



Hot Topics in Pharmaceutical Microbiology:

Pharmig's 18[™] Annual Irish Conference 2025



PLUS, a one-day meeting covering: Best Practices in Cleaning & Disinfection

Dublin (Portmarnock Hotel)

Wednesday 28[™] May 2025: Annual Irish Conference

Thursday 29TH May 2025: Best Practices in Cleaning & Disinfection

Conference: Leading industry experts will be covering key hot topics including

- Rocking regulations and galloping guidance's
- Facts or Fake? Interpretation and significance of microbiological test results
- An approach to microbiological technical risk assessments for non-sterile manufacture – A GSK perspective
- Continuous microbial monitoring in light of the drive towards continuous manufacturing and how to meet the Annex 1 Contamination Control Strategy (CCS)
- Air visualization studies
- Enzyme indicators

One-day: Best Practices in Cleaning & Disinfection

- This will consist of lecture-led presentations and a practical section covering 'back to basics' on disinfection methods
- Attend this day and receive a copy of Pharmig's latest Guide to Cleaning & Disinfection of Pharmaceutical Facilities – A Roadmap to Regulatory Compliance

EARLY BIRD OFFER:

Send 2 or more people from the same site & discounts will apply until:

Friday 5TH April

(See booking form for more information)



HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY

Pharmig's 18th Annual Irish Conference Wednesday 28th May 2025

09.00 - 09.30

Registration

09.30 - 09.40

Chairs Welcome

Patrick Nieuwenhuizen – Director/Principal Consultant, PharmaLex & Pharmig Committee

09.40 - 10.20

Rocking regulations and galloping guidance's

The past 24 months have seen an array of new regulations, standards, guidance's, and pharmacopeial monographs. Struggling to keep up with the myriads of changes and want to know what is pertinent for the pharmaceutical microbiologist and quality professional to know about? This presentation will give you an overview and a roadmap for keeping compliant.

Tim Sandle – Pharmaceutical Microbiologist & Head of QA GxP Compliance, Sterility Assurance and Quality Risk Management - Kedrion/BPL & Pharmig Committee Member

10.20 – 11.00

Facts or Fake? Interpretation and significance of microbiological test results

- (In-) Accuracy of microbial count
- Definition of specifications and limits
- Some general challenges for identification methods **Frank Mertens – Laboratory Consultant, Saercon**

11.00 – 11.30

Meet & greet the exhibitors with tea/coffee

11.30 – 12.10

An approach to microbiological technical risk assessments for non-sterile manufacture – A GSK perspective

- Overarching regulations and guidance
- What are microbiological technical risk assessments in GSK2
- GSK generic microbiological technical risk assessment for solid oral formulations

Jonathan Willis - Microbiologist, GlaxoSmithKline

12.10 – 12.50

Continuous microbial monitoring in light of the drive towards continuous manufacturing and how to meet the Annex 1 Contamination Control Strategy (CCS)

The presentation will touch on what Pharma 4.0 is about. Review Annex1 microbial monitoring requirements and look at ISO 14698:2003, EN17141:2020 and the Technology of Active Air Sampling, how to implement it alongside Particle Counters and Settle plates, selecting sample locations.

We will also touch on new technologies such as Bioluminescence and Florescence technologies for rapid micro air sampling and show a couple of case studies of how not to do microbial monitoring and the importance of smoke studies to help understand the dynamics of cleanroom air flows and why it is important to reduce interventions during aseptic manufacturing. We will also touch on some new robotic technologies and the drive to remove the random particle generators (humans) outside of the sterile manufacturing process.

- What is continuous microbial monitoring and how to apply it
- What is Pharma 4.0 and how does it tie into a CCS (Annex1:2022)
- How do you select the right microbial monitoring strategy following both ISO 14698:2003 & EN17141:2020
- Which is the best sampling location for my application and how to leverage air sampling with particle counting
- What are the advantages of Rapid Micro detection and what are the disadvantages
- Let's look at new robotic sterile manufacturing technologies
- Let's review case studies of what can go wrong when implementing a microbial monitoring system

Jason Kelly - Applications Director, Lighthouse Worldwide Solutions

12.50 - 14.00

Lunch in the exhibition area

14.10 – 14.40

Air visualization studies

- Regulatory guidance: When are air visualization studies required and what purpose do they serve?
- Principles of First Air
- Practical aspects: What to do and what not to do

Patrick Nieuwenhuizen – Director/Principal Consultant, PharmaLex & Pharmig Committee

14.40 - 15.10

Open discussion sessions

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

Go to page 3 to view open discussion sessions

HOT TOPICS IN PHARMACEUTICAL MICROBIOLOGY

Pharmig's 18th Annual Irish Conference Wednesday 28th May 2025

15.10 – 15.30

Meet & greet the exhibitors with tea/coffee

16.10 - 16.40

Strategic validation approaches to biodecontamination with enzyme indicators

- How to approach, benefit and streamline the validation lifecycle approach for bio-decontamination processes
- Includes case studies and aligned principles of enzyme indicator use

Kate Marshall - Technical Director, Protak Scientific Ltd

16.10 – 16.30

Panel discussion, additional questions and close of Conference

OPEN DISCUSSION SESSIONS

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

(Attendees to choose ONE out of the 2 listed - please tick which one on your booking form)

A) Non-Sterile open surgery

The sterile pharmaceutical sector has a well-defined set of expectations and regulations which provide clear statements relating to microbiological controls and monitoring. In contrast, the expectations for non-sterile pharmaceuticals are poorly defined, with few specifics written in either legislation or guidance publications.

Join this informal open surgery to ask questions, benchmark, find out how others have solved problems and delt with challenges in non-sterile product manufacturing. Topics may include microbial identification, objectionable organisms, risk assessment, or anything else that's challenging you now.

B) Sterile open surgery

Sterile manufacturing continues to be challenging. The past few years have seen the implementation of the new EU GMP Annex 1, the requirement for facilities to develop a detailed contamination control strategy, and the range of sterilisation technologies that vendors are using to supply materials is expanding fast.

Whether your questions are about sterilisation methods, environmental monitoring, water system controls, bioburden testing, or the overall strategy, please drop in and share your experiences with other delegates and the Pharmig committee.

Please note: All information addressed by the speakers are of their own / company opinions. Pharmig is not responsible for any content presented at the meeting.

Pharmig also has the right to change the programme at any time due to unforeseen circumstances.



BEST PRACTICES IN CLEANING AND DISINFECTION:

Technical Presentations and Practical Approaches Thursday 29[™] May 2025

09.00 - 09.30

Registration with tea/coffee

09.30 - 09.40

Chairs Welcome

Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL and Pharmig Committee

09.40 - 10.20

Cleaning and Disinfection and the GMP EU regulatory landscape – session TBC

Cleaning and disinfection processes are often undervalued. This presentation reviews the regulatory requirements and 'best practice' recommendations for cleaning and disinfection of controlled manufacturing areas. This session will focus on EU regulations and what to look for which will include. These considerations include:

- Cleaning & Disinfection, what it means
- Residues
- Rotation
- Validation
- Material transfer

Jim Polarine Jr - Principal Consultant, Technical Services, Steris Corporation

10.20 - 11.00

Disinfection Selection

- What products and methods should you choose for which scenarios? Here we will discuss some common solutions to reoccurring quandaries on what to do where?
- Rotation and residues
- Large and Small Surfaces
- Material transfer

Neil Simpson – Technical Service Group Manager EMEA, Contec Inc

11.00 – 11.30

Mingle with exhibitors over tea & coffee

11.30 – 12.10

Practicalities of performing disinfection efficacy studies

The use of disinfectants as agents to control microbiological contamination of an environment is well established and is governed by regulatory bodies in both Europe and the United States. Data demonstrating the efficacy claim of a disinfectant, whether it is bactericidal, fungicidal, sporicidal or viricidal, is a clear requirement of BPR or EPA for a disinfectant manufacturer to achieve registration. In Europe, European Norm (EN) standards provide reference to required test methods to be used by disinfectant manufacturers to support claims of microbiocidal activity.

This presentation provides an overview of the EN standards available for disinfectant efficacy testing and whilst providing an oversight to specific test phases performed for registration, will also provide guidance on how these standards may be utilized for end user validation.

Kim Morwood – Managing Director, Eurofins/MGS Laboratories & Pharmig Committee Member

12.10 - 13.10

Lunch

13.10 – 14.10

Back to basics on disinfection methods PRACTICAL SESSION

Appropriate training for all personnel dealing with cleaning and disinfection activities is vital. Training programs should include the correct application techniques for cleaning and disinfection, including:

- Mopping / Large Surface Disinfection Contec
- Wiping / Small Surface Disinfection AstraZeneca
- Material Transfer Ecolab

Delegates will be divided into smaller groups to then rotate round each practical session outlined above

14.10 – 14.30

Afternoon tea & coffee with the exhibitors

14.30 – 15.10

Phase III: In situ evaluation of a disinfectant regime

This presentation will provide an overview of the current guidance in EN 14885 and USP <1072> and elsewhere to perform an in-situ assessment. It will also outline a possible framework for a Phase III study and discuss how to handle the data generated to support the overall validation package for cleanroom disinfection.

Gary Feehan- Manager QA Aseptics, Abbvie

15.10 – 15.50

Addressing the challenge of mould in GMP environments

- Sources of mould in cleanrooms
- Risks and challenges
- Implementation of robust CAPAs

Patrick Nieuwenhuizen - Principal Consultant, PharmaLex & Michael Nguyen - Global Technical Consultant, Ecolab

BEST PRACTICES IN CLEANING AND DISINFECTION:

Technical Presentations and Practical Approaches Thursday 29TH May 2025

15.50 – 16.30

Sporicidal disinfectants: Problems of definition, application, and selection

- Sporicidal disinfection
 - Defining a sporicide
 - Some different types of sporicides available
 - Microbial resistance
- Practical issues
 - Mechanisms of actions
 - Safety concerns
- Key issues with using sporicides
 - Factors affecting efficacy
 - The importance of time

Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL and Pharmig Committee 16.30 – 16.45

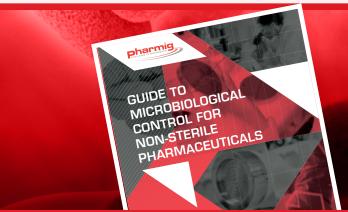
Closing remarks and end of meeting

Please note: All information addressed by the speakers are of their own / company opinions. Pharmig is not responsible for any content presented at the meeting.

Pharmig also has the right to change the programme at any time due to unforeseen circumstances.

By attending, Best Practices in Cleaning & Disinfection on Thursday 29th May you receive a copy of Pharmig's latest Guide to: Cleaning & Disinfection of Pharmaceutical Facilities - A Roadmap to Regulatory Compliance





CLICK HERE TO SEE PHARMIG'S RANGE OF PUBLICATIONS & FACT SHEETS THAT MAY BE OF INTEREST TO YOU.

PRICING / BOOKING FORMS / PAYMENT DETAILS (6&7)

DISCOUNTED OFFERS for sending 2 or more delegates ends on Friday 4th April 2025

INFORMATION ON FEES & PAYMENTS

- Please tick the relevant meeting fee(s) and dates outlined in Booking Form A, B or C below
- You will need to send pages 6&7 back to Pharmig to register your booking

MICROBIOLOGY WEDNESDAY 28 TH MAY									
-	people from the same s 2025. Please tick relevan		e a discount on the full 1st at '	ttendee rate as outlined	d below until				
MEMBER FEES 1ST MEMBER 2ND MEMBER	EURO/STERLING €787 / £645 €667 / £545		NON-MEMBER FEES 1ST NON-MEMBER 2ND NON-MEMBER	EURO/STERLING €919 / £745 €787 / £645					
BOOKING FORM B BEST PRACTICES IN CLEANING & DISINFECTION THURSDAY 29 TH MAY									
BOOK THIS MEETING AND RECEIVING A COPY OF PHARMIG'S GUIDE TO: Cleaning & Disinfection of Pharmaceutical Facilities – A Roadmap to Compliance									
Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 4th April 2025. Please tick relevant boxes below									
MEMBER FEES	EURO/STERLING		NON-MEMBER FEES	EURO/STERLING					
1ST MEMBER	€667 / £545		1ST NON-MEMBER	€919 / £745					
2ND MEMBER	€546 / £445		2ND NON-MEMBER	€787 / £645					
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If you wish to attend both meetings – further discounted fees are as follows: Please tick relevant boxes below (you will receive a copy of the Disinfectant Guide as this option includes Thursday 29th May)									
MEMBER FEES	EURO/STERLING		NON-MEMBER FEES	EURO/STERLING					
1ST MEMBER	€1324 / £1090		1ST NON-MEMBER	€1615 / £1340					

NOTE: *Euro fee is higher to cover conversion rates

€1022 / £840

2ND MEMBER

FEES INCLUDE (If attending in-person): lunch / refreshments on the day and a link to download presentations in advance of the meeting(s). **Conference fees do not include accommodation, which must be booked and paid for directly with the hotel.**

2ND NON-MEMBER

€1434 / £1190

REGISTRATION & PAYMENT INFORMATION (6&7)

Please reserve place(s) for the Pha running on Wednesday 28th & Thursd			in Environm	ental Monitoring		
Company:						
Address :						
Contact name (if different from the del	egate):					
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Job Title:		B) Sterile o	ppen surgery			
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Dietary requirements:	B) Sterile o	ppen surgery				
Email or fax your completed booking f Email: info@pharmig.org.uk Fax: t Please tick the relevant box below Please raise an invoice to cover the UK BACS Sort code: 60 19 28 Acco Wire Transfer: Natwest Bank, 118 SWIFT (BIC) NWB K IBAN GB64 NWBK (Please quote company approved pu	orm for a confirmed place: o +44 (0) 1920 871 156 delegate fee(s)	.1 1JH £/€				
I/we wish to pay by credit card (Pha						

VENUE INFORMATION

DUBLIN

THE VENUE

Portmarnock Hotel. – 10miles to the north of Dublin City and a 15-minute drive from Doublin Airport from Dublin Airport with good road access to Cork. 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 €190 (B&B single occupancy) 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.

PRIVACY POLICY

By registering for these events, I accept the processing of my Personal Data. Pharmig will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Pharmig will only send information in relation to this order or similar events/publications/training courses etc. Pharmig may send your name and company only to other companies attending the same event in the form of an attendee list.

Your full personal data will not be disclosed to third parties. See also privacy policy at https://www.pharmig.org.uk/en/privacy-policy/.

You can ask for the modification, correction or deletion of your data at any time via an email to maxine@pharmig.org.uk

Pharmig Publications, Fact Sheets & Online Training Modules

Pharmig publications, fact sheets, and on-line training modules have been written and produced by industry leaders. They contain and cover key information relating to GMP standards and regulations.

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

Guide to microbiological control for Non-Sterile pharmaceuticals

This Guide is relevant to non-sterile pharmaceutical, cosmetic and toiletry manufacturing industries. There have been significant changes in the microbiological regulations, controls, and testing of non-sterile products. Much of the changes has been prompted by the many recalls of non-sterile products worldwide.

- Microbiological testing and data handling
- Facility and equipment design
- Objectionable microorganisms
- Cleaning & disinfection
- Risk assessment & data management
- Environmental monitoring
- Regulatory expectations for nonsterile manufacture

Member £80 Non Member £110



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

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

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

Member £60 Non Member £85



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 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**



For more information contact

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

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



Guide to microbiology laboratories in the pharmaceutical industry

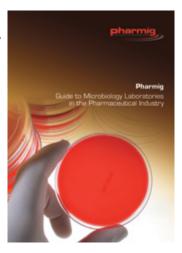
This Guide details what Pharmig considers to be best practice for establishing and operating microbiology laboratories in pharma and associated industries.

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



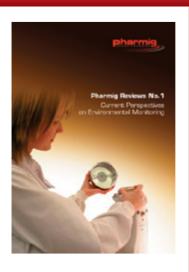
Current perspectives on environmental monitoring - Review # 1

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



Rapid & alternative microbiological methods

Rapid Microbiological Method technologies aim to provide more sensitive, accurate, precise and reproducible test results when compared with conventional, growth-ased 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'.

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.

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.



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



Commonly Occurring Organisms -Pharmig's latest series of 8 fact sheets

This series of 8 fact sheets will cover:

- Dermacoccus nishinomiyaensis
- Corvnebacterium
- tuberculostearicum
- Cutibacterium acnes
- Micrococcus luteus
- Member £30 Non Member £50
- Kocuria rhizophila
- Staphylococcus hominis
- Paenibacillus glucanolyticus
- Microbacterium liquefaciens



A series of 8 Water Microbiota **Fact Sheets**

This series of 8 fact sheets will cover:

- Ralstonia pickettii
- Stenotrophomonas maltophilia
- Burkholderia cepacia complex
- Acinetobacter baumannii
- Brevundimonas diminuta

Member £30 Non Member £50

- Sphingomonas paucimobilis
- Pseudomonas aeruginosa
- General overview of water microorganisms



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/BFT?
- 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



For more information contact

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

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



Pharmig's Interactive Online Training Modules

The Pharmig Training Portal can be used via a stand-alone log-on, or integrated into your electronic learning management system.

The Pharmig Training Portal gives your team access to high quality online training.

By watching a series of detailed videos, followed by a multiplechoice assessment, they will learn about essential subjects relating to their working environment. On successful completion of a module, participants will be issued with a certificate of completion.

Personnel training made easy, quantifiable and interactive. These training modules are aimed at those who are new to working in GMP cleanrooms including production, cleaning, QA, QC and engineering staff.



Module 1: Cleaning & Disinfection of Cleanrooms

Module Chapters Include:

- Introduction to contamination in cleanrooms
- Preparation and storage of cleaning agents and disinfectant
- Application Techniques

3

Module 2: Gowning for Non-sterile Facilities

Module Chapters Include:

- The importance of personal hygiene
- Hand hygiene washing, disinfection, gloving
- Gowning for non-sterile areas
- Gowning for laboratory areas
- Garment laundering

Module 3: Gowning for Sterile Facilities

Module Chapters Include:

- The importance of personal hygiene
- Hand hygiene washing, disinfection, gloving
- Gowning for non-sterile areas
- Gowning for sterile areas

- Gowning for laboratory areas
- Gowning qualification
- Garment laundering and sterilisation

More detailed information regarding each module chapters and learning can be found at: www.pharmig.org.uk/en/products/online-training



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