30th Annual Event

pharmig
EXCELLENCE IN MICROBIOLOGY

Celebrating Pharmig's 30th Annual Conference

The Ongoing Challenge of Microbiological Contamination Control Compliance

Hot topics at a glance:

- The new Annex 1... what is in it, what does it mean and what do we need to do? And – did you get what you wanted?
- The emperor's new clothes- the naked truth about growth-based methods and how we can replace them
- Practical application of a contamination control strategy (CCS): How to stop fungi getting into manufacturing areas
- Socialising rapid methods for QC microbiology – balancing todays capability with traditional approaches
- Insights into the risks and risk reductions with bacterial endotoxin
- Transformational technologies: Artificial intelligence for quality control in practice
- ID strategies: what's signalling your level of control?
- "Where did they come from? Considerations for test strains"
- Cleanroom energy costs vs performance: reducing energy costs & carbon emissions whilst maintaining contamination control. How far can you go?
- *Burkholderia cepacia complex* and aqueous non-sterile drug manufacture: Updates from a CDER microbiologist's perspective

PLUS...

Join in the great BCC debate

Attend the informal discussion sessions

Take part in real-time polls to gauge Industry current thinking!!

And join us at our 30th celebratory gala dinner!

Venue: The Nottingham Belfry Hotel, Mellors Way Off Woodhouse Way Nottingham, NG8 6PY

Date: 30th November & 1st December 2022

Addressed by leading microbiology experts...

Tim Sandle: BPL

Christine Farrance: Charles River

Gerald McDonnell: Johnson & Johnson

David Keen: Ecolab

Edel Fitzmaurice: Fitzmaurice Scientific ltd

Louis Ryan: Ash Technologies

Seb Hodgkin: Quell Therapeutics

Phil Greaves: Biotiq

Phil Rose: NSF International & ex-MHRA

Ian Harwood: Harwood Pharma GMP & ex-MHRA

Miriam Guest: AstraZeneca

Keith Beattie: EECO2

Kevin Wright: P&G

John Metcalfe: FDA/CDER

CELEBRATING PHARMIG'S 30TH ANNUAL CONFERENCE

WEDNESDAY 30TH NOVEMBER 2022

08.30 – 09.00 **Registration**

09.00 – 09.10 **Chairs' welcome & introduction**
David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chairman

09.10 – 09.50 ***The new Annex 1... what is in it, what does it mean and what do we need to do?***

- Changes and challenges
- Quality risk management (QRM)
- Contamination control strategy (CCS)
- How does / can this apply to non-sterile sites?
- Biologicals?
- ATMPS?
- What are the regulators likely to want?

Phil Rose – Executive Director, NSF International (ex-MHRA)

09.50 – 10.30 **The emperor's new clothes- the naked truth about growth-based methods and how we can replace them**

" We all believe in the quality promise- delivering consistent and safe products to our consumers. How we grow and count microorganisms has not changed for over 120 years and, as we know, these approaches are limited in their sensitivity and accuracy, but now (after 20 years since the first rapid methods), we can say that we are on the cusp of a revolution in microbiology that enables real-time, on-line and risk managed bioburden monitoring. This will not only allow us to deliver the quality promise but has the potential to save many millions of Pounds, Dollars and Euros across industry in reduced warehouse capacity and finished goods inventory. But to get there we have to abandon our reliance on monitoring bioburden by CFU and look to new measures of biological activity in products. Explore these changes and the challenges ahead at the Conference."

Phil Greaves - Managing Director, Biotiq & Kevin Wright – Director Corporate Quality Assurance – Industrial Microbiology, Procter & Gamble

10.30 – 11.10 **Practical application of a contamination control strategy (CCS): How to stop fungi getting into manufacturing areas**

- What is a Contamination Control Strategy (CCS)?
- What tools do you need for a successful CCS?
- What do you need to develop and implement a successful CCS – some ideas
- Know your enemy(s). Where are the potential sources of contamination?
- Identify the risks: Where are the risks in your manufacturing process & how to assess them.
- Some practical examples: Good practice and some examples where things have gone wrong

Ian Harwood – Managing Director, Harwood Pharma GMP Consulting Ltd (& recent ex- MHRA)

11.10 – 11.15 **ANNOUNCING PHARMIG'S LATEST PUBLICATIONS**

11.15 – 11.45 **Meet the exhibitors over tea/coffee**

11.45 – 12.25 **Annex 1: Did you get everything you wanted?**

This presentation is a review of Annex 1 from the Pharmig membership perspective. In 2018 and 2020 the Pharmig membership were polled as to what they thought of the Annex 1 draft and what they wanted to see in the final document. How close to this microbiological vision has the new version turned out to be?

In this presentation, Tim Sandle looks at the good points, the contentious points, and the disappointing omissions within the new Annex 1 drawing on the views and opinion of the Pharmig membership, supplementing these with some practical solutions.

Dr Tim Sandle -Pharmaceutical Microbiologist, Head of GxP Compliance & Quality Risk Management, BPL and Pharmig Committee Member

Pharmig will be using an interactive app at this year's event so that we can interact with you before, during and after the conference – and you can look to engage with your peers too!

Tick the box on the booking form which gives permission for Pharmig to contact you and we will start the ball rolling...

CELEBRATING PHARMIG'S 30TH ANNUAL CONFERENCE
WEDNESDAY 30TH NOVEMBER 2022

12.25 – 13.00 **Open discussion sessions**

13.00 – 13.30 **Pharmig AGM -** *All current members please do attend*

13.30 – 14.30 **Lunch in the exhibition areas**

14.30 – 15.10 **Insights into the risks and risk reductions with bacterial endotoxin**

- Endotoxins are high-molecular weight complexes that are naturally present in a variety of environmental sources, and commonly identified as contaminants in manufacturing environments.
- Microbiological quality best practices highlight the importance of reducing the risks and monitoring for the presence of endotoxins during product manufacturing and handling.
- Review what is new in endotoxin structure and associated toxicity effects in the body.
- Describe new results on the potential affinity of endotoxin, from various microbial sources in water, with various types of surface materials
- Describe new results on the inactivation of endotoxin from various microbial sources using cleaning and sterilization processes

Gerald McDonnell – Senior Director Microbiological Quality & Sterility Assurance – Johnson & Johnson USA (presenting virtually)

15.10 – 15.40 **Transformational technologies: Artificial intelligence for quality control in practice**

- Digital imaging
- Computer vision and artificial intelligence
- CFU characterization and counting

Philip Junker Andersen - Senior Microbiologist, IntuBio

15.40 – 16.10 **Afternoon tea/coffee with the exhibitors**

16.10 – 16.50 **DEBATE - BCC testing is here to stay – the new sterility test! Pistols at dawn debate of the year.**

Burkholderia Cepaciea Complex testing is here to stay – will it become another pointless sterility test? Should the approach to BCC be based on risk and a scientifically justified approach or, following a poor track record of compliance by industry, should a blanket test approach be put in place? The industry cannot be trusted to police itself, here comes the non-sterile products sterility test!

FOR: Edel Fitzmaurice – Quality Director/QP, Fitzmaurice Scientific Ltd
Will argue that more mandatory testing is needed. Why can't industry be trusted to self-police? How many inspection findings of companies failing to protect patients against BCC will it take? Test now, talk later!

AGAINST: David Keen – Director Pharmaceutical Microbiology, Ecolab
Will argue for a risk-based approach. Regulators should just allow industry to follow the bleedin science! Why should good sites and companies be punished by the lack of action and understanding of others? Quality departments should listen to microbiologists and not run in fear from the regulators.

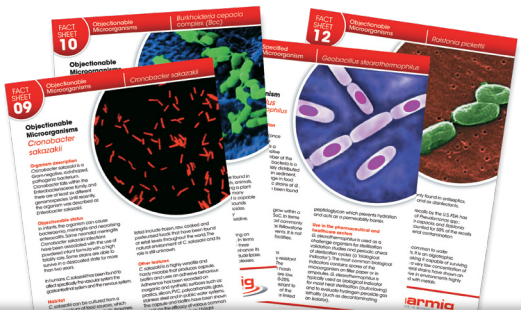
16.50 – 17.00 **Summary & close of day one**

18.30 - 19.30 **Pre-dinner drinks in the exhibition areas**

19.30 'till late **Gala dinner & dance and Pharmig's, now infamous, quiz!**
Dress code: Black tie as it's our 30th - or smart casual (no jeans) if you disklike dressing up
Drinks kindly sponsored by Steris

STERIS Life Sciences

Taxis will be provided by Pharmig to bring anyone staying at the Premier Inn Nottingham West Hotel to the Nottingham Belfry for the gala dinner.
(Own travel arrangements will need to be made for the return journey)



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

CELEBRATING PHARMIG'S 30TH ANNUAL CONFERENCE

THURSDAY 1ST DECEMBER 2022

09.00 – 09.05 **Chairman's opening remarks and champagne draw for 1st delegates to arrive!!**

09.05 – 09.45 **Socialising rapid methods for QC microbiology – balancing todays capability with traditional approaches**

Often we look to use rapid methods to accelerate quality product release as a replacement for traditional approaches. It is clear that these methods can provide greater sensitivity and quality data for faster release- but they do turn up new data- which can be difficult to explain when using traditional methods for correlation and investigation. This presentation will focus on:

- Current potential of non-growth rapid methods
- Examples from solid state cytometry, rapid PCR identification and Raman spectroscopy-based identification.
- Non-inferiority or equivalence- correlating and qualifying rapid methods relative to traditional approaches.
- Defining `good enough` for traditional and Rapid methods.
- Re-evaluating microbial release specification for risk release for consumer and patient safety

Kevin Wright – Director Corporate Quality Assurance – Industrial Microbiology, Procter & Gamble

09.45 – 10.25 **ID strategies: what's signalling your level of control?**

- Looking at data patterns
- You collect it – how do you review it?
- What really matters?

David Keen – Director Pharmaceutical Microbiology, Ecolab & Pharmig Chairman

10.25 – 11.00 **Tea/Coffee with the exhibitors**

11.00 – 11.40 **Open discussion sessions continued.**

11.40 – 12.10 **Situations where cleaning & disinfection is not that straightforward, or has some special considerations Examples from:**

- ATMPs
- NHS

Seb Hodgkin - Senior Director, Quality Assurance, Quell Therapeutics and Pharmig Committee Member

12.10 – 13.30 **Lunch in the exhibition areas**

13.30 – 13.40 **Exhibitor prize draws in the conference room**

13.40 – 14.20 **Cleanroom energy costs vs performance: reducing energy costs & carbon emissions whilst maintaining contamination control. How far can you go?**

- Consider the impact of rising energy costs & zero carbon targets on cleanroom operations
- Review typical cleanroom performance and the risks/opportunities this presents
- Recent technology advances and examine how they will change the cleanroom user experience

Keith Beattie – Director, EECO2 Ltd

14.20 – 15.00 ***Burkholderia cepacia complex* and aqueous non-sterile drug manufacture: Updates from a CDER Microbiologist's Perspective**

This presentation will:

- provide a short background regarding FDA concerns pertaining to BCC and the manufacture of non-sterile drug products
- Reference pertinent areas of the 2021 FDA Draft GFI Microbiological Quality Considerations in Non-sterile Drug Product Manufacturing
- Present recent events in the US pertaining to BCC
- Explore recent FDA Warning Letters to address Pharmig questions regarding BCC and the manufacture of non-sterile drugs

John Metcalfe – Quality Assessment Lead, FDA (presenting virtually)

15.00 – 15.40 **"Where did they come from? Considerations for test strains"**

- Background to taxonomy & factors for microbial ID
- Review of compendial test strains & their origins
- Comparison of genotypic and phenotypic attributes of culture collection strains
- Application of test strains in the pharmaceutical micro lab

Miriam Guest – Principal Microbiologist, AstraZeneca & Christine Farrance - Senior Global Scientific Affairs Liaison at Charles River Laboratories USA (presenting virtually)

15.40 - 16.00 **Q&A session / summary & close of conference**

16.00 – 16.00 **Grab and go coffee**

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.

OPEN DISCUSSION SESSIONS

The aim of these sessions is to encourage discussion, share issues, solutions and experiences in a smaller, more informal environment helping you to benchmark against other delegates/companies.

Please tick 2 out of the 4 listed below on your booking form

1. Environmental Monitoring – let's settle the debate

Join Cherwell Laboratories for an informative interactive session debating if settle plates are the right solution for your continuous monitoring. The attendee with have the opportunity to challenge industry experts about their theory and hear first-hand about the solutions to reduce risk and monitor your environment appropriately in line with annex 1.

Led by: *Cherwell*

2. Microbial identification discussion session

Discuss all things ID with the Committee experts

Led by: *Pharmig Committee*

3. Contamination Control Strategy (CCS) & Disinfection

Join Ecolab for a fun interactive session to perform a contamination control strategy for disinfection. The session will walk-through real-life examples, analysing contamination risks and mitigating them with proactive disinfection regimes. Attendees will have the opportunity to embrace some gameshow nostalgia and let their feet take them to risk assessment decisions!

Led by: *Ecolab*

4. Microbiology general Q&A surgery

Do feel free to submit your questions in advance to give the session leaders time to prepare responses and to encourage discussion within the group at large on the day.

Led by: *Pharmig Committee*

Pharmig would like to thank the following companies who have booked to exhibit and support the conference this year...

PHARMIG 30TH ANNUAL CONFERENCE

29TH & 30TH NOVEMBER 2022 REGISTRATION FORM

Please reserve ____ place(s) for Pharmig's 30th ANNUAL CONFERENCE held at The Nottingham Belfry Hotel on the 29th & 30th November 2022.

Company: _____

Address : _____

Tel: _____ **Email:** _____

MAIN CONTACT *(if different from delegates attending the Conference)*

First Name : _____ **Surname:** _____

Job Title: _____ **Telephone:** _____ **Email:** _____

DISCUSSION SESSION OPTIONS (EACH DELEGATE TO CHOOSE 2 OUT OF THE 4 LISTED BELOW)

1. **Environmental monitoring: let's settle the debate**
2. **Microbial identification discussion session**
3. **Contamination Control Strategy (CCS) & Disinfection**
4. **Microbiology general Q&A surgery**

1st Delegate *(please complete all sections)*

First Name: _____

Surname: _____

Job Title: _____

Open Discussion Sessions
Please tick 2 sessions you wish to attend.

1 2 3 4 ☐☐☐☐

Gala dinner (30th) (included in fee) ☐

☐ Please tick this box to enable Pharmig to contact you through its digital app before/during/after the conference

Please state any specific dietary requirements _____

I wish to add to the invoice £78.50 B&B per night at the Premier Inn Nottingham West Hotel: ☐ **29th Nov** ☐ **30th Nov**
(Please see accommodation notes for a detailed explanation)

2nd Delegate *(please complete all sections)*

First Name: _____

Surname: _____

Job Title: _____

Open Discussion Sessions
Please tick 2 sessions you wish to attend.

1 2 3 4 ☐☐☐☐

Gala dinner (30th) (included in fee) ☐

☐ Please tick this box to enable Pharmig to contact you through its digital app before/during/after the conference

Please state any specific dietary requirements _____

I wish to add to the invoice £78.50 B&B per night at the Premier Inn Nottingham West Hotel: ☐ **29th Nov** ☐ **30th Nov**
(Please see accommodation notes for a detailed explanation)

METHODS OF PAYMENT

(please tick relevant option)

☐ Cheque for £ _____ to follow in post. To cover the delegate fee(s) only ☐ / to cover delegate fee(s) and the Premier Inn Nottingham West accommodation. ☐ *(please tick correct option for you)*

☐ Please raise an invoice. To cover the delegate fee(s) only ☐ / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation ☐ *(please tick correct option for you)*

☐ Please quote Purchase Order Number _____ To cover the delegate fee(s) only ☐ / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation ☐ *(please tick correct option for you)*

☐ I wish to pay by credit card -Pharmig will contact you for details. To cover the delegate fee(s) only ☐ / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation ☐ *(please tick correct option for you)*

PHARMIG 30TH ANNUAL CONFERENCE

29TH & 30TH NOVEMBER 2022 CONFERENCE INFORMATION

CONFERENCE FEES

Conference fees are detailed below and include lunches, Conference gala dinner & dance, refreshments and, links sent out in advance to download conference presentations. Conference fees do not include accommodation, which must be booked and paid for directly with the hotel if staying at the Nottingham Belfry Hotel or, to be added to your Conference fee invoice if you choose to stay at the Premier Inn Nottingham West Hotel.

NB: Fees must be paid by Fees must be paid by Friday 11th November 2022 in order to guarantee a place(s) at the Conference.

PHARMIG MEMBER FEES

Delegate **£845 / €1020**

**Euro fee is higher to cover conversion rates*

NON MEMBER FEES

Delegate **£1245/ €1500**

**Euro fee is higher to cover conversion rates*

Discounted rates are available for NHS and non-profit making organisations

NHS Member Fees **£400**

Non NHS Member Fees **£550**

ACCOMMODATION

Pharmig have secured rooms at two venues this year – please read the following carefully

1. Nottingham Belfry (venue for the 2-day conference) - £115 B&B per person / per night

To book your accommodation at the Nottingham Belfry Hotel at the rate of £115 pp B&B **please contact the hotel directly on: Tel: 0115 973 9393** (state you are booking for the Pharmig Conference to receive the reduced rate). Rooms are non-refundable.

It is advised to book directly with the hotel rather than going through other websites to guarantee your room booking.

VENUE HOTEL ADDRESS:
Nottingham Belfry Hotel
Mellors Way
Off Woodhouse Way
Nottingham
NG8 6PY

2. Premier Inn Nottingham West Hotel - £78.50 B&B per person / per night (8 minute journey to the Nottingham Belfry Hotel by car)

To book this accommodation – Pharmig has to do this on your behalf. As such please mark on your booking form if you would like Pharmig to invoice you for accommodation at this hotel and – for how many nights (29th & 30th November OR just the 30th November)

Note: cancellations of rooms for this hotel can **only be made up until Friday 28th October 2022** – after that they are non-refundable.

HOTEL ADDRESS:
(8 mins by car to the Nottingham Belfry Hotel)
The Phoenix Centre
Millenium Way West
Nottingham
NG8 6AS

Taxis will be provided by Pharmig to bring anyone staying at the Premier Inn Nottingham West Hotel to the Nottingham Belfry for the gala dinner on the 30th November. (Own travel arrangements will need to be made for the return journey)

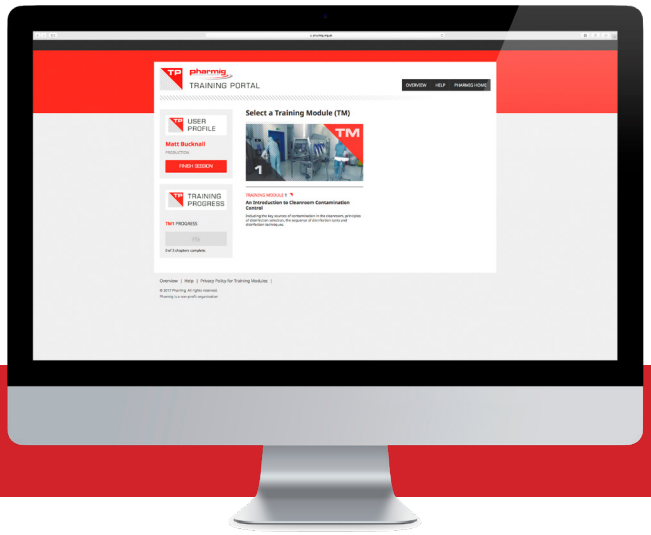
Maxine Moorey
Pharmig
T5 The Maltings
Roydon Road
Stanstead Abbotts
Hertfordshire, SG12 8HG

Tel: +44 (0) 1920 871 999
Fax: +44 (0) 1920 871 156
Email: info@pharmig.org.uk

CANCELLATION POLICY

Written cancellation will be accepted up to 30 days prior to the event, and all cancellations will incur a fee. No refunds are available 15 working days before the start date and full course fees will be due for delegates who fail to attend. Substitutions may be made at any time, preferably in writing to Maxine Moorey.

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



- 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

Cleaning and disinfection of pharmaceutical facilities - a road map to regulatory compliance

The guide has been completely revised and re-written to provide you with a roadmap to regulatory compliance for cleaning & disinfection. The new text will walk you through the steps needed to design, validate, and implement an effective cleaning and disinfection programme. Including:

- Identifying and assessing risks associated with cleaning and disinfection
- User requirements for cleaning agents and disinfectants
- Supplier qualification
- Disinfectant efficacy testing and validation
- Controls for routine use – including application methods, in-coming QC testing, and periodic review of the programme

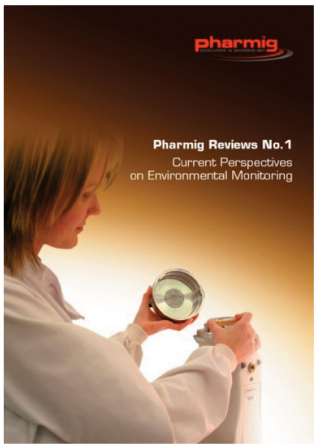
Member **£60** Non Member **£85**

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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W: www.pharmig.org.uk

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Pharmig Publications

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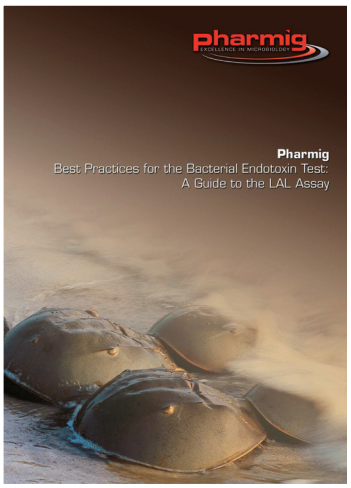
Best practices for the Bacterial Endotoxin Test: A Guide to the LAL Assay

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

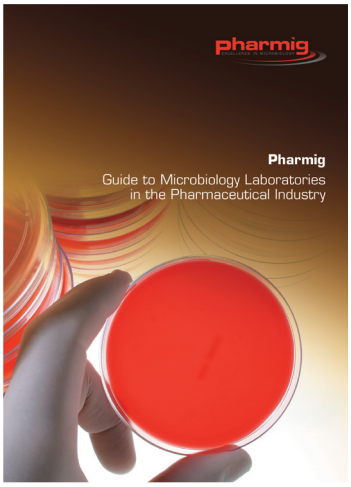
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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**



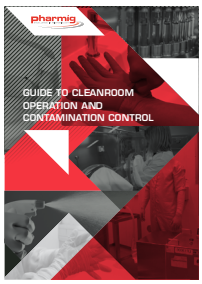
Guide to Cleanroom Operation and Contamination Control

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**



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**
Non Member **£85**

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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:

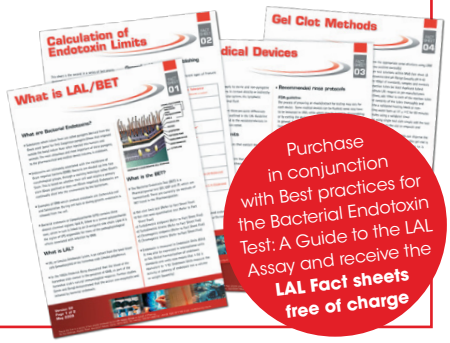
- Ralstonia pickettii
- Stenotrophomonas maltophilia
- Burkholderia cepacia complex
- Acinetobacter baumannii
- Brevundimonas diminuta
- Sphingomonas paucimobilis
- Pseudomonas aeruginosa
- General overview of water microorganisms

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**

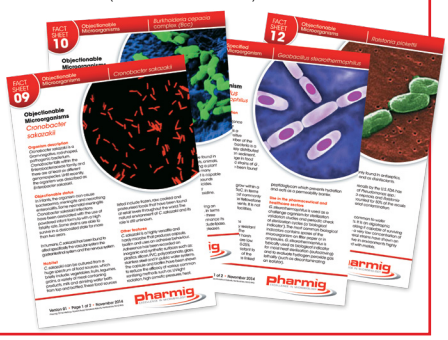
A series of 8 Microorganisms Fact Sheets

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**

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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