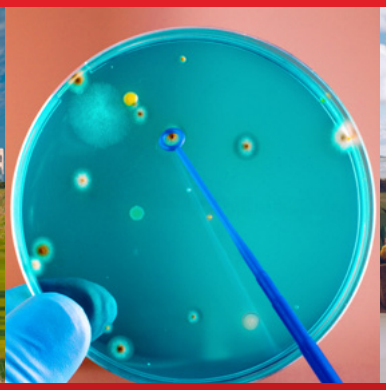
pharmig
EXCELLENCE IN MICROBIOLOGY

Presents

# Hot Topics in Pharmaceutical Microbiology Pharmig's 14th Annual Irish Conference - Wednesday 15th May 2019

# Control of Pharmaceutical Water Systems

Thursday 16th May 2019

## Leading experts include:

| | |
|---|---|
| **Andrew Hopkins** | AbbVie (ex-MHRA) |
| **Donald Singer** | GlaxoSmithKline & USP General Chapters (USA) |
| **David Keen** | Ecolab |
| **Tony Mayhall** | MQA Solutions |
| **Edel Fitzmaurice** | Fitzmaurice Scientific Ltd |
| **Gordon Farquharson** | Critical Systems |
| **Mark Thompson** | MTL Projects Ltd |
| **Sinead Cowman** | MODA |
| **Tim Sandle** | BPL |
| **Andrew Gravett** | AstraZeneca |

**Discounts apply for each event and for those wanting to attend both**

**OFFERS END 12TH APRIL 2019**

(see booking form for further information)

Venue: **Portmarnock Hotel & Golf Links, Strand Road, Portmarnock, Co. Dublin**

**Pharmig**

T5 The Maltings, Roydon Road, Stanstead Abbotts, Hertfordshire, SG12 8HG, United Kingdom.

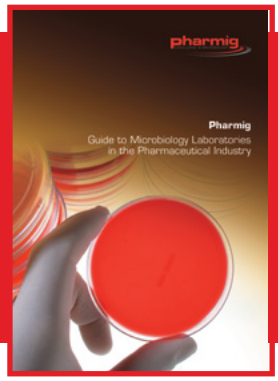
**Tel:** +44 (0) 1920 871 999 **Fax:** +44 (0) 1920 871 156

**Email:** info@pharmig.org.uk **Web:** www.pharmig.org.uk

pharmig
EXCELLENCE IN MICROBIOLOGY

# Hot Topics In Pharmaceutical Microbiology

## **Wednesday 15th May 2019** Portmarnock Hotel, Dublin




Attend and receive a copy of Pharmig's Guide to Microbiology Laboratories

**EARLY BIRD OFFER**

**Send 2 or more delegates from the same site and discounts will apply until Friday 12th April**

08.45 – 09.15 **Registration**

09.15 – 09.30 **Chairs Welcome**
David Keen – Senior Global Microbiology Consultant, Ecolab & Pharmig Chair

09.30 – 10.10 **The contamination control strategy and Annex 1**
The draft of Annex 1 that was published for public consultation in December 2017 mentions the use of the contamination control strategy (CCS) a number of times. This talk aims to explore the concept further and give a view of the following:
- The link between the use of QRM and the CCS
- Why is a CCS needed?
- What does it look like, what sort of thing should be included, is it one document?
- When and who should it be written by?
- The life cycle of the CCS?

Andrew Hopkins - Director, Operation Quality, QA Audit and Compliance, AbbVie (& ex-MHRA)

10.10 – 10.50 **Microbiological aspects of cleaning validation**
Cleaning validation is too often considered from a chemical perspective. However, microbiological risks also need to be addressed. This presentation looks at:
- Microbial contamination of equipment
- Microbial adhesion surfaces
- Cleaning techniques for equipment
- Test limits
- Validation requirements
- Avoiding cross contamination

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

10.50 – 11.20 **Meet & greet the exhibitors with tea / coffee**

11.20 - 12.00 **Current activities of the USP Microbiology Expert Committee**
**Key points:**
- Updates related to USP Chapters <1085>
- Guidelines on endotoxins Test: <60>
- Tests for *B.cepacia* complex and <1071>
- Rapid Microbial tests for release of sterile short shelf life products

Donald C. Singer, M.S. - Manger and Senior Fellow, GSK and Member USP General Chapters-Microbiology Expert Committee (USA)

12.00 – 12.30 **Open discussion sessions**

12.30 – 13.00 **Open discussion session continued…**

13.00 – 14.00 **Buffet lunch in exhibition area**

14.00 – 14.40 **Hygienic design and BAD practices**
- Considerations for hygienic design
- Overview of valves
- Do's and dont's of pipework
- Pumps and sumps
- How do you manage the risk?

Practical examples of equipment will be used during the session
Tony Mayhall, QP & Quality Consultant – MQA Solutions & Pharmig Honorary Member

14.40 – 15.20 **Data strategies and environmental monitoring**
- How to collect data, including electronic systems
- How to evaluate data
- Trend analysis tools and tips
- Setting alert and action levels
- Data integrity issues

Sinead Cowman – EU Business Development Manager, Informatics MODA

15.20 – 15.50 **Tea/coffee in the exhibition area**

15.50 – 16.30 **"Blind compliance encourages bad science"**
We are often tempted to ignore the benefits of technology & scientific developments because they challenge the norms, myths and traditions engendered by our GMPs. Our life seems to become more complex daily in the light of increasing numbers of regulatory Q&As, blogs and industry guidance notes. Where do we stand? This talk will be illustrated by examples from:
- Cleanroom HVAC systems
- Environmental monitoring is Isolators & RABS
- Draft revision of Annex 1 implications

Gordon Farquharson – Managing Director, Critical Systems Ltd

16.30 – 17.10 **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, Senior Global Microbiology Consultant – Ecolab and Pharmig Chair

17.10 – 17.15 **Summary and close of conference**

## Open Discussion Sessions Wednesday 15th May 2019

**A.** **Endotoxins – where are we now?**
Led by: Dr Tim Sandle – Head of Microbiology & Sterility Assurance, BPL & Pharmig Committee

**B.** **Rapid Methods – where are we now?**
Led by: Edel Fitzmaurice – Quality Director, Fitzmaurice Scientific Ltd & Pharmig Committee

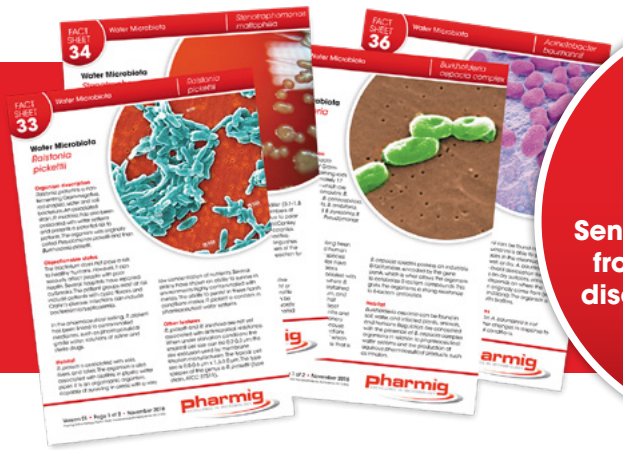
**C.** **Microbiology open 'surgery'**
Led by: David Keen – Senior Global Microbiology Consultant, Ecolab & Pharmig Chair

*Please note Pharmig reserves the right to alter the programme in the event of unforeseen circumstances. Please note that the views expressed by individual contributors are their own and do not necessarily reflect the views of Pharmig as a whole.*

# Control of Pharmaceutical Water Systems

## Thursday 16th May 2019 Portmarnock Hotel, Dublin

Attend & receive Pharmig's series of 8 Fact Sheets on Water Microorganisms




**EARLY BIRD OFFER**
**Send 2 or more delegates from the same site and discounts will apply until Friday 12th April**

08.45 – 09.15 **Registration**

09.15 – 09.30 **Chairs Welcome** - Dr. Tim Sandle – Head of Microbiology & Sterility Assurance, BPL

09.30 – 10.10 **Auditing water systems**
- What are the requirements and expectations to audit against
- How to structure a water system audit
- Common findings

Andrew Gravett – Associate Director, Global Quality Audit Group, AstraZeneca

# Control of Pharmaceutical Water Systems

## Thursday 16th May 2019 Portmarnock Hotel, Dublin

10.10 – 10.50 **Purified water systems**
- What can a purified water system consist of?
- Microbial risks of a purified water system

David Keen – Senior Global Microbiology Consultant, Ecolab & Pharmig Chairman

10.50 – 11.20 **Meet & greet the exhibitors with tea/ coffee**

11.20 – 12.00 **Three case studies relating to endotoxin contamination in water systems**
Well maintained WFI systems will not see endotoxin contamination. The operative phase is "well maintained". This presentation looks at endotoxin risks and discusses three case studies where things can go wrong:
- Failure to isolate and sanitise a water outlet following a valve change
- The risks of biofilm formation following maintenance
- The need to maintain temperature throughout the distribution loop

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

12.00 – 13.00 **Buffet lunch in exhibition area**

13.00 – 13.40 **"Pharma water systems: Regulatory compliance, best practice and system qualification"**
- Water system requirements from our GMPs and pharmacopoeias
- Impact of Annex 1 revision on WFI systems
- Best practices to control and avoid contamination (GEP)
- Industry trends and opportunities

Gordon Farquharson – Managing Director, Critical Systems Ltd

13.40 – 14.20 **Biofilms in water systems: A practical perspective**
- What the risks are to water quality
- How do you control it?
- How do you remove it?
- Microbiology testing
- Can you actually measure it?
- Impact of microbes

Mark Thompson – Director, MTL Projects Ltd

14.20 – 14.40 **Afternoon break with tea/coffee**

14.40 – 15.20 **Current hot topics and common audit citations in water**
Current hot topics
- Product recalls
- *Burkholderia cepacia* and water
- Recent regulatory updates
- Recent regulatory audit citations

Edel Fitzmaurice – Quality Director, Fitzmaurice Scientific Ltd

15.20 – 16.00 **Group workshop/ case study: You are running a manufacturing and oral dose facility and you purified water system falls over! As a group you will work out how you would:**
- Cope with bugs coming out of your purified water system
- Deal with a loss of your site water supply?

Previous case studies have been extremely well received by delegates – encouraging networking and exchange of thoughts and ideas whilst being guided by experienced leaders. An informative, thoughtful and fun way to end the meeting!

David Keen – Senior Global Microbiology Consultant, Ecolab & Pharmig Chairman

16.00 – 16.15 **Summary & closing remarks**

For those staying at the hotel attending the water meeting on the 16th - please do join us as our guests for drinks and canapés at the Sibin pub - a hidden gem located in the hotel grounds from 6pm - 7.30pm (weather permitting).

Please do make your own dinner arrangements with the hotel after the soiree has ended - thank you.

*Please note Pharmig reserves the right to alter the programme in the event of unforeseen circumstances. Please note that the views expressed by individual contributors are their own and do not necessarily reflect the views of Pharmig as a whole.*

# Booking Form and Hotel Information

**Please circle the relevant meeting fee(s) outlined in Booking Form A, B or C below**

**DISCOUNTED OFFERS FOR SENDING 2 OR MORE DELEGATES ENDS ON FRIDAY 12TH APRIL 2019**

## BOOKING FORM A

**Hot topics in Pharmaceutical Microbiology – Wednesday 15th May 2019**

**Attend & receive a copy of Pharmig's Guide to Cleanroom Microbiology Laboratories in the Pharmaceutical Industry**

**Member Fees** 1st Member - €580 / £495
2nd Member - €465 / £395

**Non Member Fees** 1st Non Member - €810 / £695
2nd Non Member - €695/ £595

**Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined above until Friday 12th April**

**Discussion Sessions**

Session A **Endotoxins** Session B **rapid Methods** Session C **Microbiology Surgery**

**Please tick which 2 discussion sessions you would like to attend**

**1st Delegate** A ☐ B ☐ C ☐ **2nd Delegate** A ☐ B ☐ C ☐

## FORM B

**Control of Pharmaceutical Water Systems – Thursday 16th May 2019**

**Attend & receive Pharmig's series of 8 Fact Sheets on Water Microorganisms**

**Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 12th April**

**Member Fees** 1st Member - €500 / £425
2nd Member - €385 / £325

**Non Member Fees** 1st Non Member - €730 / £625
2nd Non Member - €615 / £525

## FORM C

**BOOKING BOTH the One-Day Conference & Control of Pharmaceutical Water Systems - 15th & 16th May 2019**

**If you wish to attend both meetings – further discounted fees are as follows:**

**Member Fees** 1st Member - €1010 / £870
2nd Member - €780 / £670

**Non Member Fees** 1st Non Member - €1476 / £1270
2nd Non Member - €1162 / £1070

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

**Company Name & Address:** _____

_____

**Contact Name (different from those attending)** _____

**Contact Email:** _____ **Tel:** _____

**1st Delegate**

**First Name:** _____
**Surname:** _____
**Job Title:** _____
**Email:*** _____
**Dietary Requirements:** _____

**2nd Delegate**

**First Name:** _____
**Surname:** _____
**Job Title:** _____
**Email:*** _____
**Dietary Requirements:** _____

***Please include your email address if we wish to continue to be contacted by Pharmig about these and future meetings**

**Email or fax your completed booking form for a confirmed place: Email: info@pharmig.org.uk Fax: to +44 (0) 1920 871 156**

☐ **Cheque for £ sterling / € euro to cover delegate fee(s) enclosed**

☐ **Cheque for £ sterling / € euro to follow**

☐ **Total of £ sterling / € euro transferred electronically**

☐ **Please supply invoice F.A.O.:** _____

☐ **Please quote purchase order number:** _____

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

# Hotel Information

**Note:** Fees must be paid by **Friday 3rd May 2019** in order to guarantee a place(s) at the Conference or one-day meeting

**Note**: Fees for both meetings include lunch, refreshments and links to download presentations in advance of the meetings. **Documentation packs will no longer be provided on the day.**

**Fees do not include accommodation which must be booked and paid for directly with the hotel.**

## THE VENUE:

Portmarnock Hotel & Golf Links is just 15 minutes from Dublin airport and less than 25 minutes from the city centre. The hotel has full conference facilities with accommodation, dining choices and spa area.

## ACCOMMODATION:

**A limited number of bedrooms have been reserved at a special rate of €135 for overnight delegates (please book early to avoid disappointment).**

Rooms need to be booked directly with the hotel. Please call The Portmarnock Hotel & Golf Links on + 353 (0) 1 846 0611 - and quote Pharmig to ensure you receive the discounted rate.

## ADDRESS:

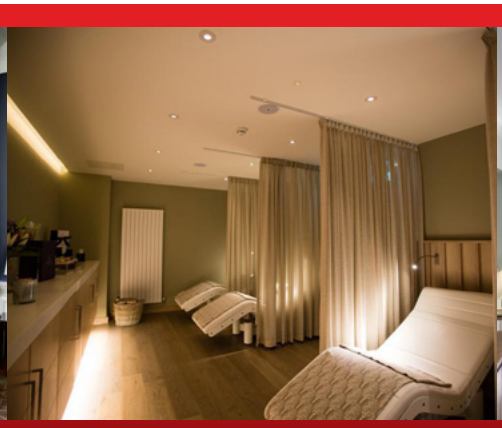
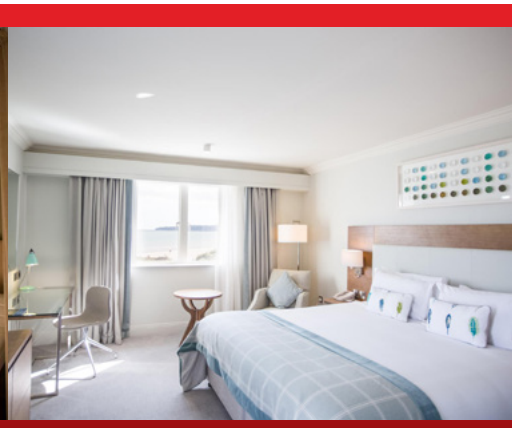
Portmarnock Hotel & Golf Links, Strand Road, Portmarnock, Co. Dublin, Ireland

## 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. Please send to:

Maxine Moorey, Pharmig, T5 The Maltings, Roydon Road, Stanstead Abbotts, Hertfordshire, SG12 8HG
or by email: maxine@pharmig.org.uk

*Please note Pharmig reserves the right to alter the programme in the event of unforeseen circumstances. Please note that the views expressed by individual contributors are their own and do not necessarily reflect the views of Pharmig as a whole.*

**Pharmig**

T5 The Maltings, Roydon Road, Stanstead Abbotts, Hertfordshire, SG12 8HG, United Kingdom.

**Tel:** +44 (0) 1920 871 999 **Fax:** +44 (0) 1920 871 156

**Email:** info@pharmig.org.uk **Web:** www.pharmig.org.uk

pharmig
EXCELLENCE IN MICROBIOLOGY

Pharmig publications have been written by industry leaders and some endorsed by the MHRA. They contain key information relating to GMP standards and regulations.

# Pharmig Publications

Fees listed are in Sterling only

## 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:

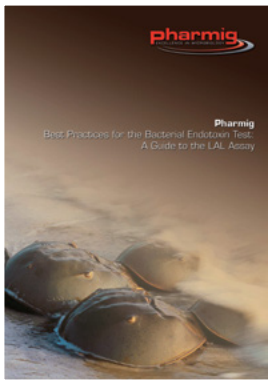
- Constructing an environmental monitoring programme
- Particle monitoring & control
- Environmental monitoring & risk assessment
- Microbiological risk assessment case study

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

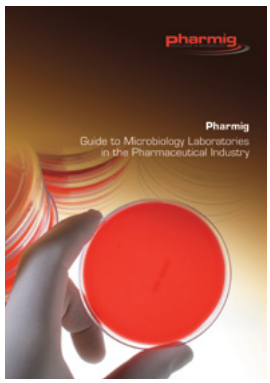
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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**



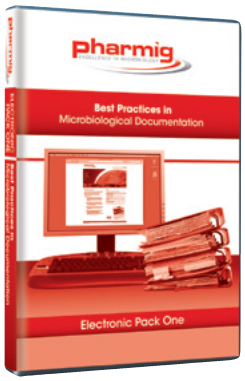

## Best Practices in Microbiological Documentation - Electronic Pack One

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**



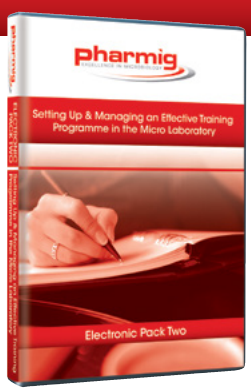

## Setting up & Managing an Effective Training Programme in the Micro Laboratory – Electronic Pack Two

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**




**For more information contact**

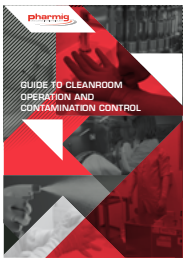
**T:** + 44 (0) 1920 871 999
**F:** +44 (0) 1920 871 156
**E:** info@pharmig.org.uk
**W:** www.pharmig.org.uk

# Pharmig Publications

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

## 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:

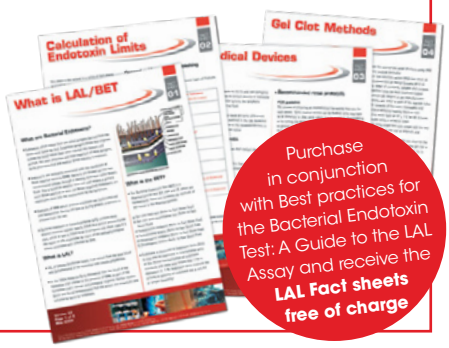
- Cleanrooms
- Different grades of cleanrooms
- The important aspects of physical control
- Contamination control and environmental monitoring
- Important cleanroom parameters required by the regulatory standards

Member **£60**
Non Member **£85**


## 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**

**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

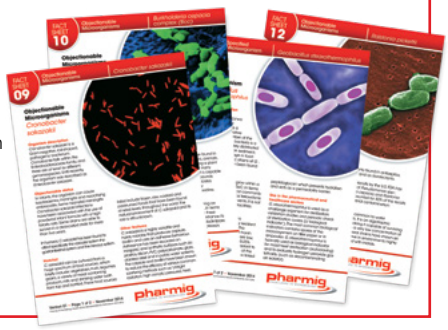
Pharmig
EXCELLENCE IN MICROBIOLOGY

# Pharmig Publications

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

## 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.

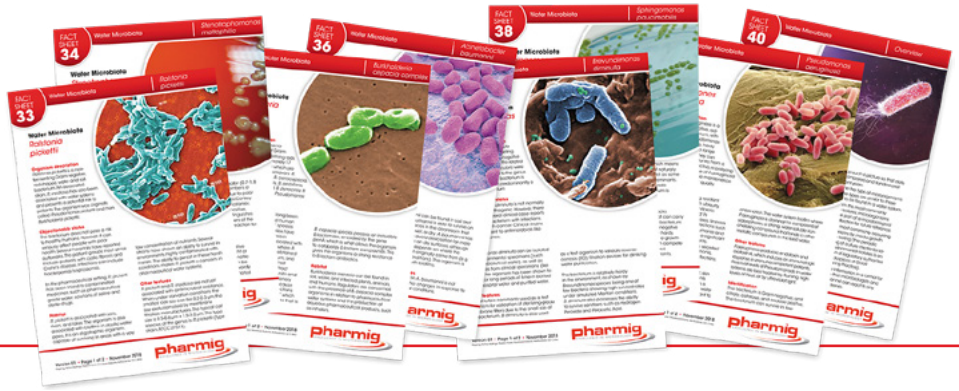
Member **£30**
Non Member **£50**

## Water Microbiota – Pharmig's latest series of 8 fact sheets – November 2018

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**



## Pharmig's first interactive on-line training module on: Cleaning and Disinfection of Cleanrooms

Introducing the NEW online training tool from the training experts.

**• EASY TO USE • CONVENIENT • QUANTIFIABLE**

The new Pharmig Training Portal gives your team access to superior online training. A series of detailed videos cover:

- **Introduction to cleanrooms**
- **Disinfectant selection, storage & usage**
- **Cleaning techniques**


These are followed by a series of multiple choice assessments on key subject areas relating to your team's role in the cleanroom environment.

On successful completion of the entire module, participants will be issued with a formal certificate.

The module is designed for Production Operators, Cleaners, and QA. This online training module can also be used as part of hygiene training for anyone that enters a GMP cleanroom (eg QC, Engineers etc).

For further information, please contact:

**E:** info@pharmig.org.uk **W:** www.pharmig.org.uk

**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