pharmig
EXCELLENCE IN MICROBIOLOGY

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Presents for the Adriatic Region: **Hot Topics in Contamination Control in Pharmaceutical Production**

One Conference – Two Locations

Tuesday 27th September 2016 – **Radisson Blu Plaza, Ljubljana**
Wednesday 28th September 2016 – **Dvorana Solidum centar, Zagreb**

Leading industry experts include:


Rachel Blount


Laura Guardi


Carsten Moschner

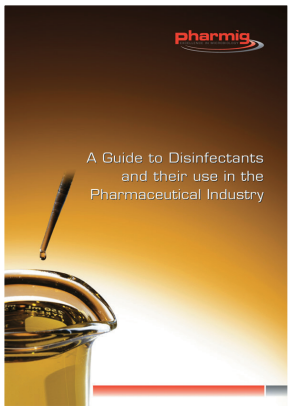

Tim Sandle

Attend and receive automatic overseas membership to Pharmig until the 31st December 2016 (see inside for more details)

Who will cover:

- Annex 1 Revisions
- Regulatory requirements in relation to contamination control
- VDI Guidelines 9.2 – Follow up on the harmonisation process within the Pharmaceutical Industry
- Choosing the correct wiper within the frame of regulatory expectations
- Body box testing - detection and measurement of airborne particles and **germs**
- Sporicidal transfer disinfection – A new era of regulatory positions
- Environmental Monitoring: Best Practices for Microbial Recovery
- Disinfectant efficacy testing
- Managing changes to cleaning and disinfectant regimes

PLUS – The first 40 delegates booking onto each of the dates listed will receive a **FREE** copy of the current **'Guide to Disinfectants and their use in the Pharmaceutical Industry'**



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

Book early to avoid disappointment

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

Programme for Tuesday 27th & Wednesday 28th September 2016

CONTINUED OVERLEAF

08.15 – 08.45 **Registration**

08.45 – 09.00 **Welcoming Speech: Local Contact Chairing the Meeting: Pharmig**

09.00 – 09.45 **Updates to EU GMP Annex 1**
- What is likely to go into the revised Annex including:
  - Terminal sterilisation vs aseptic processing
  - WFI produced by reverse osmosis
  - Guidance for media simulation trials
  - Changes to cleanroom classification (ISO 14644)

Tim Sandle - Head of Microbiology, BPL & Pharmig Committee Member (TBC)

09.45 – 10.25 **Regulatory Overview of Current Cleaning and Disinfection Standards**
- Covering MHRA/FDA/USP/PDA guidelines
- Interpreting requirements
- Hot topics

Laura Guardi – Senior QA Auditor, AstraZeneca

10.25 – 10.55 **VDI Guideline 9.2 – Follow up on the Harmonisation Process within the Pharmaceutical Industry**
The VDI Standard applies to all consumables used in contamination-controlled areas. In addition this standard contains guidance on the selection of products.
Carsten Moschner – Chairman 2083-9.2, VDI Association

10.55 – 11.15 **Morning break with tea/coffee**

11.15 – 11.55 **Sporicidal Transfer Disinfection – A New Era**
- Regulatory positions
- Sources of organisms and risk to the transfer disinfection process
- Optimising the transfer disinfection process
- Establishing contact times
- Appropriate techniques

Rachel Blount - Global Validation Manager, Team Leader, ECOLAB

11.55 – 12.25 **Choosing the Correct Wiper: Essential for Efficient Contamination Control!**
- Technical documentation - what is really declared on up-dated data sheets
- Manufacture differences during cutting of wipes
- Cleanroom wipes as part of an entire cleanroom cleaning system influenced by different factors

Carsten Moschner – Chairman 2083-9.2, VDI Association

12.25 – 13.25 **Lunch with the exhibitors**

13.25 – 13.55 **Body Box Testing**
- An advanced system for detection and measurement of airborne particles and germs dependent on the clothes that are worn
- To understand the body-box test method as test in step with actual practice.

Carsten Moschner – Chairman 2083-9.2, VDI Association

13.55 – 14.40 **Environmental Monitoring – Best Practices for Microbial Recovery**
- What is environmental monitoring trying to do?
- Methods and limitations
- Problems and myths of incubation, such as:
  - Which agar should you select?
  - Should one or two agars be used?
  - Which is the optimal temperature?
  - How long should you incubate for?
- What types of microorganisms can you expect to detect?
- Cleanroom microbiota

Tim Sandle - Head of Microbiology, BPL & Pharmig Committee Member (TBC)

14.40 - 15.00 **Afternoon break with tea/coffee**

15.00 – 15.40 **Strategies for Disinfection Validation: A Practical Approach**
- Selection of methods and adaptation
- A matrix approach of surfaces and organisms

Rachel Blount – Global Validation Manager, ECOLAB

15.40 – 16.20 **Workshop: Factors to Consider when Designing a Disinfectant Efficacy Test and Interpretation of Results**
Delegates, working in small groups, will be provided with a set of data and asked to develop a rationale for a disinfectant regime and interpretation of results
Led by: Rachel Blount – Ecolab, Laura Guardi - AstraZeneca & Tim Sandle - BPL

Programme for Tuesday 27th & Wednesday 28th September 2016 – Continued

16.00 - 16.40 **Managing Changes to Cleaning and Disinfectant Regimes**
- Making a justification for change
- Performing an impact assessment
- Typical pre-implementation actions

Laura Guardi – Senior QA Auditor, AstraZeneca

16.40 – 16.50 **Closing remarks**

About Your Presenters

Rachel Blount

Rachel Blount has over 25 years of experience in Contamination Control and started her career in Microbiology. She has been responsible for the implementation of the new 3rd party manufacturer for all sterile disinfectants and the standards and processes required. She has also been involved in numerous projects with Customers and routinely carried out Audits, Training and coordinated the Disinfectant studies for Pharmaceutical sites.

In her current role Rachel provides technical support advising on: cleaning and disinfection queries, performing site surveys, presents at seminars and also project manages the third party laboratories that perform disinfectant efficacy studies. She is an accredited IRCA auditor and is a long standing Pharmig Committee member.

Laura Guardi

Laura has almost 20 years experience in the Pharmaceutical and Biotech industry. She has experience in a range of biological QC techniques (including tissue culture, virology and molecular biology, as well was as classical microbiology), vaccine production, and is an experienced auditor (Lead Auditor for GMP/PQMS and ISO 9001). Laura initially studied at Manchester University for her BSc(hons) degree in Microbiology.

She been responsible for the set-up of new QC Virology laboratories, technology transfer of assays from Development to QC and supervision of laboratory teams in routine operation.

Laura - as a Corporate and Regulatory Compliance Team Manager has also been responsible for internal compliance, vendor management, and the regulatory inspection process (MHRA and FDA). She was also the site's subject matter expert for TSE Compliance.

As a Global Validation Manager Laura provided technical support to customers, advising on cleaning and disinfection of cleanroom environments and project managing the third party laboratories that perform disinfectant efficacy studies.

Since 2015 Laura has been a Senior QA Auditor as part of the World Wide Audit Group that is responsible for auditing all sites, their suppliers and contract manufacturers. Laura is also a current Pharmig Committee member.

Dr Tim Sandle

Tim Sandle is the Head of Microbiology and his current role involves overseeing a range of microbiological tests, batch review, microbiological investigation and policy development. In addition, Tim is an honorary consultant with the School of Pharmacy and Pharmaceutical Sciences, University of Manchester and is a tutor for the University's Pharmaceutical Microbiology MSc course. Tim is a chartered biologist and holds a first class honours degree in Applied Biology; a Master degree in education; and a PhD in microbiology.

Tim serves in several national and international committee relating to pharmaceutical microbiology and cleanroom contamination control (including the ISO cleanroom standards), and he has acted as a spokesperson for several microbiological societies. Tim has written over one hundred-and-fifty book chapters, peer reviewed papers and technical articles relating to microbiology. He is also a long standing Pharmig Committee member.

About Your Presenters

Carsten Moschner (put forward by Sanolabor)

Carsten Moschner is an active and renowned expert within the field of Contamination Control. He regularly contributes and shares his knowledge via numerous published articles with regard to the topic "Cleanroom Garments", in industry leading magazines. He is also a co-author for according specialized books.

Currently, he had been appointed as a Chairman at VDI for the new guideline page 2083- 9.2,"Consumables for cleanrooms". This guideline provides policy for selection and standardisation of products for controlled environments in the industrial areas, and as well process requirements and guidance on the logistics.

About Pharmig

Pharmig is a non-profit making professional organisation, established in 1991, that represents the interests of individuals who work in, have responsibility for, or work alongside microbiology within Pharmaceutical, Healthcare, Cosmetics & NHS Industries. It provides a focus for continuing professional development and serves as a unique network for the exchange of microbiological information through training courses, conferences, publications and its website forum.

The Group has grown significantly since 1991 expanding the portfolio of products it now offers to the Membership whilst remaining true to the initial needs of microbiologists which include:

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

Attend and you will receive automatic Pharmig overseas membership to the end of December 2016

Overseas membership includes:

- A quarterly technical newsletter (PDF version only)
- Member rates to join Pharmig webinars to the end of 2016
- Member rates to purchase any of Pharmig publications at the member listed prices. Visit the Pharmig website for more information www.pharmig.org.uk.

SEE PAGES 7 & 8 FOR ALL PHARMIG PUBLICATIONS

Exhibitor Opportunities

- There are limited exhibition places at the meetings being held on both the 27th & 28th September.

Fees to exhibit:

- €611+local taxes (£500 Sterling) to exhibit at one meeting
- Exhibiting at both meetings (27th and 28th) – a discount €134 will apply.
  TOTAL €1088 + local taxes (£900 Sterling)

The booking form is located on page 5 of this PDF. Bookings will be accepted on a first come-first serve basis and payment is due by Friday 9th September at the latest to confirm attendance.

Booking Forms / Payment / Venues / Accommodation Info

DELEGATE FEES:

€90 + local taxes per person (£77 Sterling) - and receive automatic overseas Pharmig membership to end of December 2016)

DELEGATE BOOKING FORM

Please tick which meeting you would like to attend

☐ Tuesday 27th September, Ljubljana ☐ Wednesday 28th September, Zagreb

Company Name: _____

Company Address: _____

1st Delegate

First Name: _____

Surname: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

2nd Delegate

First Name: _____

Surname: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

If you want to send more than 2 people - please add additional names to the booking form and they will be charged accordingly.

Note: Individual fee includes refreshments, lunch, Seminar presentations and Certificate of Participation
Note: It excludes accommodation which needs to be booked directly with the hotel(s)
Note: Payments MUST be made in advance by Friday 9th September to guarantee a place at either meeting

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EXHIBITOR FEES:

- **Exhibiting at one meeting | €611 + local taxes (£500 Sterling) to exhibit**
- **Exhibiting at both meetings (subject to availability) | €1088 + local taxes (£900 Sterling)**

EXHIBITOR BOOKING FORM

Please tick which meeting you would like to exhibit at

☐ Tuesday 27th September, Radisson Blu Plaza Hotel, Ljubljana ☐ Wednesday 28th September, Dvorana Solidum Centar, Zagreb

☐ Exhibit at both meetings (27th & 28th September)

EXHIBITOR INFORMATION

Company Name: _____

Company Address: _____

1st Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

2nd Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

Note: Fees include 1 stand table, up to 2 representatives, refreshments, lunch and Seminar presentations
Note: It excludes accommodation which needs to be booked directly with the hotel(s)
Note: Payments MUST be made in advance by Friday 9th September to guarantee a place at either meeting

Booking Forms / Payment / Venues / Accommodation Info

PAYMENT

- Email / Fax booking forms to info@pharmig.org.uk / +44 (0) 1920 871 156 for a provisional place
- Pharmig can invoice you in Euros / Sterling (Please mark on your booking form which currency you prefer

or

- Individual provisional bookings can also be made via the Pharmig website www.pharmig.org.uk and click on meetings (Sterling payments only can be taken via the website)
- Payment(s) can also be made via Sanolabor (Slovenia) – details outlined below:

Sanolabor, d.d., Leskoškova 4, 1000 Ljubljana
Bank: ABANKA d.d.
Bank account details: IBAN: SI56 0510 0800 0105 334
BIC: ABANSI2X
Reference code: Pharmig conference 2016

- Payment(s) can also me made via Sanol H (Croatia) – details outlined below:

Sanol H d.o.o., Škorpikova 11, 10090 Zagreb

Bank: Zagrebačka banka d.d.
Bank account details: IBAN: HR9023600001102388424
SWIFT CODE: ZABAHR2X
Reference code: Pharmig conference 2016

Note: Payments MUST be made in advance by Friday 9th September 2016 to guarantee a place at either meeting

VENUES

Tuesday 27th September
Address: Radisson Blu Plaza Hotel,
Bratislavska cesta 8, 1000 Ljubljana, Slovenia

Wednesday 28th September
Address: Dvorana Solidum Centar,
Škorpikova 11, 10090 Zagreb, Croatia

ACCOMMODATION

Meeting at the Radisson Blu Plaza Hotel, Ljubljana – Tuesday 27th September

- Limited accommodation has been reserved at this hotel at €95 + taxes B&B per night
- Rooms need to be booked directly with the hotel **(please quote Sanolabor /Pharmig meeting to ensure you receive the reduced rate)**
- **Contact number: +386 1 243 00 00 / Email: info.ljubljana@radissonblu.com**

Meeting at Dvorana Solidum Centar, Zagreb - Wednesday 28th September

- Limited accommodation has been reserved at the Hotel Antunović, Zagrebačka avenija 100, 10090, Zagreb at €100 + taxes B&B per night
- Rooms need to be booked directly with the hotel **(please quote Sanol H/Pharmig meeting to ensure you receive the reduced rate)**
- **Contact number: +385 (0) 1 2041 201 / Email: rezervacije@hotelantunovic.com**

QUESTIONS

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

THANK YOU

Pharmig would like to thank Sanolabor and Sanol H for their help and support in organising these meetings

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

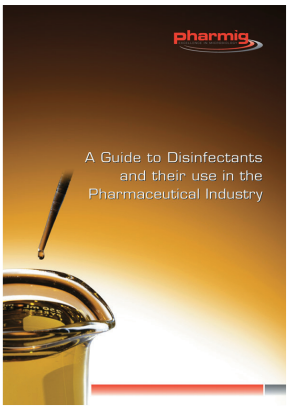
Guide to Disinfectants & their use in the Pharmaceutical Industry

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**



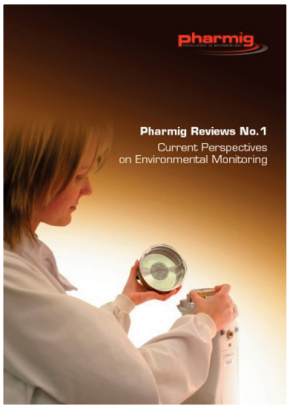
Current perspectives on Environmental Monitoring - Review # 1

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

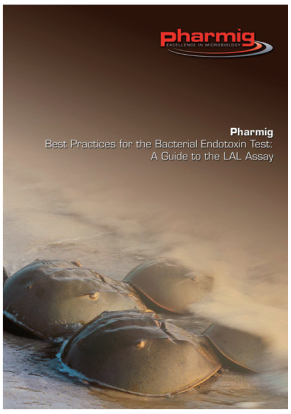
Member **£60** Non Member **£85**



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

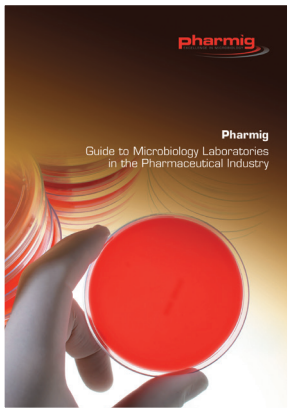
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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**



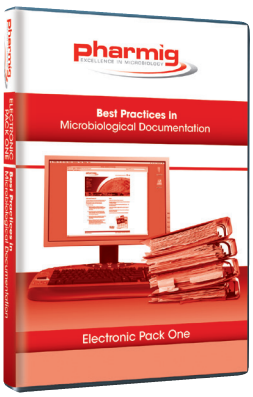
Best Practices in Microbiological Documentation - Electronic Pack One

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**



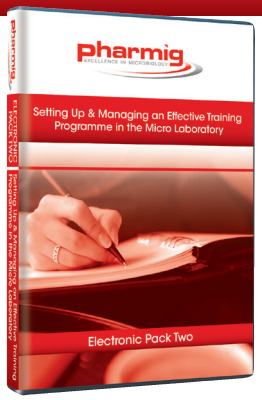
Setting up & Managing an Effective Training Programme in the Micro Laboratory – Electronic Pack Two

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**



Pharmig Publications

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

LAL Fact Sheets

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

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

Member **£20**
Non Member **£35**

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

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**

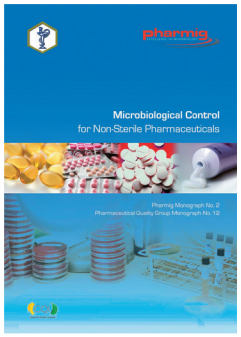
Microbiological Control for Non-Sterile Pharmaceuticals

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**



A series of 8 Microorganisms Fact Sheets

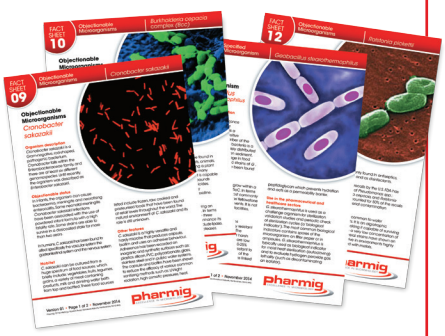
The microbial enumeration test and test for specified microorganisms can represent a challenging area for pharmaceutical microbiology. To act as a training aid for new staff, and an aide memoire for more experienced staff, Pharmig have produced eight fact sheets. Seven of the fact sheets profile each 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 have 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**