pharmig
EXCELLENCE IN MICROBIOLOGY

Presents

Hot Topics Pharmaceutical Microbiology – India

ONE CONFERENCE - TWO LOCATIONS

Tuesday 17th July 2018 – **Hilton Bangalore Embassy Golf Links, Bangalore**

Thursday 19th July 2018 – **Hyatt Hyderabad Hotel, Hyderabad**

Leading experts include:

David Keen

Julie Roberts

Dr. Tim Sandle

Manish Bhaktar

Who will cover:

- Annex 1 updates
- Data integrity & new expectations
- Aseptic processing
- Developing a meaningful environmental monitoring programme
- Transfer disinfection
- Preparing for an audit
- How to operate in an aging facility

Attend and receive automatic overseas membership to the end of December 2018

Book early to avoid disappointment

Pharmig

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

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EXCELLENCE IN MICROBIOLOGY

Programme for Tuesday 17th July and Thursday 19th July

08.30 – 09.00 **Registration with tea/coffee**

09.00 – 09.15 **Chairs Introduction**

09.15 – 10.00 **Annex 1 update**
David Keen – Senior Global Microbiology Consultant, Ecolab & Pharmig Chair

10.00 – 10.45 **Data integrity and new expectations**
- Requirements for good data integrity - 'ALCOA'
- Common audit observations from regulators
- Implementation of a data integrity compliance programme
- Managing data integrity in your laboratory and at your production facility

Julie Roberts – Quality Director, J Roberts Associates Ltd & Pharmig Committee Member

10.45 – 11.15 **Morning break with tea/coffee and meet the exhibitors**

11.15 – 12.00 **Aseptic processing**
- Process simulation test (media fills) – requirements & expectations
- Common audit observations
- Development of media fill program
- Investigation and managing media fill failure
- Failure investigation – case study(s)

Speaker: Manish Bhatkar – Founder & CEO, RedLotus Pharmtech

12.00 – 12.45 **Developing a meaningful environmental monitoring programme** Via Video Link
- Methods of monitoring, specifications and alert levels
- Risk analysis and selection of sampling locations
- Data management; trending and review of data
- Annual review of the EM programme

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

12.45 – 13.00 **Introducing Pharmigs on-line interactive training module on: Cleaning and Disinfection of Cleanrooms**
Pharmig Committee Member

13.00 – 13.45 **Lunch and meet the exhibitors**

13.45 – 14.30 **Transfer disinfection**
- Regulatory position on sporicidal use
- Sources of organisms and risk to the transfer disinfection process
- Optimising the transfer disinfection process
- Establishing contact times
- Appropriate techniques

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

14.30 – 15.15 **Preparing for an audit – A practical approach**
- How to prepare your staff for the inspectors
- Getting documentation packages ready for presentation (qualification packages, trend reports etc)
- Presenting poor data

Julie Roberts – Quality Director, J Roberts Associates Ltd & Pharmig Committee Member

14.45 – 15.15 **Afternoon break with tea/coffee and meet the exhibitors**

15.15 – 16.00 **How to operate in an aging facility**
- Operating in an aging facility – what are the issues?
- How to manage the risks as your facility gets older

Speaker: Manish Bhatkar – Founder & CEO, RedLotus Pharmtech

16.00 – 16.45 **Practical and interactive workshop on: Risk Assessments – When they go wrong!**
- When should they not have been used?
- What are the consequences?

Led by: David Keen and supported by speakers present

16.45 – 17.00 **Closing remarks**

Please note:
All information addressed by the speakers are of their own/ their company opinions and viewpoints.
Pharmig is not responsible for any content presented at the meeting.
Pharmig also has the right to change the programme at any time due to unforeseen circumstances.
Pharmig has the right to cancel a meeting due to unforeseen circumstances. If this occurs attendees will only have their attendance fees reimbursed

About Your Presenters

David Keen

Senior Global Microbiology Consultant, Ecolab Lifesciences

David is a microbiologist working for Ecolab as a Senor Global Microbiology Consultant for their Lifesciences division. David got his first taste of Pharmig quite a depressing number of years ago. In 2007 he became a committee member of Pharmig. In November 2013 he had the honor of being elected as Pharmig Chair.

David started life at GSK Barnard Castle. Here he performed environmental monitoring and clean room qualification before moving on to sterile finished product testing.

David then moved to a small startup company called SCM Pharma. Here he set up a new microbiology lab and developed a new microbiology team. He helped design and qualify the new clean rooms. He then moved from microbiology to project management and became the technical manager.

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 events 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 makes bulk sterile antibiotics. It uses isolator technology in a primary environment, which was a bit of a steep learning curve.

David started a new role as a microbiological consultant for Ecolab in March 2018. In this role David utilizes his experience to help Ecolab's clients with microbiological and manufacturing issues, across the globe.

David is experienced in most drug dose forms from sterile needless 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. He is now dipping his toe into the world of disinfectants and contamination control – a microbiologists best friend.

Julie Roberts

Julie has 25 years in the Pharmaceutical industry working for multi-national companies such as AstraZeneca, GSK and Eli Lilly. In recent years she has worked in an international corporate role assessing sites for due diligence and inspection readiness across all dosage forms. As an experienced microbiologist, Julie has also designed, set up, managed and audited microbiology laboratories and provided remedial support where required. With a strong technical competency in API operations and parenteral manufacture, Julie has practical experience in water system design and qualification, clean room classification, EM programmes. Julie became eligible to work as a Qualified Person in Europe in 2001, is a power user of TrackWise and has lean Six Sigma experience as a Green Belt.

Since becoming an independent Consultant Julie has worked extensively in Asia, Europe and the US conducting on-site gap analyses against EU and US regulations, coaching, training and educating staff to remediate gaps and prepare them for FDA inspections and EMA/MHRA audits. Julie conducts work under her own company name 'J Roberts Associates' and also as a consultant for the US-based consultancy group 'Jeff Yuen & Associates Inc.', and the Irish-based consultancy group 'McGee Pharma International' and is a current Pharmig committee member.

Dr. Tim Sandle

(presenting via video link)

Tim is the Head of Microbiology at the UK Bio Products Laboratory. His 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 on several national and international committees relating to pharmaceutical microbiology and cleanroom control (including the ISO cleanroom standards), and he has acted as spokesperson for several microbiological societies. He is a committee member of the microbiology society Pharmig. Tim has written over one hundred-and-fifty book chapters, peer reviewed papers and technical articles relating to microbiology.

About Your Presenters

Manish Bhatkar

Manish Bhatkar is an experienced pharma professional, diligent in his core functional area (pharmaceutical technical operations) and committed to the profession. Before founding RedLotus Pharmtech Private Limited (A Technical Services Company) in 2016, in his 25 years of service, he has discharged executive as well as leadership responsibilities in the areas of design & development, manufacturing, qualification & validation, operations management, quality assurance, quality management, audits & compliance, regulatory affairs, technology transfer, project management, and technical consulting. He has worked in R&D, API's, formulations and technical consulting environments and has demonstrated equivalent capabilities in managing manufacturing, technical as well as quality operations with ease.

He was instrumental in establishing and growing the validations & GMP compliance services business vertical for a German pharmaceutical engineering house Pharmaplan GmbH (Now, NNE Pharmaplan) in India. As head of the Dabur Oncology Plc. Operations, in his 5 years' tenure in UK, he single handedly lead the efforts in resolving complex technological, regulatory and GMP compliance issues (including USFDA warning letter) that resulted in making commercial manufacturing and product supplies possible from the site. As head of Lupin Limited' Technical Services, he lead the mission to transform the quality mindset and culture at their Goa manufacturing facility for meeting the exceptional and extreme Japanese quality requirements/ expectations. International experience of working in different geographies and work cultures helped him further strengthen his technical as well as leadership skills and capabilities.

His main area of expertise is aseptic processing & areas of interests are sterility assurance, manufacturing technology, process validation, failure investigations, trouble-shooting, continuous improvement and resolution of complex technical/ regulatory/ GMP issues. Additionally, he has lead team of experts in preparing the inspectional observations of various regulatory agencies, such as WHO, ISO, USFDA, UK-MHRA, ANVISA, ENVIMA, Russia, Romania, Hungary, Germany etc.

Manish has worked with medium to large, well respected pharmaceutical products manufacturing and services organizations like Dr. Reddy's Laboratories Ltd., Lupin Limited, Dabur Oncology Plc. UK, Pharmaplan (India) Ltd., and Zydus Cadila. He has been involved in many projects from concept design to successful delivery of commercial product to the continuous improvement phases and also led organization(s) efforts and teams in managing and resolving regulatory challenges like regulatory review/ inspectional observations, warning letters and consent decree.

He is a postgraduate in Pharmaceutical Sciences and an active member of professional associations like ISPE, PDA, and IPA. In addition to being a pharma-professional he is also a regular speaker in industry & academia seminars/ conferences and a trainer on the topics like qualification and validation, process validation, quality systems etc. He is well travelled and has also worked on short and long international assignments particularly in the UK, USA & Japan.

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 Industries as well as the NHS and other not-for-profit related organisations

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 2018

Overseas membership includes:

- A quarterly technical newsletter (PDF version only - October)
- January / April / July editions will be emailed to you
- Member rates to join Pharmig webinars
- 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 is availability to exhibit at either or both locations (17th & 19th July)
- Bookings will be accepted in the order that completed forms are sent back
- Exhibitor booking form can be found on page 6 of this PDF

Fees:

To exhibit at one meeting:

- 45,702 INR + local taxes at 18% = total to pay 46,525 INR
- £500 sterling (equivalent fee)

To exhibit at both meetings:

- 82,262 INR + local taxes at 18% = total to pay 83,743INR
- £900 sterling (equivalent fee)

Booking Forms / Payment / Venues

DELEGATE FEES:

7313 INR + local taxes @ 18% = 7445INR Total to pay per person
£80.00 Sterling equivalent
(Cheques / bank transfers can be made payable to Shell Spark at the address listed below)

DELEGATE BOOKING FORM

Please tick which meeting you would like to attend

☐ **17th July – Bangalore** ☐ **19th July - Hyderabad**

1st Delegate

First Name: _____

Surname: _____

Job Title: _____

Company Name: _____

Address: _____

_____

_____

Email: _____

☐ **Please tick this box to allow Pharmig to contact you**

Dietary Requirements: _____

_____

2nd Delegate

First Name: _____

Surname: _____

Job Title: _____

Company Name: _____

Address: _____

_____

_____

Email: _____

☐ **Please tick this box to allow Pharmig to contact you**

Dietary Requirements: _____

_____

If you want to send more than 2 people - please add additional names to the booking form

Note: Individual fee includes refreshments, lunch and links to download presentations in advance of each meeting

Note: It excludes accommodation which needs to be booked directly with the hotel(s)

Note: Payments MUST be made in advance by Friday 6th July to guarantee a place at either meeting

Booking Forms / Payment / Venues

EXHIBITOR FEES

Attending 1 meeting 45,702 INR + local taxes at 18% = Total to pay 46,525 INR/ £500 Sterling
Attending both meetings (subject to availability) 82,262 INR + local taxes at 18% = Total to pay 83,743INR / £900 Sterling (Discount of 9,600 INR (£900 Sterling)

EXHIBITOR BOOKING FORM - Please tick which meeting you would like to exhibit at

☐ 17th July 2018, Hilton Bangalore Embassy Golf Links - Bangalore

☐ 19th July 2018, Hyatt Hyderabad Hotel – Hyderabad

EXHIBITOR INFORMATION

Company Name: _____

Company Address: _____

1st Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

1st Representative Name: _____

Job Title: _____

Email: _____

Dietary Requirements: _____

Note: Fees include an allocated 'space' in the exhibition area of 3m (length) x 2m (width), up to 2 representatives, refreshments and lunch, links to download presentations in advance of the meetings and delegate list (name and company).

Note: Fees exclude accommodation which needs to be booked directly with the hotel(s)

Note: Exhibitors to bring their own stands to fit within the space measurements allocated. The hotel(s) will provide a small dressed take and chairs if required.

Note: Payments MUST be made in advance by Friday 6th July to guarantee a place at either meeting

VENUES

Tuesday 17th JULY
Address: Hilton Bangalore Embassy Golf Links:

Embassy Golf Links Business Park, Off Intermediate Ring Road, Bangalore 560071 ,India

T: +91 80 66799999 M: +91 7090712009 F: +91 80 6679 9000

EMAIL VISIT WEBSITE

Thursday 19th JULY
Address: Hyatt Hyderabad, Gachibowli :

Hyatt Hyderabad Gachibowli Road No.2, I.T Park, Gachibowli, Hyderabad, 500019, India,

T: +91 40 4848 1234 F: +91 40 4848 1235

EMAIL VISIT WEBSITE

PAYMENT

- Email / Fax booking forms to info@pharmig.org.uk / +44 (0) 1920 871 156 for a provisional place
- Individual provisional bookings can also be made via the Pharmig website www.pharmig.org.uk and click on meetings
- Payments can be made by DD (Demand Draft) or Cheque (at par) using the following details.

Account Name: Shell Spark
Bank Name: ICICI BANK Limited
Branch name: Vasant Vihar branch
Branch Address: 114, 1st Floor block no.2, Hiranandani Meadows, off Pokharan Road 2 emerald plaza, Thane west Mumbai-400610, Maharashtra
IFSC Code: ICIC0000927
MICR No: 400229101

Note: Payments MUST be made in advance by Friday 6th July to guarantee a place at either meeting

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 Shell-Spark for their help and support in organising these meetings

SHELL-SPARK

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**

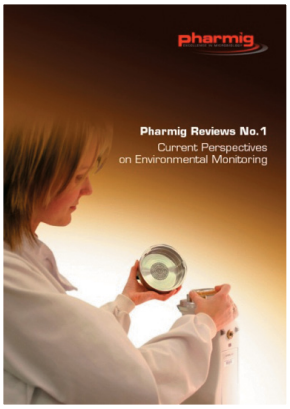
Current perspectives on Environmental Monitoring - Review # 1

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

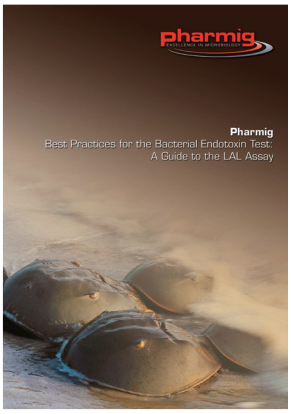
Member **£60** Non Member **£85**



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

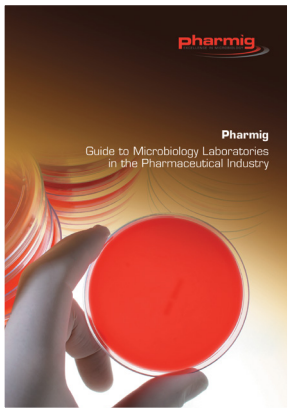
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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**



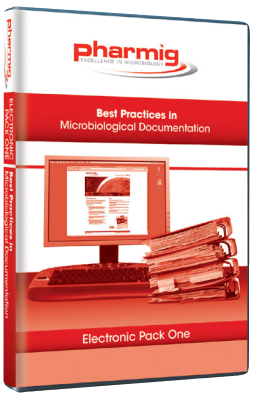
Best Practices in Microbiological Documentation - Electronic Pack One

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**



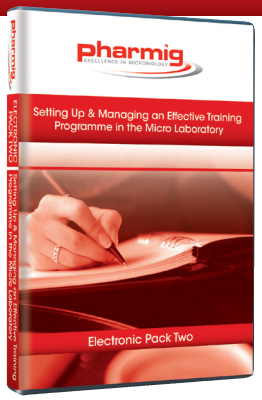
Setting up & Managing an Effective Training Programme in the Micro Laboratory – Electronic Pack Two

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

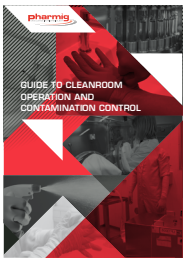
Publication orders can be placed via the website - www.pharmig.org.uk

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



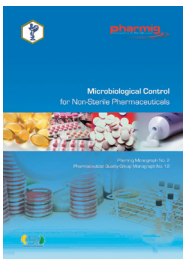
Member **£60**
Non Member **£85**

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.

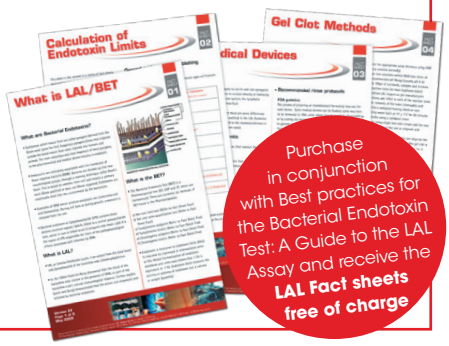
This publication is produced and sold as a PDF document only and is for the sole use of the individual purchasing it.

Member **£40**
Non Member **£60**

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**

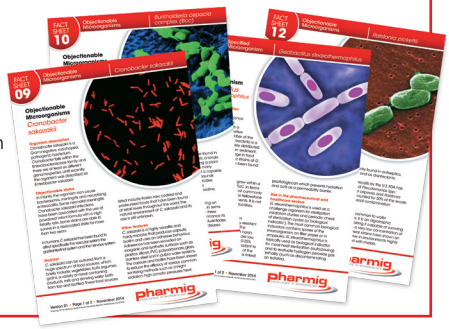
A series of 8 Microorganisms Fact Sheets

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**