pharmig
EXCELLENCE IN MICROBIOLOGY

Researched with contacts in the Adriatic Region

BUT – the topics could be relevant to you too.

This virtual meeting does not replace our **28th Annual Virtual Conference 2nd & 3rd December 2020.**

This agenda can be viewed at **www.pharmig.org.uk**

Hot Topics & Best Practices in Pharmaceutical Production and Microbiology for the Adriatic Region

Supported by:

Sanol H **Sanol S** **Sanolabor**

Dates:

Wednesday 21st October & Thursday 22nd October 2020

Two half-day virtual meetings (via Zoom)

For more information please contact Pharmig:
T: + 44 (0) 1920 871 999 **F:** +44 (0) 1920 871 156
E: info@pharmig.org.uk **W:** www.pharmig.org.uk

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EXCELLENCE IN MICROBIOLOGY

Conference Programme

KEY RE: TIMES

BLUE – GMT (Greenwich Mean Time)
GREEN – CET (Central Eastern Time)

Wednesday 21st October 2020

09.20 –09.30
10.20 –10.30 **Chairman's welcome and introduction**
David Keen - Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

09.30 – 10.10
10.30 – 11.10 **Latest 2020 changes to the draft Annex 1 and the impact on cleaning and disinfection**

- History of the Annex 1 change and why updated
- Changes to guidance on
  - Cleaning
  - Disinfection
  - In house preparation
  - Residues
  - Validation
  - Rotation
  - ransfer disinfection
- Best Practice Recommendations to remain compliant to the new draft Annex 1

Matthew Cokely – Global Technical Consultant, Ecolab

5 minutes for questions and speaker change over

10.15 – 10.55
11.15 – 11.55 **Impact of novel coronavirus SARS-CoV-2 in cleanroom operations**

- Looking at the threat – what is SARS-CoV-2?
- Understanding the threat – how the virus is transmitted
- Considering viral transmission risk in relation to:
  - Cleanroom changing practices
  - Disinfection practices
  - Social distancing
  - PPE
  - Cleanroom design
  - Measures to strengthen cleanroom operations

Dr. Tim Sandle - Head of Microbiology & Sterility Assurance, BPL & Pharmig Committee

5 minutes for questions and speaker change over

11.00 - 11.10
12.00 –12.10 **Update on Pharmig's current publications & on-line training modules**
Pharmig Committee Member

11.10 – 11.25
12.10 – 12.25 **Virtual break**

11.25 – 12.05
12.25 – 13.05 **Challenges in performing in disinfectant efficacy validation studies and the potential for harmonisation**

- Differences between disinfectant efficacy test methods
- Differences between registration testing and pharmaceutical companies testing
- Method development for a harmonised method
- Test parameters selected
- Surfaces and organism selection
- Matrix approach to validation
- Further development for a harmonized wipe method

Matthew Cokely – Global Technical Consultant, Ecolab

5 minutes for questions and speaker change over

12.10 – 12.50
13.10 – 13.50 **Biofilms in water systems**

- What are the risks?
- How do you control it?
- How do you remove it?
- Microbiology testing?
- Can you measure it?
- What is the impact?
- Prevention is better than cure

David Keen - Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

13.50 – 14.00
14.50 – 15.00 **General Q&A session with the speakers and closing remarks on day 1**
David Keen, Matthew Cokely, Tim Sandle

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Thursday 22nd October 2020

KEY RE: TIMES

BLUE – GMT (Greenwich Mean Time)
GREEN – CET (Central Eastern Time)

09.20 – 09.30
10.20 –10.30 **Chairman's welcome and introduction**
David Keen - Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

09.30 – 10.10
10.30 – 11.10 **Microbiological culture media: use and application in healthcare and pharmaceuticals**

- The main outcomes from the Pharmig culture media survey
- What types of media are used and why?
- How is media tested?
- Are companies using environmental isolates?
- How should media be incubated?
- How should we control our suppliers?

Dr. Tim Sandle - Head of Microbiology & Sterility Assurance, BPL & Pharmig Committee

5 minutes for questions and speaker change over

10.15 – 10.55
11.15 – 11.55 **Aseptic manufacturing: the open flaw in using humans in your critical operations**

- Human behaviours and error
- Nudge theory
- Using a little bit of knowledge to help humans behave

David Keen - Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

5 minutes for questions and speaker change over

11.00– 11.40
12.00 – 12.40 **The Challenges of Fungal and Bacterial Spores for Cleanrooms**

- What is the concern with spores?
- Differentiation between Fungal spores and Bacterial spores
- Spores in your operations
- Influences on resistance
- Decontamination

Matthew Cokely – Global Technical Consultant, Ecolab

11.40 – 12.00
12.40 – 13.00 **General Q&A session with the speakers and closing remarks on day 2**
David Keen, Matthew Cokely, Tim Sandle

Please note: all information addressed by the speakers are of their own / company opinions. 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.

About Pharmig

Pharmig is a non-profit making professional organisation, established in 1991, that represents the interests of individuals who work in, have responsibility for, or work alongside microbiology within pharmaceutical, healthcare, cosmetics & NHS Industries. It provides a focus for continuing professional development and serves as a unique network for the exchange of microbiological information through training courses, conferences, publications and its website forum. The Group has grown significantly since 1991 expanding the portfolio of products it now offers to the Membership whilst remaining true to the initial needs of microbiologists which include:

- Organising meetings, training courses, conferences and producing publications that provide topical information and views on microbiologically related topics
- Advancing the science of microbiology and its practical application
- Influencing the development of regulations and guidelines surrounding microbiology
- Acting as a confidential forum for the dissemination of information concerning all aspects of microbiology

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FEES TO ATTEND AS A VIRTUAL DELEGATE OUTSIDE OF THE ADRIATIC REGION:

(which covers 2 half-day events on the 21st & 22nd October 2020)

Member Fees
Member Delegate - £300 / €357

Non-Member Fees
Non-Member Delegate - £500 / €565

NHS Member Fees
Member Delegate - £150

NHS Non-Member Fees
Non-Member Delegate - £250

NOTE: *Euro fee is higher to cover conversion rates

INFORMATION ON ZOOM SET UP:

- **Once you have sent back your registration form Pharmig will add you to the Zoom list for the meeting.**
- **An email will be sent out a few days before the meeting date(s) outlining the Zoom link information for both Wednesday 21st October and Thursday 22nd October morning sessions.**
- **For those not familiar with Zoom – we will do a quick tour around the screen (it's all very straightforward) during the welcome speech.**
- **Please do check with your IT department in advance of the meeting that you have access to Zoom.**
- **You will not need to download the Zoom system – you just need to have access to click to join.**

QUESTIONS:

If you have any questions or require further information please email Pharmig at info@pharmig.org.uk

THANK YOU:

Pharmig would like to thank Sanolabor and Sanol H once again for their continued help and support in organising the 2020 meeting

Sanol H Sanol S Sanolabor

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BOOKING FORM: HOT TOPICS & BEST PRACTICES IN PHARMACEUTICAL PRODUCTION AND MICROBIOLOGY FOR THE ADRIATIC REGION VIRTUAL MEETING

Company: _____ Address: _____

_____

Contact Name (If different from those attending) _____

Email: _____ Tel: _____

DELEGATE ONE

Name: _____

Surname: _____

Job Title: _____

Email:* _____

DELEGATE TWO

Name: _____

Surname: _____

Job Title: _____

Email:* _____

* please provide an email address

Privacy Policy: *By registering for this event, 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 me information in relation to this order or similar events/publications/training courses etc. My personal data will not be disclosed to third parties (see also privacy policy at https://www.pharmig.org.uk/en/privacy-policy/). I note that I can ask for the modification, correction or deletion of my data at any time via an email to maxine@pharmig.org.uk*

METHODS OF PAYMENT

*** Email / Fax booking forms to info@pharmig.org.uk / +44 (0) 1920 871 156 for a provisional place**

Please tick relevant option

☐ **Cheque for £ _____ to follow in post. To cover the delegate fee(s)**

☐ **Please raise an invoice. To cover the delegate fee(s) - £ _____**

☐ **Please quote Purchase Order Number To cover the delegate fee(s) _____**

☐ **I wish to pay by credit card - Pharmig will contact you for details. To cover the delegate fee(s)**

Please Note: *Fees must be settled in advance of the meetings(s) in order to gain attendance*

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) being held by both parties.*

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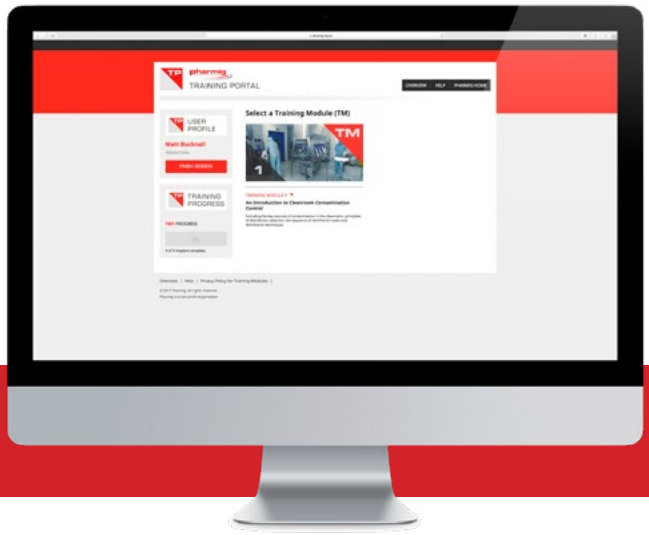
PHARMIG'S INTERACTIVE ON-LINE TRAINING MODULE ON: CLEANING AND DISINFECTION OF CLEANROOMS



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.

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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Water Microbiota – Pharmig's latest series of 8 fact sheets

This series of 8 fact sheets will cover:

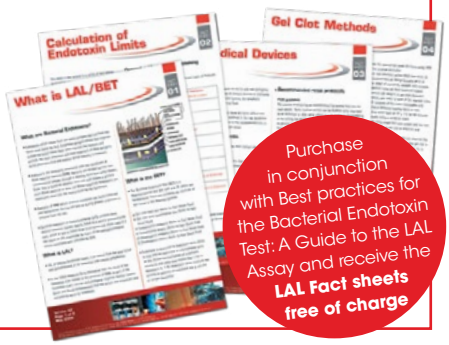
- Ralstonia pickettii
- Stenotrophomonas maltophilia
- Burkholderia cepacia complex
- Acinetobacter baumannii
- Brevundimonas diminuta
- Sphingomonas paucimobilis
- Pseudomonas aeruginosa
- General overview of water microorganisms

Member **£30** Non Member **£50**

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**

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**

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**

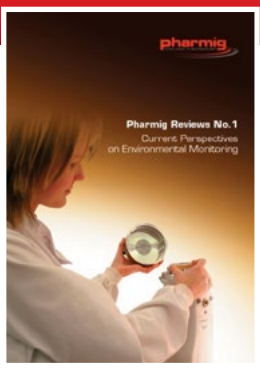
Current perspectives on Environmental Monitoring - Review # 1

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

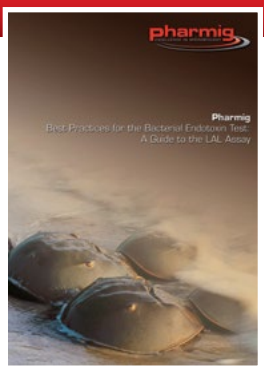
Member **£60** Non Member **£85**



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**



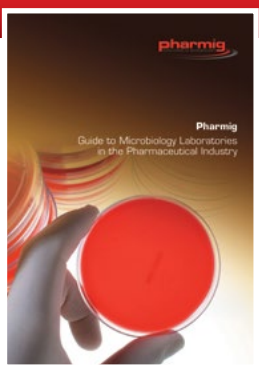
Guide to Microbiology Laboratories in the Pharmaceutical Industry

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**



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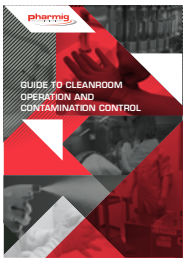
Guide to Cleanroom Operation and Contamination Control

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



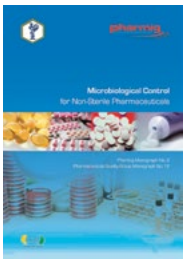
The guide examines:

- 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**

Microbiological Control for Non-Sterile Pharmaceuticals

This publication is relevant to pharmaceuticals/cosmetics & toiletry industries and aims to provide guidance around GMP.



Topics include:

- Facility, design and requirements
- Micro control
- Cleaning & disinfection
- Risk assessment & management
- Microbiological monitoring

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 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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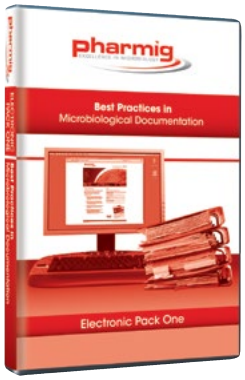
Best Practices in Microbiological Documentation - Electronic Pack One

This CD provides an overview of the most efficient practices in maintenance of the QC aspect of the microbiology laboratory and its associated documentation with reference to current regulatory expectations.



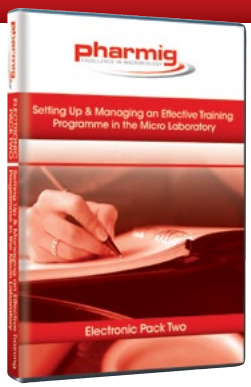
Topics range from:

- General documentation
- Equipment documentation
- Laboratory test documentation
- Electronic documentation management systems
- Non conformance documentation
- Example documents are also included to assist companies in improving their documentation practices.

Member **£75** Non Member **£99**

Setting up & Managing an Effective Training Programme in the Micro Laboratory – Electronic Pack Two

This training pack aims to help you gain a clear understanding of the structure of a regulatory acceptable and compliant training programme and includes example documents to assist companies in improving / aiding their current training programmes.



Topics range from:

- Employee development & appraisal
- GMP introduction
- Training in microbiological techniques & non conformances
- Train the trainer
- Training matrix

Member **£75** Non Member **£99**

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