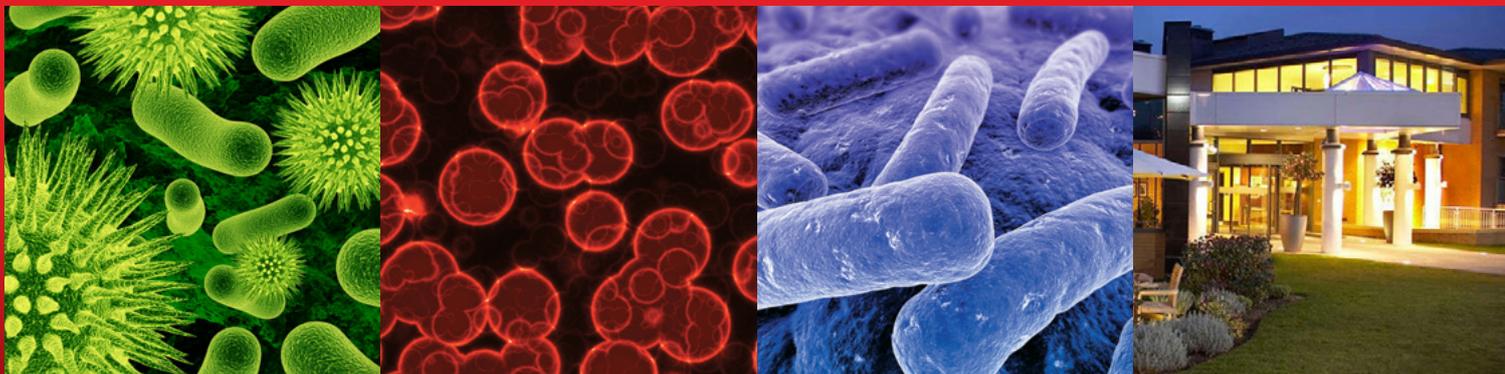


**26<sup>th</sup> Annual  
Event**

**Pharmig**  
EXCELLENCE IN MICROBIOLOGY

## Latest Updates and Hot Topics in Microbiology



### Attend and hear about:

- **MHRA current inspection findings and Annex 1 update!**
- **Remediating pharmaceutical water system biofilms**
- **Microbiological culture media: use and application in healthcare and pharmaceuticals**
- **Sterility assurance strategy without borders**
- **Hygienic design and BAD practices**
- **Aseptic manufacturing: the open flaw in using humans in your critical operations**
- **Endotoxin testing: What could possibly go wrong?**
- **Fungal and bacterial spores excursions in cleanrooms – case studies**
- **Developing a strategy for the implementation of modern microbiological methods**
- **When risk assessments go wrong!**
- **And more....**

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

Book before the  
12th October and  
the 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

**Karen Capper**  
AstraZeneca

**Tim Sandle**  
BPL

**Paul Newby**  
GlaxoSmithKline

**Veronika Wills**  
Associates of  
Cape Cod (USA)

**Tony Mayhall**  
MQA Solutions

**Seb Hodgkin**  
Cell Medica

**Jim Polarine**  
Steris

**David Keen**  
Ecolab

**T.C. Soli**  
Soli PharmaSolutions (USA)

**Miriam Guest**  
AstraZeneca

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

**Date:** 28th & 29th November 2018

# Latest Updates and Hot Topics in Microbiology

## Wednesday 28th November 2018

09.00 – 09.30

**Registration**

09.30 – 09.45

**Chairman's welcome and introduction**

*David Keen – Senior Global, Microbiology Consultant, Ecolab, Life Sciences*

09.45 – 10.25

**Current inspection findings in microbiology (steriles & non-steriles) and Annex 1 update**

- What is the Inspectorate seeing both in the UK and overseas with regards to deficiencies in microbiology?
- Annex 1 revision: background to revision, progress and current status.

*Philip Rose – GMDP Inspector, Inspection, Enforcements and Standards, MHRA*

10.25 – 11.05

**Microbiological challenges in the manufacturing of cellular and gene therapy advanced therapeutic medicinal products (ATMPs)**

- Overview of somatic cellular and gene therapies (ATMPs) and their manufacture
- Sterility assurance considerations
  - Differences and challenges compared to traditional pharmaceutical products
- Microbiological testing of cellular and gene therapy products
- Future challenges

*Seb Hodgkin – Vice President Quality, Cell Medica*

11.05 – 11.15

**Announcing Pharmig's latest publications**

11.15 – 11.45

**Meet the exhibitors over tea/coffee**

11.45 – 12.25

**Remediating pharmaceutical water system biofilm – What to do after it gets ahead of you**

- Are you sure there is a problem?
- What is the scope of the problem?
- What caused the problem?
- What can remediate the problem?
- What can prevent its recurrence?
- Are you sure it worked?
- Prevention is far easier than remediation!

*Teri C. ("T.C.") Soli, Ph.D. – President, Soli Pharma Solutions, Inc. & Expert Committee Member, United States Pharmacopeia*

12.25 – 13.00

**Open discussion sessions (see booking form for 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 area**

14.30 – 15.10

**Hygienic design and BAD practices**

- Considerations for hygienic design
  - Overview of valves
  - Do's and don't's of pipework
  - Pumps and sumps
- Practical examples of equipment will be used during this session

*Tony Mayhall - QP & Quality Consultant, MQA Solutions & Pharmig Honorary Member*

15.10 – 15.40

**Microbiological culture media: use and application in healthcare and pharmaceuticals**

The results of the Pharmig culture media survey revealed, including:

- What tests are run for the QC of culture media?
- Are environmental isolates necessary? If so, when and how many?
- Which temperatures are best for growth promotion?
- Does the validation of culture media differ from routine testing?
- Are supplier audits required?

These and many other questions are addressed through Pharmig's benchmarking of industry best practice.

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

15.40 – 16.10

**Afternoon tea / coffee with the exhibitors**

16.10 – 16.50

**Aseptic manufacturing: The open flaw in using humans in your critical operations**

- Human behaviours and error
- Nudge theory
- Using a little bit of microbiological knowledge to help change how humans behave

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

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 and Dance (Smart/Casual Dress Code)**

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)

# Latest Updates and Hot Topics in Microbiology

## Thursday 29th November 2018

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

**09.05 – 09.45** **Sterility assurance strategy without borders**

- Case study overview of a multi-site product
- Input materials coming together from multiple locations
- Strategic approach to assuring sterility on storage and shipping

**Miriam Guest – Associate Principal Scientist, AstraZeneca**

**09.45 – 10.25** **Endotoxin testing: What could possibly go wrong?**

- Assay performance
- User performance
- Sample interference
- Trending: Out of trend / Out of specification results

**Veronika Wills – Associate Manager, Technical Services, Associates of Cape Cod**

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

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

**11.40 – 12.20** **A careful step towards WFI harmonization?**

- Why a "Careful Step"?
- Challenge of tight microbial and endotoxin control
- History of WFI microbial specifications
- Microbial control = endotoxin control (mostly)
- Forms of endotoxin and removal strategies
- Sounds easy. How hard can this be?
- Cost impact of EP WFI monograph changes
- Anticipated problems
- Validation and inspection scrutiny
- Avoiding easily preventable excursions
- Who wants to be first?

**Teri C. ("T.C.") Soli, Ph.D. – President, Soli Pharma Solutions, Inc. & Expert Committee Member, United States Pharmacopeia**

**12.20 – 13.30** **Lunch in the exhibition area**  
**Fungal and bacterial spores excursions in cleanrooms – case studies**

Industry has seen an increase in the number and species of bacterial endospores and

mold spores found in many facilities. This presentation will focus on ways to proactively limit bacterial and mold spore contamination from incoming items into cleanrooms and limit other sources of spore contamination control. Current industry regulations in the US and Europe will be discussed related to sporicides and disinfectants. Additionally, the presentation will convey a robust approach to addressing bacterial and fungal spores by covering personnel practices, in coming items into cleanrooms, facility design and conditions, and the products used to address bacterial and mold spores as well as more resistant bacterial spore species such as *bacillus cereus*. New and recent case studies will be covered which focus on new antimicrobial chemistries and their performance against fungal and bacterial spores in cleanrooms.

**Jim Polarine, Senior Technical Services Manager – Steris Corporation**

**14.10 – 14.50** **Consortium activities on developing a strategy for the implementation of Modern Microbiological Methods in place of traditional testing for new products**

- Drivers for modernisation of microbiology methods
- Challenges for implementation in place of traditional methods
- Modern methods, potential applications and readiness levels
- Implementation strategies
- MHRA regulatory engagement and the benefits of early engagement and using the innovation centre
- Consortium purpose, status and activities

**Karen Capper - Head of Microbiology, Global Product Development, Astra Zeneca & Paul Newby - Microbiology Modernisation Lead, ASD – Future Analytical & Control Technologies - GlaxoSmithKline**

**14.50 – 15.30** **When risk assessments go wrong!**

- When should they not have been used?
- What are the consequences?

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

**15.30 – 15.45** **Summary and close of conference**

**15.45 – 16.00** **Departure tea & coffee**

## 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. Endotoxins: Current hot topics and issues

### C. Back-to-basics microbiology discussion group

Are you new to industry or need a quick refresher / validation of what you already know about core micro related skills such as lab techniques, media testing, ID, sampling etc? If the answer is yes – do feel free to join this discussion group at the 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.

### B. Rapid methods

Where is industry at and are you considering using a RM?

### D. Microbiology general Q&A surgery including Annex 1 discussion - where is it at?

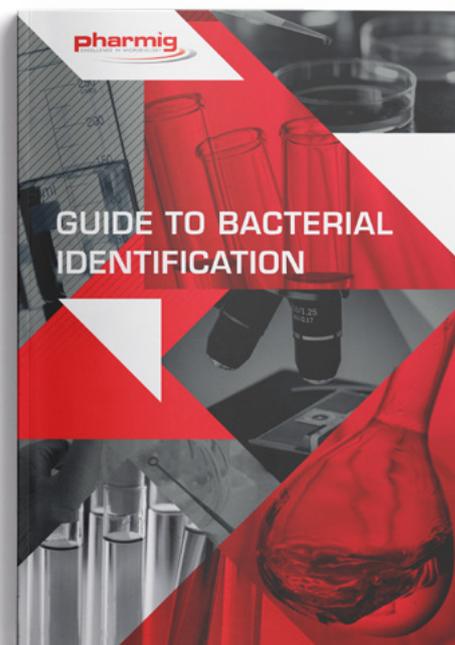
- Submit your questions in advance to give the session leaders time to prepare responses and to encourage discussion within the group at large on the day

## Launching Pharmig's

# Guide to Bacterial Identification

Written by Dr. Anna Lovatt (GlaxoSmithKline) and Dr. Tim Sandle (BPL) with the foreword written by Andrew Hopkins (MHRA) - this Guide acts either as a training aid for those new to the pharmaceutical microbiology or, as a means for laboratories to benchmark their systems against. It explains and discusses:

- *Microbial taxonomy*
- *Differential staining and growth based approaches to identification*
- *Phenotypic identification methods*
- *Genotypic methods*
- *Polypasic approaches to identification*
- *Identification system qualification*
- *Common errors that occur when performing identifications*
- *The basis of an identification strategy for your laboratory*



**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.

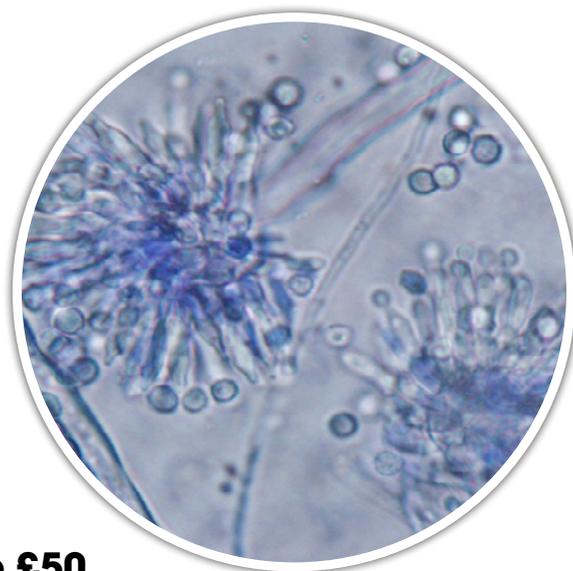
[www.pharmig.org.uk](http://www.pharmig.org.uk) Or Email: [info@pharmig.org.uk](mailto:info@pharmig.org.uk)

Launching Pharmig's

## Series of 8 Fact Sheets on Water Microorganisms

These will cover:

- *Ralstonia pickettii*
- *Stenotrophomonas maltophilia*
- *Burkholderia cepacia complex*
- *Acinetobacter baumannii*
- *Brevundimonas diminuta*
- *Sphingomonas paucimobilis*
- *Pseudomonas aeruginosa*
- General overview of water microorganisms



Member price £30

Non Member price £50

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





# PHARMIG 26<sup>TH</sup> ANNUAL CONFERENCE

## 28TH & 29TH NOVEMBER 2018 REGISTRATION FORM

Please reserve \_\_\_\_\_ place(s) for Pharmig's 26th ANNUAL CONFERENCE held at The Nottingham Belfry Hotel on the 28th & 29th November 2018.

\* To be eligible for additional attendee discounted rates advertised – all proposed delegates from the same site must be booked on at the same time by Friday 12th October 2018.

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

1. Endotoxins

3. Back-to-basics microbiology discussion group

2. Rapid Methods

4. Microbiology general Q&A surgery

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

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

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

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

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

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

**1st Delegate**

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

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

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

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

**Open Discussion Sessions**

*Please tick 2 sessions you wish to attend.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Gala dinner (28th) (included in fee)</b>
<input type="checkbox"/>				

**2nd Delegate**

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

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

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

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

**Open Discussion Sessions**

*Please tick 2 sessions you wish to attend.*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Gala dinner(28th) (included in fee)</b>
<input type="checkbox"/>				

**ACCOMMODATION AT THE PREMIER INN NOTTINGHAM WEST HOTEL ONLY (PLEASE SEE ACCOMMODATION NOTES FOR A DETAILED EXPLANATION)**

**DELEGATE 1:** I wish to add to the invoice £90.50 B&B per night at this hotel:  27th November  28th November

**ACCOMMODATION AT THE PREMIER INN NOTTINGHAM WEST HOTEL ONLY**

**DELEGATE 2:** I wish to add to the invoice £90.50 B&B per night at this hotel:  27th November  28th November

Please tick this box to enable Pharmig to continue to contact you the attendee(s) about the Conference and other events:

Email or fax your completed booking form for a confirmed place:

Email: info@pharmig.org.uk

Fax: to +44 (0) 1920 871 156

Cheque for £ \_\_\_\_\_ sterling / € \_\_\_\_\_ euro to cover delegate fee(s) enclosed

Cheque for £ \_\_\_\_\_ sterling / € \_\_\_\_\_ euro to follow

Total of £ \_\_\_\_\_ sterling / € \_\_\_\_\_ euro transferred electronically

Please supply invoice F.A.O.: \_\_\_\_\_

Please quote purchase order number: \_\_\_\_\_

I wish to pay by credit card (Pharmig will contact you for details)

# PHARMIG 26<sup>TH</sup> ANNUAL CONFERENCE

28<sup>TH</sup> & 29<sup>TH</sup> NOVEMBER 2018 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 16th November 2018 in order to guarantee a place(s) at the Conference. LAST YEAR WAS A SELL-OUT!

### PHARMIG MEMBER FEES

Delegate £745 / €860

\*Euro fee is higher to cover conversion rates

### NON MEMBER FEES

Delegate £1145 / €1310

\*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) - £107 B&B per person / per night

To book your accommodation at the Nottingham Belfry Hotel at the rate of £105 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 - £90.50 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 (27th & 28th November OR just the 28th November)

**Note:** cancellations of rooms for this hotel can **only be made up until Monday 22nd October** – after that they are non-refundable.

*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)*

#### HOTEL ADDRESS:

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

Maxine Moorey  
Pharmig  
T5 The Maltings  
Roydon Road  
Stanstead Abbotts  
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  
T5 The Maltings  
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Hertfordshire  
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