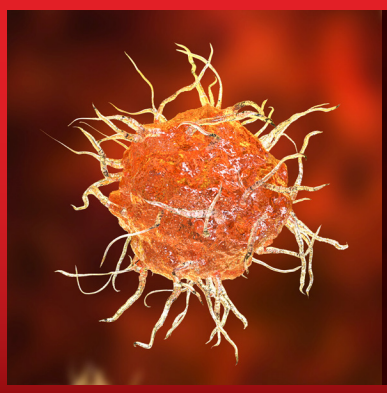
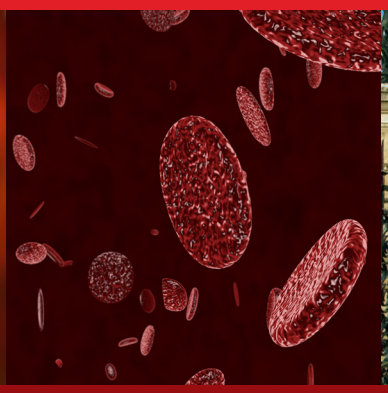
25th Annual Event

pharmig
EXCELLENCE IN MICROBIOLOGY

Pharmaceutical Microbiology: The Past; Present; and Future





Attend and hear about:

- The Use of Rapid Microbiological Methods: An MHRA perspective
- *Burkholderia Cepacia* Complex and Aqueous Non-sterile Drugs: A CDER Perspective
- Industry Case Study: A Microbial Investigation of Contamination by *Burkholderia multivorans*
- An Alternative Approach to Equipment Sanitization
- Understanding Human Error: Our Role as Ambassadors for Future Human Error Prevention
- Regulatory Updates and the Implications of Brexit Relevant to Microbiology and Industry as a Whole
- Risk Assessment and Quality Risk Management – 10 Years On and Where We Need to Go in Microbiological QRM
- The Development of thermostable Adenylate Kinase (tAK) Indicators for Decontamination Process Monitoring in Pharmaceuticals
- Changes to the USP around Sterility Testing and Parametric Release
- What Innovative 'Eco-Microbiology' has Potential for the Needs of the Next Decade?

Early Bird Offer

Sending 2 or more delegates from the same site?

Book by Friday 29th September and additional delegates receive a 20% discount on listed prices*

PLUS

Special discounts for NHS

See booking page for further details

Hear From The Regulators:

Andrew Hopkins
MHRA

Kevin O'Donnell
HPRA

John Metcalfe
CDER, FDA

Plus Leading Industry Experts:

Geet Verdonk
Merck

Willy Verstraete
LabMET

Edward Tidswell
Merck

Neil Lewis
P&G

Les Meader
Foresight Innovations Ltd

Mark Sutton
Public Health England (PHE)

Venue: Crowne Plaza Heythrop Park, Chipping Norton, Oxfordshire

Date: 29th & 30th November 2017

Pharmaceutical Microbiology: The Past; Present; and Future

Wednesday 29th November 2017

09.00 – 09.30 **Registration**

09.30 – 09.35 **Chairman's Welcome and Introduction**
David Keen – Microbiology Manager, GlaxoSmithKline and Pharmig Chair

The Past

09.35 – 09.50 **Past Microbiology: How it has Changed over the Last 25 Years. An Ex-Inspectors & Microbiologist Point of View**
David Begg & Sharon Johnson - Pharmig Honorary Members

The Present: Current Topics and 'Hot' Issues & The Future: Where Are We Going?

09.50 – 10.30 **The Use of Rapid Microbiological Methods: An MHRA perspective**
Andrew Hopkins – Expert GMDP Inspector, MHRA

10.30 – 11.15 ***Burkholderia Cepacia* Complex and Aqueous Non-sterile Drugs: A CDER Perspective**
- US code of federal regulations and objectionable organisms
- FDA current thinking: *Burkholderia Cepacia* complex risk to non-sterile aqueous drugs
- Case Study: *Burkholderia cepacia* complex contamination of a non-sterile nasal spray: is a recall warranted?

John Metcalfe, PhD, Master Microbiology Reviewer, CDER, FDA

11.15 – 11.45 **Meet the Exhibitors over Tea / Coffee**

11.45 – 12.25 **Industry Case Study: A Microbial Investigation of Contamination by *Burkholderia multivorans***
- A contamination by *Burkholderia multivorans*: "the Perfect Storm"

Geert Verdonk – Director Global Center of Expertise Microbiology, Merck

12.25 – 13.05 **Open Discussion Sessions**
Previous informal discussion sessions have been extremely well received by delegates encouraging networking and exchange of thoughts outside of the 'lecture-led presentations. Delegates will be able to attend TWO of the following topics:
- Cleaning & Disinfectants
- Endotoxins
- Rapid Methods
- Environmental Monitoring
- Data Integrity
- Microbiology General Q&A Surgery

13.05 – 13.30 **Pharmig AGM**
All Members please do attend

13.30 – 14.30 **Finger Buffet Lunch in the Exhibition Area**

14.30 – 15.15 **An Alternative Approach to Equipment Sanitization**
Effective sanitization is difficult to prove, positive verification is rare/difficult due to the inherent contamination risks. This presentation provides an alternative methodology for the validation of sanitization conditions which could both simplify and optimize the sanitization process. This approach can lead to reduced costs, sustainable processes and microbiological control together with documented proof of efficacy.
Neil Lewis – Global Household Care Microbiologist, P&G (USA)

15.15 – 15.30
Are you looking to enhance your cleanroom operator training programme? Pharmig now offers interactive online training. This session will introduce you to the first training module: "Cleaning and Disinfection of Cleanrooms"

15.30 – 16.00 **Tea / Coffee with the Exhibitors**

16.00 – 16.45 **Understanding Human Error: Our Role as Ambassadors for Future Human Error Prevention**
- Defining an error
- Why errors occur
- The brain's role in human error
- Contributing factors; behaviours; processes; organisation
- Your role in human error
- Prevention in the future

Les Meader – Managing Director, Omnia CS Ltd & Managing Director, Foresight Innovations Limited

16.45 – 16.55 **Announcing Pharmig's Latest Publications that are Due to be Launched Very Soon!**

16.55 – 17.00 **Summary & Close of Day One**

18.30 – 19.30 **Pre-dinner drinks in the Enstone Suite Hall**

19.30 'till late **Gala Dinner and Dance**
(Black Tie preferable / Smart Dress Code)

Pharmaceutical Microbiology: The Past; Present; and Future

Thursday 30th November 2017

09.00 – 09.05 **Chair's Opening Remarks and Champagne Draw**

The Present: Current Topics and 'Hot' Issues & The Future: Where Are We Going?

09.05 – 09.40 **Regulatory Updates and the Implications of Brexit Relevant to Microbiology and Industry as a Whole - A Snapshot of:**

- Annex 1
- Brexit
- EMA/FDA coordination

Andrew Hopkins – Expert GMDP Inspector, MHRA

09.40 – 10.20 **Risk Assessment and Quality Risk Management – 10 Years On and Where We Need to Go in Microbiological QRM**

- Common and evolving challenges
- Risk-based concepts in standards, guidance, regulations, technical papers
- Past, present, future?
- Industry quality performance metrics
- Common deficiencies in risk assessments – 4 issues, and 5 tools to address them
- Changing the paradigm of aseptic manufacturing risk assessment – future state
- So, where are we?

Edward Tidswell, PhD - Executive Director, Microbiology Quality Assurance, Merck & Co., Inc. &
Kevin O'Donnell – Market Compliance Manager, HPRA

10.20 – 11.00 **Tea/Coffee with Exhibitors**

11.00 – 11.40 **Open Discussion Sessions Continued**

11.40 – 12.20 **The Development of thermostable Adenylate Kinase (tAK) Indicators for Decontamination Process Monitoring in Pharmaceuticals**

- Development of tAK indicators as a rapid read-out surrogate marker for assessing decontamination process efficacy
- Demonstration of the correlation between tAK indicator inactivation and BI kill in gaseous decontamination systems
- Building a case to support implementation of tAK indicators in pharmaceuticals

Mark Sutton – Scientific Leader for Healthcare Biotechnology, PHE (Public Health England)

12.20 – 13.30 **Finger Buffet Lunch in the Exhibition Area**

13.30 – 14.15 **Changes to the USP around Sterility Testing and Parametric Release**

Edward Tidswell, PhD - Executive Director, Microbiology Quality Assurance, Merck & Co., Inc

14.15 – 15.25 **Spotlight on the Regulators – Q&A Session**

Submit your questions in advance or on the day (anonymously if preferred) and Pharmig will present them to the regulator panel for discussion

Andrew Hopkins – MHRA,
John Metcalfe - CDER, FDA,
Kevin O'Donnell - HPRA

15.25 – 16.10 **What "Innovative Eco-Microbiology" has Potential for the Needs of the Next Decade ?**

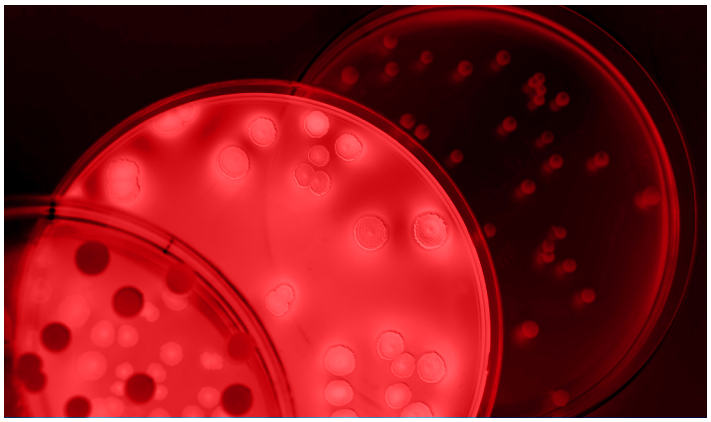
Willy Verstraete - LabMET, University of Ghent, Belgium

16.10 – 16.20 **Summary and Close of Conference**

16.20 **Departure Tea & Coffee**

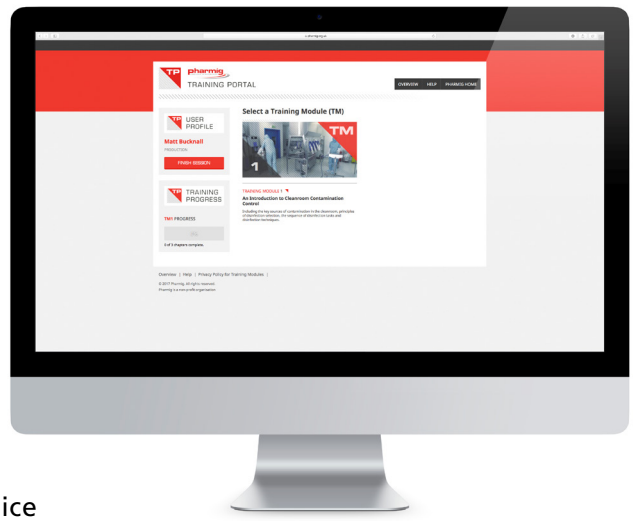
Please note: all information addressed by the speakers and discussion session leaders are of their own/ their company opinions and viewpoints. Pharmig is not responsible for any content presented at the meeting.

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



Launching Pharmig's first interactive on-line training module on:

Cleaning and Disinfection of Cleanrooms



- Pharmig is proud to announce its new training portal. A dynamic interactive online training tool which will make:
  - Personnel training easy
  - Convenient
  - Quantifiable
- The Pharmig Training Portal (TP) features high quality demonstration footage for the training of cleanroom operatives in the Pharmaceutical, Healthcare, Cosmetics and Medical Device Industries
- Each training video is followed by detailed multiple choice questions about the subjects covered in the video modules.
- Each user is issued with a personalised certificate upon successful completion of the module
- The Pharmig Training Portal features full administrator control enabling you to:
  - Set the required pass mark
  - Monitor and manage user activity
- All of which results in better trained operatives working to best practice

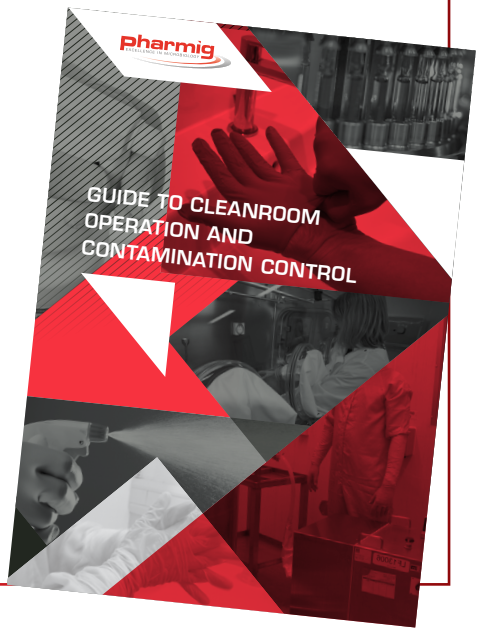
Interested?

Then please do visit the Pharmig stand for more information and a video demonstration of the on-line Training Portal capabilities

PLUS

It's finally here…and available to order now…

Pharmig's Guide to Cleanroom Operation and Contamination Control

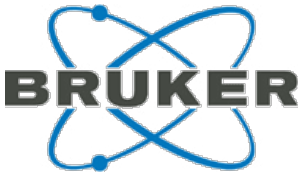


This publication provides a short and informative introductory guide to cleanrooms. Cleanrooms provide controlled, critical environments for both sterile and non-sterile pharmaceutical manufacturing and as such this Guide covers the following:

- Introduction to cleanrooms
- Contamination control
- Cleanroom standards
- Cleanroom classification
- Critical cleanroom parameters
- Additional microbiological considerations

Visit the Pharmig website www.pharmig.org.uk to order on-line
or
Email: info@pharmig.org.uk

Pharmig would like to thank the following companies who have already booked to exhibit at this year's conference



PHARMIG 25TH ANNUAL CELEBRATORY CONFERENCE

29TH & 30TH NOVEMBER 2017

DELEGATE REGISTRATION FORM

Please reserve ____ place(s) for Pharmig's 25th Annual Conference held at Crowne Plaza Heythrop Park, Chipping Norton, Oxfordshire on the 29th & 30th November 2017.

** 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 29th September 2017.*

DISCUSSION SESSION OPTIONS (EACH DELEGATE TO CHOOSE 2 OUT OF THE 6 TOPICS LISTED BELOW)

1. Cleaning & Disinfectants
2. Endotoxins
3. Rapid Methods
4. Environmental Monitoring
5. Data Integrity
6. Microbiology General Q&A Surgery

Company: _____

Address : _____

MAIN CONTACT (IF DIFFERENT FROM DELEGATES ATTENDING THE CONFERENCE)

First Name: _____ **Surname:** _____

Tel: _____ **Email:** _____

1st Delegate *(please complete all sections)*

First Name: _____

Surname: _____

Job Title: _____

Email: _____

Open Discussion Sessions
Please tick 2 sessions you wish to attend.

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

I wish to attend the gala dinner on the 29th (inc in fee) ☐

Please state any specific dietary requirements: _____

2nd Delegate *(please complete all sections)*

First Name: _____

Surname: _____

Job Title: _____

Email: _____

Open Discussion Sessions
Please tick 2 sessions you wish to attend.

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

I wish to attend the gala dinner on the 29th (inc in fee) ☐

Please state any specific dietary requirements: _____

If you wish to send more colleagues – please complete another booking form and send with this one

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 25TH ANNUAL CELEBRATORY CONFERENCE
29TH & 30TH NOVEMBER 2017

CONFERENCE INFORMATION

HOTEL INFORMATION

Conference fees are detailed below and include: lunches, refreshments, Conference gala dinner & dance, 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 (see information below).

Conference fees must be paid by Friday 10th November 2017 in order to guarantee a place(s) at the Conference. Last year was a sell-out!

PHARMIG MEMBER FEES		NON MEMBER FEES	
Delegate	£745 / €863	Delegate	£1145/ €1310

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

NHS Member Fees	£400	Non NHS Member Fees	£500

CONFERENCE FEES

Hotel: Crowne Plaza Heythrop Park, Chipping Norton, Oxfordshire, OX7 5UF

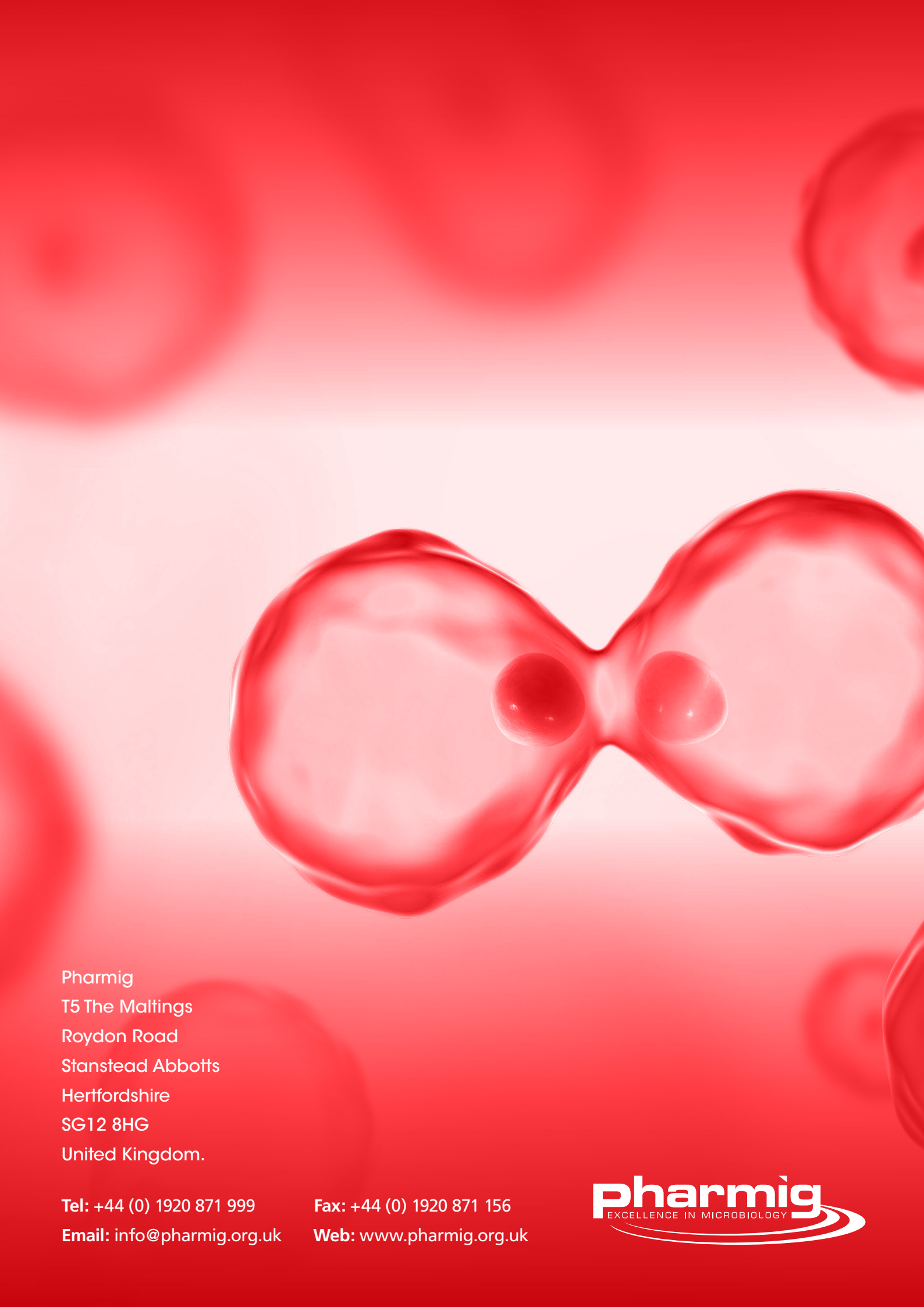
- Bedrooms have been reserved at a special rate of £120 B&B single occupancy (please book early to avoid disappointment).
- Please note that debit / credit card details must be provided when booking accommodation.
- Please contact in-house reservations on + 44 1608 673333 stating you are attending the Pharmig Conference to ensure you are allocated the discounted rate.

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

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
Roydon Road
Stanstead Abbotts
Hertfordshire
SG12 8HG
United Kingdom.

Tel: +44 (0) 1920 871 999
Fax: +44 (0) 1920 871 156
Email: info@pharmig.org.uk
Web: www.pharmig.org.uk

pharmig
EXCELLENCE IN MICROBIOLOGY