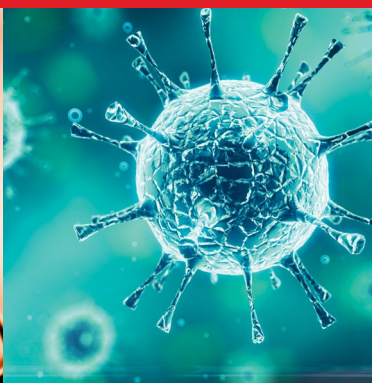


**27<sup>th</sup> Annual  
Event**

**Pharmig**  
EXCELLENCE IN MICROBIOLOGY

## Latest Updates & Hot Topics in Pharmaceutical Microbiology



### Attend and hear about:

- **MHRA:** Recent findings and expectations
- Contamination control strategy
- Wipe efficacy test methods and opportunities for development
- API filling in isolators
- Current activities of the USP Microbiology Expert Committee
- Microbiological considerations for ATMPs
- Microbial biomass production in a multitude of novel contexts
- Challenges in viable colony counting by visual inspection of growth media as part of environmental monitoring programs
- Round up of new standards and regulations during the past year
- Control of raw materials, quality, specs, and suppliers
- The new Annex 1 and its impact on environmental monitoring activities
- Cleanroom cost, quality, and environmental sustainability – can you afford to compromise? A microbiological perspective
- And more....

### Early Bird Offer Sending 2 or more people?

Book by Friday 20th  
September and additional  
delegates receive a  
**20% discount** on  
listed prices\*

### PLUS Special discounts for NHS

See booking page  
for further  
details

### Leading microbiology experts include:

**Philip Rose**  
MHRA

**Mark Hodgson**  
GlaxoSmithKline

**Laurent LeBlanc**  
bioMeriëux

**Kate Coleman**  
Pharmalex Ireland

**Jeanne Moldenhauer**  
Excellent Pharma  
Consulting (USA)

**Donald C. Singer**  
USP Microbiology  
Expert Committee (USA)

**Willy Verstraete**  
Ghent University  
Belgium

**Ulrich Herber**  
Charles River  
Laboratories

**Helena Windsor**  
Mycoplasma  
Experience

**Kim Morwood**  
MGS Laboratories

**Robert Smith**  
Smiro Qualitas

**Dr. Tim Sandle**  
BPL

**Dr. Anna Lovatt**  
GlaxoSmithKline

**Venue:** The Nottingham Belfry Hotel, Mellors Way,  
Off Woodhouse Way, Nottingham, NG8 6PY

**Date:** 13th & 14th November 2019

# Latest Updates & Hot Topics in Pharmaceutical Microbiology

## Wednesday 13th November 2019

**08.30 – 09.00** Registration

**09.00 – 09.10** Chairman's welcome & introduction  
*David Keen – Senior Global, Microbiology Consultant, Ecolab & Pharmig Chairman*

**09.10 – 09.50** MHRA: Recent findings and expectations  
*Philip Rose – Senior GMDP Inspector, MHRA*

**09.50 – 10.30** Contamination control strategy

- New regulatory requirements
- How these requirements may affect your processes
- Issues with implementation
- How the requirements are affected by other regulatory groups

*Jeanne Moldenhaeur – Vice President, Excellent Pharma Consulting (USA)*

**10.30 – 11.10** Wipe efficacy test methods and opportunities for development

- Existing EU and US methods and key differences
- Identification of critical test parameters
- Industry requirements and end user application
- Future developments

*Kim Morwood – Director, MGS Laboratories*

**11.10 – 11.15** Announcing Pharmig's latest publications

**11.15 – 11.45** Meet the exhibitors over tea/coffee

**11.45 – 12.25** API filling in isolators  
*Mark Hodgson – Process Manager, GlaxoSmithKline*

**12.25 – 13.00** Open discussion sessions (please see the booking form for the list of topics to choose from)

**13.00 – 13.30** Pharmig AGM - All current members please do attend

**13.30 – 14.30** Lunch in the exhibition areas

**14.30 – 15.10** Current activities of the USP Microbiology Expert Committee

- Updates related to USP Chapters :
  - Guidelines on endotoxins Test: <1085>
  - Tests for *B.cepacia* complex and <60>
  - Rapid Microbial tests for release of sterile short shelf life products: <1071>
- Donald C. Singer, M.S. – ASQ Fellow & GSK Senior Fellow, Member of USP General Chapters - Microbiology Expert Committee (USA)*

**15.10 – 15.45** Microbiological considerations for ATMPs

- What is an ATMP?
- Achieving an appropriate sterility assurance level
- Practical microbiological challenges
- Rapid microbiological methods
- Lessons learnt

*Robert Smith – Director, Smiro Qualitas Ltd*

**15.45 – 16.10** Afternoon tea/coffee with the exhibitors

**16.10 – 16.50** A thought provoking presentation to end the first day on: Microbial biomass production in a multitude of novel contexts  
*Consumers and policy makers struggle with aspects of novel protein production for food and feed. They also have to deal with a variety of concerns in terms of environmental sustainability and climate change. A surprising opportunity is that aerobic fermentation of microbial biomass can provide positive contributions to all of these issues.*  
*Willy Verstraete – Professor, Ghent University Belgium*

**16.50 – 17.00** Summary & close of day one

**19.00 – 20.00** Pre-dinner drinks in the exhibition areas

**20.00 'till late** Gala dinner & dance and Pharmig's, now infamous, quiz! (Dress code: smart / casual)

Taxis will be provided by Pharmig to bring anyone staying at the Premier Inn Nottingham West Hotel to the Nottingham Belfry for the gala dinner. (Own travel arrangements will need to be made for the return journey)



Pharmig will be using an interactive app at this year's event so that we can interact with you before, during and after the conference – and you can look to engage with your peers too!

# Latest Updates & Hot Topics in Pharmaceutical Microbiology

## Thursday 14th November 2019

**09.00 – 09.05** Chairman's opening remarks and champagne draw

**09.05 – 09.45** New research: Challenges in viable colony counting by visual inspection of growth media as part of environmental monitoring programs

- Presentation of a methodology to evaluate the performance of the human eye in detection
- Inter-personnel variability of operators performing visual inspection
- Determination of key critical parameters for reading

**Laurent LeBlanc - Pharmaceutical and Culture R&D Manager, bioMérieux, Healthcare Business**

**09.45 – 10.25** Round up of new standards and regulations during the past year  
**Dr. Tim Sandle – Head of Microbiology & Sterility Assurance, BPL**

**10.25 – 11.00** Tea / coffee with the exhibitors

**11.00 – 11.40** Open discussion sessions continued...

**11.40 – 12.20** Control of raw materials, quality, specs, and suppliers

- Strategy to approach microbiological specification development systematically
- 'Real' raw material quality
- Your role in the excipient customer-supplier partnership
- Organizations can influence microbiological control

**Donald C. Singer, M.S. – ASQ Fellow & GSK Senior Fellow, Member of USP General Chapters - Microbiology Expert Committee (USA)**

**12.20 – 13.30** Lunch in the exhibition area

**13.30 – 13.35** Exhibitor prize draws in the conference room

**13.35 – 14.15** The new Annex 1 and its impact on environmental monitoring activities

- The novel focus on trending environmental monitoring data
- The powerful requirements in detail
- Why they make sense – case studies
  - Which will include a case study on: *seasonal changes in the microflora*

*and its impact on cleaning, disinfection, product validations etc*

- How to implement – a proposal  
**Ulrich Herber – Director of Technology & Market Development, Charles River Laboratories**

**14.15 – 14.55** Cleanroom cost, quality, and environmental sustainability – can you afford to compromise? A microbiological perspective How to get the balance right between:

- Reducing capital cost for new cleanroom facilities and managing an increasing cost of quality as a cleanroom ages
- Preventing contamination and reducing cleanroom waste
- Keeping the cleanroom environment at the correct level of control while reducing energy consumption

**Kate Coleman - Senior Consultant/ Director Quality and Compliance, Pharmalex Ireland**

**14.55 – 15.15** Afternoon tea/coffee with the exhibitors

**15.15 – 15.55** Mycoplasma safety testing: adapting detection methods to the new biopharmaceutical kids on the block

- Evolution of mycoplasma testing in the biopharmaceutical industry
- NAT based detection vs culture
- Mycoplasma safety testing for ATMPs
- Selecting a test method which is 'fit for purpose' for your product

**Helena Windsor – Managing Director, Mycoplasma Experience**

**15.55 – 16.35** Fungi: The good, the bad, and the ugly!

- How fungi has a negative effect on cleanroom operations
- Medical issues with fungi
- New research opportunities and areas of study using fungi
- How new research can affect our current thinking

**Jeanne Moldenhaeur – Vice President, Excellent Pharma Consulting (USA)**

**16.35 – 16.40** Summary & close of conference

*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.*

## 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.

Please tick 2 out of the 4 listed below on your booking form

**A. Measurement of disinfection residues: a practical demonstration and discussion**

Matt Cokely – Ecolab and additional member suppliers

**B. Microbial identification discussion session**

Dr. Anna Lovatt – GlaxoSmithKline and additional member suppliers

**C. Environmental monitoring discussion session**

Tim Sandle – BPL additional member suppliers

**D. General microbiology surgery**

Led by: Pharmig member consultants / Pharmig Committee

*Do feel free to submit your questions in advance to give the session leaders time to prepare responses and to encourage discussion within the group at large on the day. Please email your questions to [info@pharmig.org.uk](mailto:info@pharmig.org.uk)*

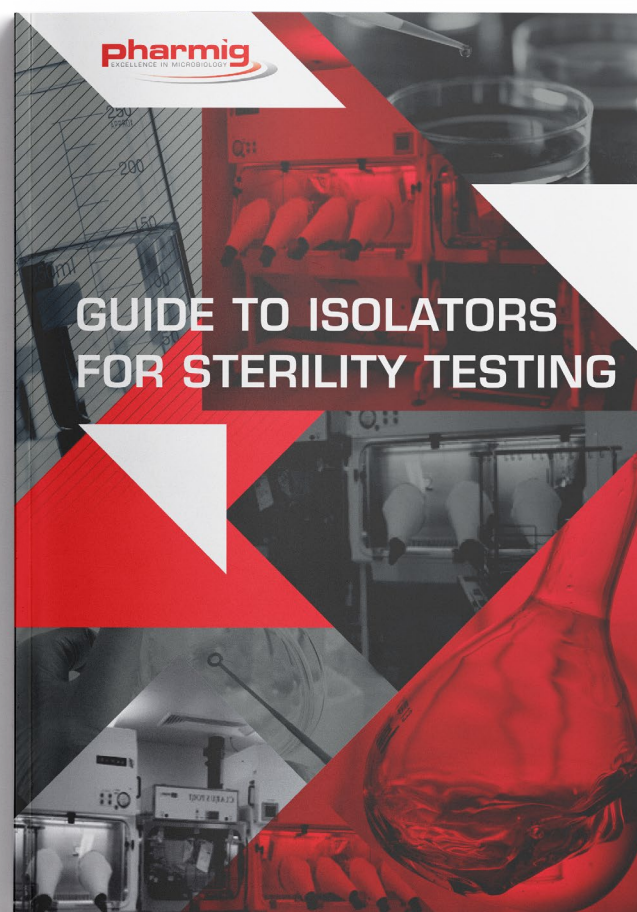
Launching Pharmig's

## Guide to Isolators for Sterility Testing

Pharmaceutical isolators are commonly used for the sterility test and provide an effective means for controlling contamination, providing they are designed and operated effectively. Pharmig's latest publication discusses design, construction, commissioning, maintenance, use and monitoring of pharmaceutical sterility testing isolators. The approach to validation protocols is explained and the guide includes some useful technical recommendations, along with details on vapour hydrogen peroxide decontamination, in-use and periodic isolator tests and environmental monitoring. The guide will assist both those purchasing a new isolator and will act as useful reference source for those currently operating isolators, in relation to meeting current GMP expectations.

**Member price £60**

**Non Member price £85**



Please do visit the Pharmig stand to see sample copies of all our publications and fact sheet series and to pick up a publication order form. Alternatively, visit the Pharmig website to order online.

**[www.pharmig.org.uk](http://www.pharmig.org.uk) Or Email: [info@pharmig.org.uk](mailto:info@pharmig.org.uk)**

**Pharmig would like to thank the following companies who have booked to exhibit and support the conference this year.**





# PHARMIG 27<sup>TH</sup> ANNUAL CONFERENCE

## 13TH & 14TH NOVEMBER 2019 REGISTRATION FORM

Please reserve \_\_\_\_\_ place(s) for Pharmig's 27th ANNUAL CONFERENCE held at The Nottingham Belfry Hotel on the 13th & 14th November 2019.

\* To be eligible for additional attendee discounted rates advertised – all proposed delegates from the same site must be booked on at the same time.

Company: \_\_\_\_\_

Address : \_\_\_\_\_ Tel: \_\_\_\_\_

\_\_\_\_\_ Email: \_\_\_\_\_

**MAIN CONTACT** (if different from delegates attending the Conference)

First Name : \_\_\_\_\_ Surname: \_\_\_\_\_

Job Title: \_\_\_\_\_ Telephone: \_\_\_\_\_ Email: \_\_\_\_\_

### DISCUSSION SESSION OPTIONS (EACH DELEGATE TO CHOOSE 2 OUT OF THE 4 LISTED BELOW)

- |   |                                     |
|---|-------------------------------------|
| 1. Measurement of disinfection residues | 2. Microbial Identification         |
| 3. Environmental Monitoring             | 4. Microbiology general Q&A surgery |

**1st Delegate** (please complete all sections)

First Name: \_\_\_\_\_

Surname: \_\_\_\_\_

Job Title: \_\_\_\_\_

#### Open Discussion Sessions

*Please tick 2 sessions you wish to attend.*

1	2	3	4	Gala dinner(13th) (included in fee)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Please tick this box to enable Pharmig to contact you through its digital app before/during/after the conference

Please state any specific dietary requirements \_\_\_\_\_

I wish to add to the invoice £92.50 B&B per night at the Premier Inn Nottingham West Hotel: ☐ 12<sup>th</sup> Nov ☐ 13<sup>th</sup> Nov  
(Please see accommodation notes for a detailed explanation)

**2nd Delegate** (please complete all sections)

First Name: \_\_\_\_\_

Surname: \_\_\_\_\_

Job Title: \_\_\_\_\_

#### Open Discussion Sessions

*Please tick 2 sessions you wish to attend.*

1	2	3	4	Gala dinner (13th) (included in fee)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Please tick this box to enable Pharmig to contact you through its digital app before/during/after the conference

Please state any specific dietary requirements \_\_\_\_\_

I wish to add to the invoice £92.50 B&B per night at the Premier Inn Nottingham West Hotel: ☐ 12<sup>th</sup> Nov ☐ 13<sup>th</sup> Nov  
(Please see accommodation notes for a detailed explanation)

## METHODS OF PAYMENT

(please tick relevant option)

- ☐ Cheque for £ \_\_\_\_\_ to follow in post. To cover the delegate fee(s) only / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation (please circle/highlight correct option)
- ☐ Please raise an invoice. To cover the delegate fee(s) only / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation (please circle/highlight correct option)
- ☐ Please quote Purchase Order Number \_\_\_\_\_. To cover the delegate fee(s) only / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation (please circle/highlight correct option)
- ☐ I wish to pay by credit card -Pharmig will contact you for details. To cover the delegate fee(s) only / to cover delegate fee(s) and the Premier Inn Nottingham West the accommodation (please circle/highlight correct option)

# PHARMIG 27<sup>TH</sup> ANNUAL CONFERENCE

13<sup>TH</sup> & 14<sup>TH</sup> NOVEMBER 2019 CONFERENCE INFORMATION

## CONFERENCE FEES

Conference fees are detailed below and include lunches, Conference gala dinner & dance, refreshments and, links sent out in advance to download conference presentations. Pharmig has 'gone green' and will no longer be providing printed documentation folders. Conference fees do not include accommodation, which must be booked and paid for directly with the hotel if staying at the Nottingham Belfry Hotel or, to be added to your Conference fee invoice if you choose to stay at the Premier Inn Nottingham West Hotel.

NB: Fees must be paid by Friday 25th October 2019 in order to guarantee a place(s) at the Conference.

### PHARMIG MEMBER FEES

Delegate £745 / €826

\*Euro fee is higher to cover conversion rates

### NON MEMBER FEES

Delegate £1145 / €1260

\*Euro fee is higher to cover conversion rates

Discounted rates are available for NHS and non-profit making organisations

NHS Member Fees £400

Non NHS Member Fees £500

## ACCOMMODATION

Pharmig have secured rooms at two venues this year – please read the following carefully

### 1. Nottingham Belfry (venue for the 2-day conference) - £112 B&B per person / per night

To book your accommodation at the Nottingham Belfry Hotel at the rate of £112 pp B&B **please contact the hotel directly on: Tel: 0115 973 9393** (state you are booking for the Pharmig Conference to receive the reduced rate). Rooms are non-refundable.

*It is advised to book directly with the hotel rather than going through other websites to guarantee your room booking.*

#### VENUE HOTEL ADDRESS:

Nottingham Belfry Hotel  
Mellors Way  
Off Woodhouse Way  
Nottingham  
NG8 6PY

### 2. Premier Inn Nottingham West Hotel - £92.50 B&B per person / per night (8 minute journey to the Nottingham Belfry Hotel by car)

To book this accommodation – Pharmig has to do this on your behalf. As such please mark on your booking form if you would like Pharmig to invoice you for accommodation at this hotel and – for how many nights (12th & 13th November OR just the 13th November)

**Note:** cancellations of rooms for this hotel can **only be made up until Monday 21<sup>st</sup> October** – after that they are non-refundable.

#### HOTEL ADDRESS:

**(8 mins by car to the Nottingham Belfry Hotel)**  
The Phoenix Centre  
Millenium Way West  
Nottingham  
NG8 6AS

*Taxis will be provided by Pharmig to bring anyone staying at the Premier Inn Nottingham West Hotel to the Nottingham Belfry for the gala dinner on the 13th. (Own travel arrangements will need to be made for the return journey)*

Maxine Moorey  
Pharmig  
T5 The Maltings  
Roydon Road  
Stanstead Abbots  
Hertfordshire, SG12 8HG

Tel: +44 (0) 1920 871 999  
Fax: +44 (0) 1920 871 156  
Email: [info@pharmig.org.uk](mailto:info@pharmig.org.uk)

#### 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.

Pharmig  
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