pharmig
EXCELLENCE IN MICROBIOLOGY

Supported by:
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Presents: **Hot Topics in Pharmaceutical Microbiology for the Adriatic Region**

Date: Wednesday 18th October 2017
Venue: OTOČEC - Hotel Šport, Grajska Cesta 2, 8222 OtoČec, Slovenija

Leading industry experts include:


Laura Guardi


David Keen


Dr. Tim Sandle


Bruno Šimek

Who will cover:

- Data integrity: Experience from GMP practice (laboratory, IT systems, production, documentation) and new expectations in field.
- Environmental monitoring: Incubation strategies; Deviations in results and impact on further decisions with respect to batch release.
- Batch release and deviations – QP perspective.
- Best practice in the effective management of sterility test failures.
- Practical approaches to microbiological audits – hosting an audit.

PLUS – An interactive group workshop on: Root cause analysis and Relevant Tools

Attend and you will also receive automatic overseas membership in Pharmig until the 31st December 2017

(see inside for more details)

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: Wednesday 18th October 2017

08.45 – 09.15 **Registration**

09.15 – 09.30 **Chairman's Welcome and Introduction**
David Keen – Microbiology Manager, GlaxoSmithKline and Pharmig Chair

09.30 – 09.50 **Data Integrity and New Expectations**
- Data integrity within the microbiology laboratory
- Requirements for good data integrity – 'ALCOA'
- Understanding the expectations from regulators
- Managing data integrity in your laboratory and at your production facility
- Regulatory guidance on data integrity

David Keen – Site Microbiologist, GlaxoSmithKline & Pharmig Chair

09.50 – 10.20 **Data integrity – Experience from GMP practice (Laboratory, IT Systems, Production, Documentation)**
- Discussion of the background for each sample (reasons for forming)
- Discussion of the consequences (monitored and supervised, patient oriented, company oriented)
- Reference on the leading background

Bruno Šimek – Managing Director, Arguo d.o.o

10.20 – 10.30 **Q&A – Data integrity**

10.30 – 11.00 **Morning break with tea/coffee**

11.00 – 11.40 **Environmental Monitoring: Incubation Strategies**
- What is environmental monitoring trying to do?
- Which agar should you select?
- Should one or two agars be used?
- Which is the optimal temperature?
- For how long should you incubate for?
- What types of microorganisms can you expect to detect?

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

11.40 – 12.10 **Practical Approaches to Microbiological Audits – Hosting an Audit**
- How to prepare your staff for the inspectors
- Preparing documentation packages ready for inspection
- Presenting poor data

Laura Guardi – Senior QA Auditor, AstraZeneca & Pharmig Committee Member

12.10 – 12.20 **Q&A – EM & Audits**

12.20 – 12.30 **Short Presentation to Introduce Pharmig's First On-Line Interactive Training Module Based Around: Cleanroom Contamination, Disinfectants (selection, storage and use of) and, Cleaning Techniques**

12.30 – 13.20 **Lunch with the exhibitors**

13.20 – 14.00 **Deviations in Environmental Monitoring Results and the Impact on Further Decisions with respect to Batch Release**
David Keen – Site Microbiologist, GlaxoSmithKline & Pharmig Chair

14.00 – 14.25 **Batch Release and Deviations – A QP Perspective**
- QP perspective - ability to see big picture
- Risk analysis - best practice
- Content of new EU GMP Annex 16 (handling of unexpected deviations)

Bruno Šimek – Managing Director, Arguo d.o.o

14.25 – 15.00 **Group Workshop based around Root Cause Analysis and Related Tools**
Led by: Bruno Šimek
Supported by: Laura Guardi, David Keen, Dr. Tim Sandle

15.00 – 15.10 **Q&A – Deviations & Root cause**

15.10 – 15.35 **Afternoon break with tea/coffee**

15.35 – 16.20 **Best Practice in the Effective Management of Sterility Test Failures**
- Best practices for reporting the sterility test failure
- Key things to examine in relation to production
- Key things to examine in relation to laboratory error
- Bringing the production and laboratory reviews together
- Addressing root causes

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

16.20 – 16.40 **Q&A and Closing Remarks**

About Your Presenters

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 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 has 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.

David Keen

David is a microbiologist working for GlaxoSmithKline as the site microbiology manager and got his first taste of Pharmig a number of years ago as an industry member and in 2007 he became a committee member. In November 2013 he had the honour of being elected to the position of Pharmig Chair which he continues to hold.

David started life as a swab monkey working for GSK Barnard Castle. Here he performed environmental monitoring and clean room qualification before moving on to sterile finished product testing.

He then moved to a small start-up company now called SCM Pharma. Here he set up a new microbiology lab and a new microbiology team. He helped design and qualify the new clean rooms then implemented EM, raw material and finished product testing. He then moved from microbiology to project management and became the technical manager where he designed isolators for fun!

David then moved to Reckitt Benckiser at their Hull site where he discovered the magic and pain of working in an FMCG environment. His role was to improve microbiological awareness on the site and a large amount of time was spent investigating significant microbial contamination event with suppliers and products. He was lucky enough to be sent across the world investigating microbiological issues on behalf of the company. If you get caught by him at the bar, he can bore you to death on the wonders of seaweed.

In 2012 David moved back to GSK at the Ulverston site in the Lake District. This is a large scale primary API manufacturing site which makes bulk sterile antibiotics. It uses cutting edge isolator technology in a primary environment, which was a bit of a steep learning curve.

David is experienced in most drug dose forms from sterile needles injection systems, explosive aseptic ampoules to inhalation devices, oral doses of microbial sensitive products and sticky capsules. Plus a great deal of primary manufacturing to boot.

Dr Tim Sandle

Tim Sandle is the Head of Microbiology at Bio Products Laboratory (BPL) 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 committees relating to pharmaceutical microbiology and cleanroom contamination control (including the ISO cleanroom standards), and he has acted as a spokesperson for serval 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

Bruno Šimek – Arguo

(put forward by Sanolabor & Sanol H)

Bruno graduated at the Faculty of Pharmacy and Medical Biochemistry in Zagreb, Master of Pharmacy Programme, and finished a postgraduate study in the field of Industrial Pharmacy at the School of Pharmacy, University of Manchester.

During his career he gained experience through all key areas within the pharmaceutical industry including production, quality control, development of formulations, pharmaceutical regulation and various segments of quality management.

He worked as Quality Assurance Director and also was responsible for batch release in pharmaceutical production.

In 2011, Bruno successfully launched a new business project company Arguo which is focused on providing support in various segments of the pharmaceutical industry. Among other things, this includes implementation and optimization projects of the GMP process, preparation for GMP inspections, support in specific processes such as validation and qualification, organization of educational programs from different GMP areas and implementation of GMP audits.

He is active in the Croatian Pharmaceutical Society, leading the Working Group for Industrial Pharmacy.

In all professional challenges, Bruno approaches each project with three fundamental principles: simplicity, pragmaticity and efficiency.

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 till the end of December 2017

Overseas membership includes:

- A quarterly technical newsletter (PDF version only) - January / April / July editions will be sent to you
- Member rates to attend additional meetings / conferences / training courses during the remainder of 2017
- Member rates to join Pharmig webinars to the end of 2017
- 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 LAST PAGE FOR ALL PHARMIG PUBLICATIONS

Exhibitor Opportunities

- There are limited exhibition places at the conference being held on Wednesday 18th October 2017.

Application will have to be approved by Sanolabor in the first instance and Sanolabor has the right to politely decline a company from exhibiting at the meeting.

Fees to exhibit:

- €575 + local taxes

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 29th September at the latest to confirm attendance.

Booking Form

DELEGATE FEES:

€90 + local taxes per person (£83 Sterling) - and receive automatic overseas Pharmig membership December 2017

DELEGATE BOOKING FORM

Company Name: _____

Company Address: _____

1st Delegate	2nd Delegate
First Name: _____	**First Name:** _____
Surname: _____	**Surname:** _____
Job Title: _____	**Job Title:** _____
Email*: _____	**Email*:** _____
Dietary Requirements: _____	**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.
** please provide your email address to receive further Pharmig information.*

Note: Individual fee includes refreshments, lunch and links to download presentations in advance of the meeting if available
Note: Fees exclude accommodation which needs to be booked directly with the hotel
Note: Payments MUST be made in advance by Friday 29th September to guarantee a place at the meeting

EXHIBITOR FEES:

- **Exhibiting €575+ local taxes to exhibit**

EXHIBITOR INFORMATION

Company Name: _____

Company Address: _____

1st Representative Name: _____	**2nd Representative Name:** _____
Job Title: _____	**Job Title:** _____
Email*: _____	**Email*:** _____
Dietary Requirements: _____	**Dietary Requirements:** _____

** please provide an email address to receive further Pharmig information.*
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 29th September to guarantee a place at the meeting

Payment

- Email / Fax booking forms to info@pharmig.org.uk / +44 (0) 1920 871 156 for a provisional place
- Pharmig can invoice you in Euro / 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 with click on meetings (only Sterling payments can be taken via the website)
- **Payment(s) can also be made via Sanolabor (Slovenia) – details outlined below:**

Bank: ABANKA d.d.
Slovenska cesta 58, 1517 Ljubljana, Slovenia
Bank account details: IBAN: SI56 0510 0800 0105 334
BIC: ABANSI2X
Reference code: Pharmig conference 2017

Note: Paymentš MUST be made in advance by Friday 29th September 2017 to guarantee a place

Venues

Hotel Address: HOTEL ŠPORT, GRAJSKA CESTA 2; SLOVENIA 8222 OTOCEC

Accommodation

- Limited accommodation has been reserved at HOTEL ŠPORT at €57 + taxes B&B per night – single occupancy. This price includes use of the hotel swimming pool and sauna
- Rooms need to be booked directly with the hotel **(please quote Sanolabor/Sanol H/Pharmig meeting** to ensure you receive the reduced rate)
- Hotel contact number: +386 08 20 50 300

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 continued help and support in organising the 2017 conference

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**

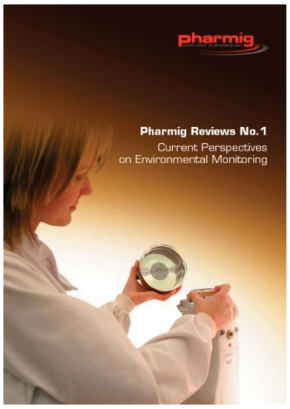
Current perspectives on Environmental Monitoring - Review # 1

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

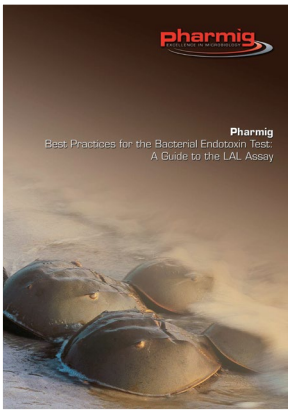
Member **£60** Non Member **£85**



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

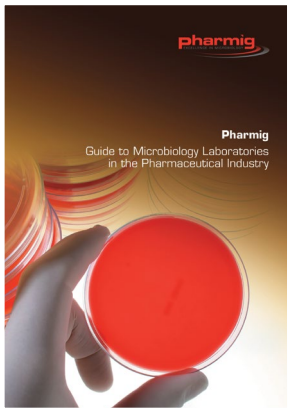
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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**



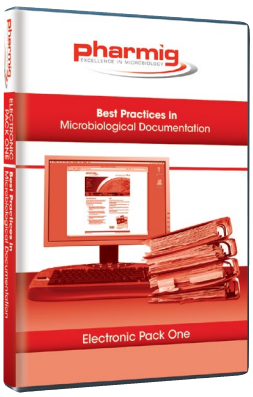
Best Practices in Microbiological Documentation - Electronic Pack One

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**



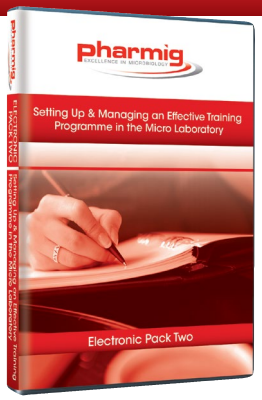
Setting up & Managing an Effective Training Programme in the Micro Laboratory – Electronic Pack Two

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

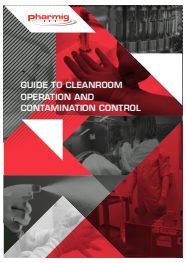
Publication orders can be placed via the website - www.pharmig.org.uk

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



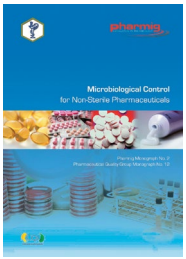
Member **£60**
Non Member **£85**

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.

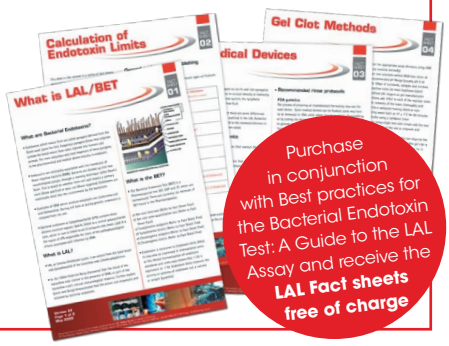
This publication is produced and sold as a PDF document only and is for the sole use of the individual purchasing it.

Member **£20**
Non Member **£35**

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**

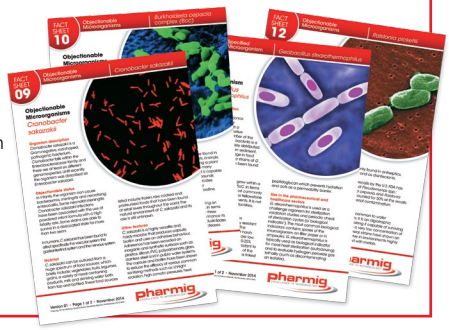
A series of 8 Microorganisms Fact Sheets

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**