29TH ANNUAL EVENT

pharmig

EXCELLENCE IN MICROBIOLOGY

Latest Updates & Hot Topics in Pharmaceutical Microbiology




EARLY BIRD DISCOUNT

Virtually sending 2 or more delegates from the same site? **Book by Friday 22ND October and** additional delegates receive a 20% discount on listed prices. 1ST attendee pays full fee*

Virtually attend and presenters will address:

- **Annex 1 latest updates, GMP findings and regulatory expectations**
- **Microbiological recalls – an overview**
- **EN17141 - What to make of the new Biocontamination Control Standard?**
- **Virucidal efficacy testing – 'Pushing the envelope'**
- **Megalab experience – testing for SARS-CoV-2 RNA: Update**
- **What do I need to know to control *Burkholderia cepacia*?**
- **Continuous microbial quality monitoring of pharmaceutical water systems**
- **The use of enzymatic indicators in conjunction with biological indicators for validating a sterile fill isolator**
- **Transformational technologies: Artificial intelligence for quality control in practice**

PLUS FREE ATTENDANCE*

To the virtual sponsored technical 2 half-day meetings on the 16TH & 19TH Nov (or you can nominate a colleague to attend in your place)

*This offer only applies if you have booked as a delegate on to the virtual conference (17TH & 18TH November)

2 HALF-DAY MEETINGS (VIA ZOOM) - 17TH & 18TH NOVEMBER 2021

LATEST UPDATES & HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY WEDNESDAY 17TH NOVEMBER 2021

13.00 – 13.10
08.00 – 08.10

Chair's welcome and introduction
David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

13.10 – 13.50
08.10 – 08.50

Annex 1 latest updates, GMP findings and regulatory expectations
Alan Moon – Senior GMDP Inspector, MHRA

13.50 – 13.55
08.50 – 08.55

Q&A session and changing over of speaker

13.55 – 14.35
08.55 – 09.35

Microbiological recalls – an overview.
This session will look at recent recalls across the pharmaceutical and healthcare industries, highlighting key trends and the impact such incidents have.

Intro

- Definition of a recall
- Factors leading to a recall
- Impact of a recall
- Prevention is key

Microbial contamination recalls

- Review of up to last 5 years of data – sterile, non-sterile products focusing on drugs and cosmetics
- Common reasons for such recalls and why, how could they be prevented
  - Significant recalls in history

Anna Lovatt – Consumer Healthcare Microbiology Manager, GlaxoSmithKline & Pharmig Committee Member

14.35 – 14.40
09.35 - 09.40

Q&A session and changing over of speaker

14.40– 15.20
09.40 – 10.20

EN17141 - What to make of the new Biocontamination Control Standard?
In 2020 a new contamination control standard has been issued, specifically focusing on biocontamination control, titled EN 17141: 2020 "Cleanrooms and associatedcontrolled environments — Biocontamination control". Does this standard address the needs of the industry? This does not seem to be the case. While the standard covers a number of important areas, there are stand-out gaps and some inaccuracies to be addressed. Tim Sandle looks at these in the context of what is needed for a robust biocontamination control program.
The presentation will cover:

- What is the EN 17141:2020 standard? Where did come from and what does it cover?
- What is biocontamination and control?
- The standard's risk-based approach to contamination
- Considerations in developing a contamination control program
- Sample locations and sample frequencies
- Methods and their application
- Limit setting, trending and data distribution
- Microbiota
- Overall assessment of the standard and the gaps to be filled

Dr Tim Sandle – Head of Risk Compliance & Risk Management, BPL & Pharmig Committee Member

15.20 – 15.35
10.20 – 10.35

Q&A session and changing over of speaker

15.35 – 16.05
10.35 – 11.05

Virucidal efficacy testing – 'Pushing the envelope'
More and more facilities are working in vaccine production and research, this session will look in more detail at viruses, the disinfectant efficacy testing available to claim virucidal efficacy, and the additional work that would need to be carried out by the end user.

- Classification of viruses
- How to approach a virucidal disinfection study.
  - Requirements for a disinfectant supplier to claim virucidal activity
  - What the regulators are looking for?
  - Additional work required by an end user?

Neil Simpson – Technical / R&D Manager, Contec

16.05 – 16.10
11.05 – 11.10

Q&A session and changing over of speaker

16.10 – 16.40
11.10 – 11.40

Lighthouse Lab experience – testing for SARS-CoV-2 RNA: Update
Dr M Sudhanva MBBS, MD (Microbiology), FRCPath (Virology)Kings College Hospital NHS, Foundation Trust, Lead Clinical Advisor for COVID mass, testing Lighthouse Labs and local, advisor for Milton Keynes & Consultant Virologist, South London Specialist Virology Centre & Clinical Director of Pathology for the Viapath laboratories at King's College Hospital | Viapath & Chair of Panel of Examiners in Virology, Royal College of Pathologists

16.40 – 17.00
11.40 – 12.00

Q&A session / summary and close of Pharmig's virtual conference day 1

LATEST UPDATES & HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY THURSDAY 18TH NOVEMBER 2021

Click here to see Pharmig's latest Fact Sheets & Publications that maybe of interest to you.

13.00 – 13.10
08.00 – 08.10 **Chair's welcome**
David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chair

13.10 – 13.50
08.10 – 08.50 **What do I need to know to control *Burkholderia cepacia?***
- Is this a risk assessment opportunity?
- Clarification of pharmacopeial terms relating to microbial species of concern
- What is the concern for presence of B. cepacia, clinical or GMP?
- When should I use the method of USP <60>?
- How can I use USP <1115> appropriately?

Donald. C. Singer – Chair, USP General Chapters - Microbiology Expert Committee (USA)

13.50 – 13.55
08.50 – 08.55 **Q&A session and changing over of speaker**

13.55 – 14.35
08.55 – 09.35 **Continuous microbial quality monitoring of pharmaceutical water systems**
- Considerations of the differences between bioburden testing and continuous microbial quality monitoring
- Application of data from continuous monitoring, interpreting events and responding to results
- Using data to enable energy and water savings, as well as increasing efficiencies in the microbiology laboratories

Benjamin Pickard – Associate Scientist, New Modalities & Parenteral Development, Pharmaceutical Technology & Development, Operations, AstraZeneca, Macclesfield UK and Pharmig Apprentice of the year winner – 2021

14.35 – 14.40
09.35 - 09.40 **Q&A session and changing over of speaker**

14.40– 15.20
09.40 – 10.20 **The use of enzymatic indicators in conjunction with biological indicators for validating a sterile fill isolator**
- Introduction to the project
- Rationale for validating an isolator's VHP cycle with Enzymatic Indicators (EIs) and Biological Indicators (BIs)
- Practical considerations
- Advantages and disadvantages
- What can EIs tell you about your cycles

Vicky Stoyel – Senior QA Officer & Veronica Puga Garcia – Validation Manager, Oxford Biomedica

15.20 – 15.35
10.20 – 10.35 **Q&A session, virtual break and changing over of speaker**

15.35 – 16.05
10.35 – 11.05 **Implementing a rapid sterility method: success story and detailed validation strategy**
Rapid microbial methods have been discussed (frequently) and implemented (much less frequently!) for many years; one reason being that there remain challenges (technical/regulatory/company culture) to implementing them. Sharing is important to support wider adoption in the industry. This success story will cover how we identified the opportunity, how we set up our validation strategy, and the detailed acceptance criteria and statistics. We will share lessons learned, including health authority approval and feedback and hope that they will inspire you too, to take on bold rapid micro projects

Joanny Salvas – Senior Manager, Pfizer

16.05 – 16.10
11.05 – 11.10 **Q&A session and changing over of speaker**

16.10 – 16.30
11.10 – 11.30 **Transformational technologies: Artificial intelligence for quality control in practice**
- Digital imaging
- Computer vision and artificial intelligence
- CFU characterization and counting
- Particle / glass detection in syringes and vials

Louis Ryan – R&D Director, Ash Technologies Ltd

16.30 - 16.50
11.30 - 11.50 **Microbiology labs of tomorrow: what could the future look like in practice**
- Applying new technology to routine activities
- Harnessing the data rich world of tomorrow
- Data connectivity and holistic approaches to data interpretation

Miriam Guest - Associate Principal Microbiologist, New Modalities & Parenteral Development, Pharmaceutical Technology & Development, Operations, AstraZeneca, Macclesfield UK

16.50 - 17.00
11.50 - 12.00 **Q&A session / summary and close of Pharmig's virtual conference day 2**

KEY RE: TIMES
BLUE – GMT (Greenwich Mean Time)
GREEN – EST (Eastern Standard Time)

SPONSORED TECHNICAL VIRTUAL EVENTS

16TH & 19TH NOVEMBER - 2 HALF-DAY MEETINGS (VIA ZOOM)

FREE TO ATTEND if you have booked onto the 29TH Annual Virtual Conference as a delegate
These sessions run for 45mins with 10mins built in for Q&A

TUESDAY 16TH NOVEMBER AGENDA

12.00 – 12.10
07.00 – 07.10 **Welcome from Pharmig Committee Member**

12.10 – 13.05
07.10 – 08.05 **The QC lab of the future**

Lonza Pharma & Biotech

- Planning your roadmap - Identifying at risk process steps
  - Sampling – schedule, consumables, personnel
  - Testing – multiple SOPs/methods/suppliers
  - Reporting/auditing – easy access/unified
  - System Maintenance – predictive
  - Data collection/analytics/trending – timely/relevant
- Business drivers
  - Efficiency/Error-proofing
  - Future-proofing/sustainability/3R's
  - Reduction in animal use
  - Faster time to results
  - Operator safety/Reduction in RSI
  - Effective use of resources/removal of non-value-added steps
- Key stakeholders and their requirements, are they aligned with your plan?
  - QC analysts/manager
  - QA/Reg Affairs
  - IT
  - Validation/MSAT
  - Procurement/Purchasing
  - HR/Training
- Technologies
  - Digitalisation/integrated systems/predictive analytics
  - Sustainable testing methods/3R's
  - Automation
  - Rapid testing methods

Ruth Noe - Senior Product Manager & Sinead Cowman - Global Business Development & Marketing Manager, Lonza

13.05 – 13.10
08.05 – 08.10 **Virtual speaker change over and introduction**

13.10 – 14.05
08.10 – 09.05

SARTORIUS

Intervention-free continuous microbial air monitoring

The manufacturing of sterile pharmaceuticals, especially biologics, must be performed under strictly controlled conditions. Environmental monitoring programmes are therefore important in assessing the effectiveness of implemented contamination control strategies. The EU GMP Annex 1 revision on the manufacture of sterile medicinal products specifies that in Grade A areas, any growth detected in one cubic metre of sampled air should result in an investigation. It is therefore recommended that any risk caused by interventions of the monitoring operations be avoided. Most environmental monitoring programs are not restricted to the collection of only one cubic meter of air but rather involves the monitoring of the entire duration of the manufacturing shift. This can prove challenging for traditional monitoring methods that require regular replacement of agar plates, in order to avoid dehydration and a loss of microbial recovery.
In this study, we determined if long-term air filtration compromised the efficacy of gelatine membrane filters and if microbial recovery was adversely affected following long-term sampling. We found that there was no loss of microbial recovery following 8 hours of continuous sampling using gelatine membrane filters. Our study is also important since the new European standard for biocontamination control, the EN 17141, recommends that a membrane filtration method, be used to qualify the biological efficiency of air samplers. Our findings show that gelatine membrane filters, manufactured by Sartorius AG, are fully qualified for continuous, intervention-free active air monitoring for the tested period of 8 hours - the period of a typical manufacturing shift.

Eric Arakel - Global Product Manager, Sartorious

SPONSORED TECHNICAL VIRTUAL EVENTS

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TUESDAY 16TH NOVEMBER AGENDA cont...

14.05 – 14.10
09.05 – 09.10 **Virtual speaker change over and introduction**

14.10 – 15.05
09.10 – 10.05 **Next generation sequencing for strain-to-strain comparison and differentiation**

Strain to strain comparison can be valuable when tracing the source of objectionable organisms
A survey we carried out at a recent Pharmig conference highlighted that while most of the people we spoke to valued the ability to undertake this analysis, they did not have a good understanding of the methods available. Methods available include multilocus sequence typing and whole genome sequencing
This presentation will introduce and compare these two approaches and the different data they provide
It will also give an overview of recent advances in sequencing technology that make whole genome sequencing a more economical and practical approach to strain-to-strain comparison than it was in the past.
Vikki Warren – Identification Services Manager NCIMB

15.05 – 15.20
10.05 – 10.20 **15-minute break with virtual speaker change over and introduction**

15.20 – 16.15
10.20 – 11.15 **Proposed methods to meet Annex 1 requirements for continuous viable monitoring throughout an entire production run**

How will you prove zero cfu counts during a production run are not due to inadequate methods or media?
Continuous Active Air Sampling for 4 hours on a single 9cm TSA plate.
Real Time Microbial Monitoring (BioTrak)
John Cobb – Microbiologist, PMT

16.15 – 16.20
11.15 – 11.20 **Virtual speaker change over and introduction**

16.20 – 17.15
11.20 – 12.15 **Endotoxin testing: The recombinant landscape**

The session will provide an overview of the different technologies available; the regulatory positions plus, a review of contemporary data. Finally, the session will provide delegates with an overview of how to validate these methods
Veronika Wills – Manager Technical Services, Associates of Cape Cod, Inc

17.15 – 17.20
12.15 – 12.20 **Summary and closing remarks**

KEY RE: TIMES
BLUE – GMT (Greenwich Mean Time)
GREEN – EST (Eastern Standard Time)

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.

SPONSORED TECHNICAL VIRTUAL EVENTS

16TH & 19TH NOVEMBER - 2 HALF-DAY MEETINGS (VIA ZOOM)

FREE TO ATTEND if you have booked onto the 29TH Annual Virtual Conference as a delegate
These sessions run for 45mins with 10mins built in for Q&A

FRIDAY 19TH NOVEMBER AGENDA

12.00 – 12.10
07.00 – 07.10 **Welcome from Pharmig Committee Member**

12.10 – 13.05
07.10 – 08.05

1 hour testing for mycoplasma contamination in bioproduction samples using the BIOFIRE® FILMARRAY® 2.0 Industry system

The BIOFIRE® FILMARRAY® 2.0 Industry system provides 1 hour detection of mycoplasma contamination with less than 2 minutes of hands-on time. Internal validation data indicate suitable specificity and limit of detection to be used as both an in-process control and release test. Evaluations performed by bioproduction manufacturers confirm suitability of the BIOFIRE FILMARRAY 2.0 Industry system in the presence of high-density monoclonal antibody producing Chinese hamster ovary (CHO) cells as a rapid mycoplasma test for in-process control or release at harvest.

Felix Montero Julian, Ph.D., Scientific Director, bioMerieux

13.05 – 13.10
08.05 – 08.10 **Virtual speaker change over and introduction**

13.10 – 14.05
08.10 – 09.05

Considering cleaning and disinfection in our contamination control strategies

The Contamination Control Strategy (CCS) has become a fundamental for the pharmaceutical industry, driven by its broad inclusion in the revised Annex 1 of the EU GMP guidelines. The CCS it is a cyclical process designed to prompt manufacturers to identify, evaluate and control the risk of contamination to the quality of their product and ultimately protect the end user and is a critical tool for proactive risk management covering all aspects of the manufacturing process. Here we will focus on facility management and how the CCS is used to determine the contamination risks which can be mitigated with a comprehensive validated cleaning and disinfection program. The presentation will consider identification of the facility risk factors, the mitigation steps, the monitoring processes to determine control, and the feedback into the living CCS document.

Helen Gates – Global Technical Consultant, Ecolab

14.05 – 14.10
09.05 – 09.10 **Virtual speaker change over and introduction**

14.10 – 15.05
09.10 – 10.05

The cleaning of cleanrooms

The cleaning of cleanrooms has always been important, but will now get even more attention with the Introduction of the new Annex 1. In our presentation, we will emphasize the impact of the new Annex 1 on cleaning, discuss challenges, share cleaning techniques and best practises and discuss the benefits of good planning and documentation.

Arthur Lettinga – Product Manager Western Europe, Elis

15.05 – 15.20
10.05 – 10.20 **15-minute break with virtual speaker change over and introduction**

15.20 – 16.15
10.20 – 11.15

Annex 1: 7 key areas impacting the future of environmental monitoring in pharmaceuticals

Key interest areas and changes within annex 1 and their possible impact for EM programs: physical efficiency, sample size, sampling proximity, identification, biological efficiency, event investigation and use of settle plates

Gethin Jones, Pinpoint Scientific & TBC, Cherwell Laboratories

16.15 – 16.20
11.15 – 11.20 **Virtual speaker change over and introduction**

16.20 – 17.15
11.20 – 12.15

Biofilm remediation strategies

Biofilm remains a substantial challenge in maintaining clean processes within GMP regulated industries. It is often difficult to determine the best approach to address the situation given the myriad of key factors that can influence what products to test and conditions to evaluate

Paul Lopolito – Technical Services Manager, Steris Corporation

17.15 – 17.20
12.15 – 12.20 **Summary and closing remarks**

PHARMIG 29TH ANNUAL CONFERENCE

17TH & 18TH NOVEMBER 2021 VIRTUAL CONFERENCE INFORMATION

INFORMATION ON FEES & PAYMENTS

- The fees advertised cover 2 half-days on the 17TH & 18TH November (with FREE attendance to the sponsored meetings on the 16TH & 19TH November)
- And the 2 half-day sponsored technical meeting fees if you are only attending those dates (16TH & 19TH)
- Pharmig **cannot reduce these fees** if you can only attend one of the afternoon sessions at either the virtual conference event or the technical sponsored meeting events.
- **Fees must be paid in advance** in order to attend these virtual events. This can be done via credit card payment OR by an approved company purchase order number OR payment can be extended via prior agreement with Pharmig – please email **maxine@pharmig.org.uk.**

CONFERENCE FEES VIRTUAL 29TH ANNUAL CONFERENCE FEES

This covers the 2 half-day conference on the 17TH / 18TH November 2021 & FREE attendance to the virtual sponsored meetings on the 16TH / 19TH November.
OR you can nominate a colleague to take your place to attend the sponsored meetings.
See booking form for more info.

PHARMIG MEMBER FEES
Delegate **£400 / €490**
*Euro fee is higher to cover conversion rates

NON MEMBER FEES
Delegate **£550 / €665**
*Euro fee is higher to cover conversion rates

NHS PHARMIG MEMBER FEES
Delegate **£200**

NHS NON MEMBER FEES
Delegate **£300**

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

SPONSORED TECHNICAL MEETINGS (16TH & 19TH NOVEMBER) FEES IF ATTENDING THESE EVENTS ONLY

(FREE to those attending the conference)

PHARMIG MEMBER FEES
Industry/Commercial **£150 / €193**
NHS **£50**
*Euro fee is higher to cover conversion rates

NON MEMBER FEES
Industry/Commercial **£250 / €310**
NHS **£80**
*Euro fee is higher to cover conversion rates

VIRTUALLY SENDING 2 OR MORE DELEGATES FROM THE SAME SITE?

BOOK BY THE FRIDAY 22ND OCTOBER AND ADDITIONAL ATTENDEES WILL RECEIVE A 20% DISCOUNT ON LISTED FEES.
Note: 1ST delegate pays the full fee

PHARMIG 29TH ANNUAL CONFERENCE

17TH & 18TH NOVEMBER 2021 AND SPONSORED TECHNICAL MEETINGS 16TH & 19TH NOVEMBER **REGISTRATION FORM**

Please reserve _____ place(s) for the Pharmig's VIRTUAL 29TH Annual Conference being held across 2 half days on the 17TH & 18TH November 2021

Company: _____

Address : _____ **Tel:** _____

_____ **Email:** _____

Contact name (if different from the delegate): _____

Tel: _____ **Email:** _____

Please tick which events you wish to attend.

1st Delegate

First & Last Name: _____

Title: _____

Email: _____

Conference Fee (17TH/18TH Nov) ☐

£/€ _____

TOTAL £/€ _____

Sponsored Technical Events (16TH & 19TH Nov) ☐
Free if attending Conference

£/€ _____

2nd Delegate

First & Last Name: _____

Title: _____

Email: _____

Conference Fee (17TH/18TH Nov) ☐

£/€ _____

TOTAL £/€ _____

Sponsored Technical Events (16TH & 19TH Nov) ☐
Free if attending Conference

£/€ _____

* please provide an email address

OVERALL TOTAL £/€ _____

Nominated name and relevant information for those booking onto the Conference who cannot attend the sponsored technical meetings on the 16TH & 19TH November and wants to be replaced by a colleague

1. Nominated Name _____ **Job Title** _____ **Email** _____

2. Nominated Name _____ **Job Title** _____ **Email** _____

METHODS OF PAYMENT

(please tick relevant option)

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

☐ Total of £ _____ /€ _____ euro transferred electronically (this must be received before the event

☐ Please quote company approved purchase order number _____

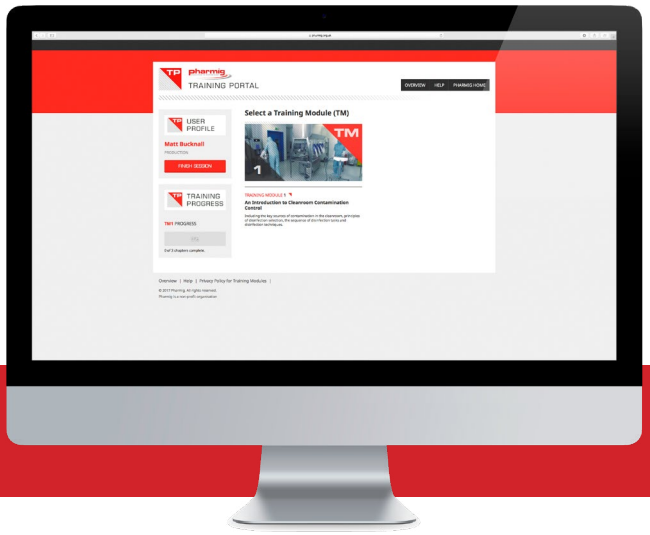
☐ I wish to pay by credit card (Pharmig will contact you for details)

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) being held 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 **TWO SEPARATE ZOOM LINKS** (one for each day) for you to click onto for the 17TH & 18TH November 2021. 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 morning of the 17TH November 2021. Two additional Zoom links will also be sent to those booking on to the 16TH & 19TH events.*

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 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***

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.**

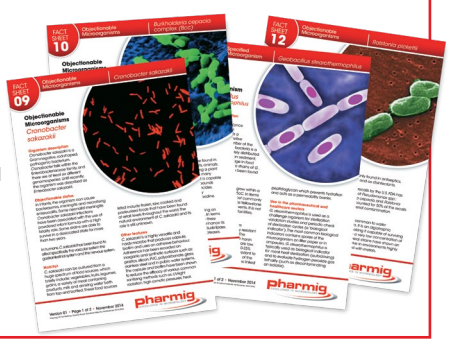
If you would like a more detailed 'virtual' demonstration led by a Pharmig Committee Member, please do email Pharmig at **info@pharmig.org.uk** and we will schedule in a time that suits you.

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**

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

Pharmig
EXCELLENCE IN MICROBIOLOGY

Pharmig Publications

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

Commonly Occurring Organisms – 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**

A series of 8 Water Microbiota 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

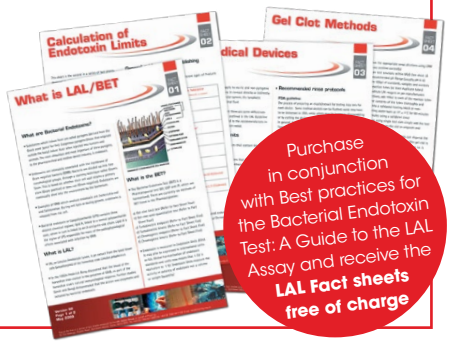
Member **£30** Non Member **£50**

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**

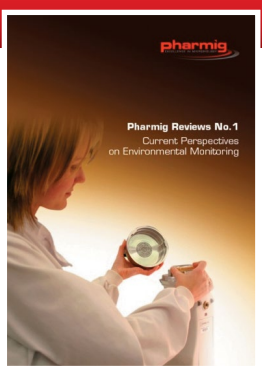
Current perspectives on Environmental Monitoring - Review # 1

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**



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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.

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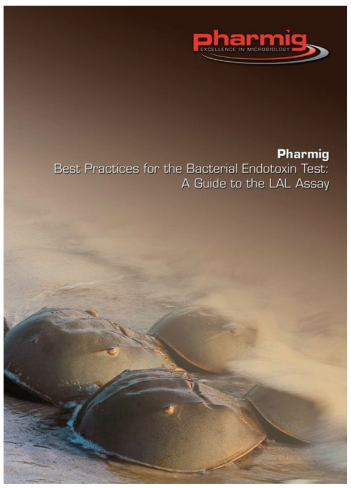

Guide to Microbiology Laboratories in the Pharmaceutical Industry

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

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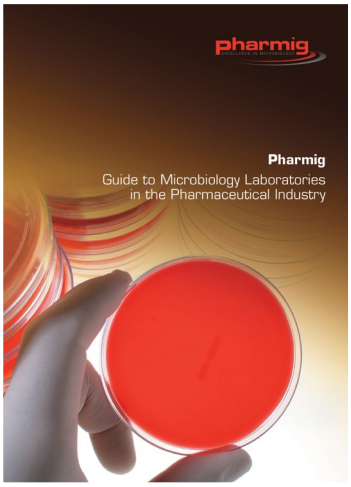

Guide to Cleanroom Operation and Contamination Control

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

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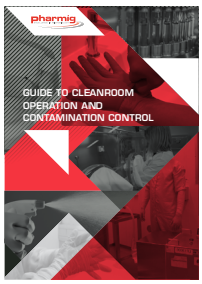

Rapid & Alternative Microbiological Methods

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

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