seven of the fact sheets profile some of the most important objectionable microorganisms (together with Geobacillus stearothermophilus, used for biological indicators). An eighth fact sheet provides useful information about risk assessing objectionable microbes.

Member **£30**
Non Member **£50**

A series of 8 Pharmaceutically Important Fungi Fact Sheets

This set of fact sheets features seven fungi which feature high in causes of fungal contamination of pharmaceutical products and which have led to several major pharmaceutical product recalls. Each fact sheet presents information about the fungus, including growth conditions and product / patient risks. Each sheet details a striking photograph of the fungus macroscopically, growing on suitable agar, and microscopically (as a methylene blue stain.) The eighth fact sheet is a guide on the staining and microscopic examination of fungi, including key features to note to help you with identification. The fact sheets are laminated, making them suitable for the laboratory bench, and come enclosed within a presentation folder.

Member **£30**
Non Member **£50**

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Commonly occurring organisms in your facility – Pharmig's latest series of 8 fact sheets

This series of 8 fact sheets will cover:

- Dermacoccus nishinomiyaensis
- Corynebacterium tuberculostearicum
- Cutibacterium acnes
- Micrococcus luteus
- Kocuria rhizophila
- Staphylococcus hominis
- Paenibacillus glucanolyticus
- Microbacterium liquefaciens

Member **£30** Non Member **£50**

Water Microbiota – Pharmig's series of 8 fact sheets

This series of 8 fact sheets will cover:

- Ralstonia pickettii
- Stenotrophomonas maltophilia
- Burkholderia cepacia complex
- Acinetobacter baumannii
- Brevundimonas diminuta
- Sphingomonas paucimobilis
- Pseudomonas aeruginosa
- General overview of water microorganisms

Member **£30** Non Member **£50**

Guide to Disinfectants & their use in the Pharmaceutical Industry

The objective of this Guide is to review current standards to aid in the selection and validation of disinfectants.

Key topics include:

- Types & selection of disinfectants
- Validation of disinfectants detailing the BSEN current test methods
- Practical use of disinfectants

Member **£60** Non Member **£85**

A series of 8 Microorganisms Fact Sheets

The microbial enumeration test and test for specified microorganisms can represent a challenging area for pharmaceutical microbiology. To act as a training aid for new staff, and an aide memoire for more experienced staff - Pharmig has produced eight fact sheets. Seven of the fact sheets profile each one of the key microorganisms (or microbial groups), using colour photographs illustrating growth on agar and by Gram-stain. These are supported by facts relating to the organism's profile and methods for identification. The eighth sheet offers some useful guidance about the interpretation of the test.

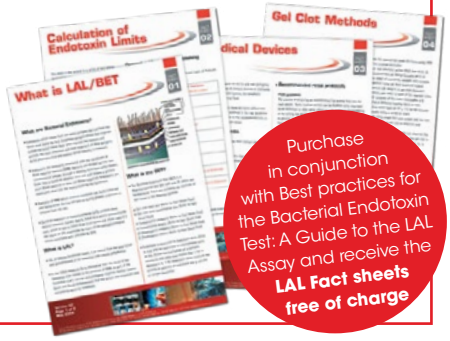
Member **£30**
Non Member **£50**

LAL Fact Sheets

A series of Limulus Amoebocyte Lysate (LAL) laminated Fact Sheets on pyrogen/endotoxin testing have been produced by the LAL Action Group.
The series of 6 LAL fact sheets (as a package) currently available are:

- What is LAL/BET?
- Calculation of Endotoxon Limits
- Medical Devices
- Gel Clot Methods
- Photometric Methods
- Product Validations Quantitative Methods

Member **£20**
Non Member **£35**



Purchase in conjunction with Best practices for the Bacterial Endotoxin Test: A Guide to the LAL Assay and receive the **LAL Fact sheets free of charge**

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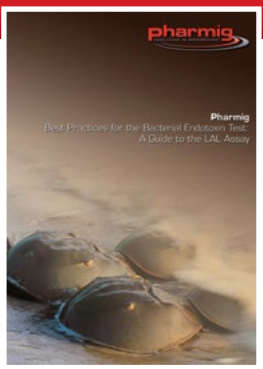
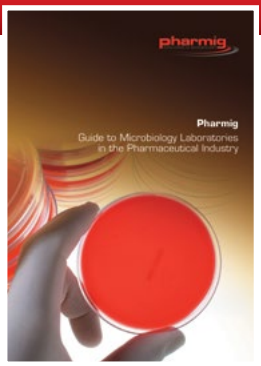
Best practices for the Bacterial Endotoxin Test: A Guide to the LAL Assay



This guide to the Bacterial Endotoxin Test (BET) provides the reader with an overview of the history, regulation and practical use of the different BET assays. Information on method development, validation and routine testing are discussed as well as more advanced subjects such as depyrogenation, medical devices, trouble shooting and problem samples. The guide should provide a useful reference document for LAL users and laboratory management.

Member **£50** Non Member **£75**

Guide to Microbiology Laboratories in the Pharmaceutical Industry



This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

The Guide describes considerations to be applied to the design, set up and running of the microbiology unit. Topics range from:

- Test methods
- Environmental monitoring
- Documentation
- Method verification and validation

Member **£60** Non Member **£85**

Current perspectives on Environmental Monitoring - Review # 1

This review surveys some of the current practices, trends and approaches to environmental monitoring.

Technical articles include:

- Constructing an environmental monitoring programme
- Particle monitoring & control
- Environmental monitoring & risk assessment
- Microbiological risk assessment case study

Member **£60** Non Member **£85**

Rapid & Alternative Microbiological Methods

Rapid Microbiological Method technologies aim to provide more sensitive, accurate, precise and reproducible test results when compared with conventional, growth-based methods. They normally involve some form of automation and they often capture data electronically.

Microbiologists can be inundated with literature advertising equipment and courses relating to 'Rapid Microbiological Methods' and 'Alternative Microbiological Methods'.

Often, however, the literature does not explain whether the method will work for the company's product range, whether it is cost effective, how it should be validated, how any changes to microbiological risk are managed and if the purchase can be justified.

Whilst costs cannot be discussed, this document has been prepared:

- to describe the range of well developed, established, commercially available methods and their suitability for evaluating the microbiological quality of products or raw materials;
- to provide some guidance for microbiologists who are investigating the use of R/AMM in routine quality control of cosmetics personal care products and pharmaceuticals.

This publication is produced and sold as a PDF document only and is for the sole use of the individual purchasing it.

Member **£20**
Non Member **£35**

Guide to Cleanroom Operation and Contamination Control

This publication provides a short and informative introductory guide to cleanrooms. Cleanrooms provide controlled, critical environments for both sterile and non-sterile pharmaceutical manufacturing.

The guide examines:

- Cleanrooms
- Different grades of cleanrooms
- The important aspects of physical control
- Contamination control and environmental monitoring
- Important cleanroom parameters required by the regulatory standards

Member **£60**
Non Member **£85**

Guide to Bacterial Identification

Microbial identification represents an important part of the microbiology function. This includes screening products for objectionable organisms, profiling the environmental microbiota, and investigating out-of-limits events with a view to assigning a probable point of origin. In deciding what and when (and subsequently to what level) to identify, and by the way of which methods, requires an identification strategy. This is a document each microbiology laboratory should develop.

During a Pharmig presentation on microbial identification strategy and a Q&A session that followed there was a variation in approach, and sometimes a lack of clarity, concerning good identification practices and in outlining a strategy of what to identify and when. To provide guidance for members and other microbiologists, in the way of a training aid, and to provide the basis for microbiology laboratories to benchmark against, this guide was put together.

The foreword has kindly been written by Andrew Hopkins – MHRA

Chapters within the Guide include:

- Cleanrooms
- Different grades of cleanrooms
- The important aspects of physical control
- Contamination control and environmental monitoring
- Important cleanroom parameters required by the regulatory standards

Member **£60**
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