

Hot Topics in Pharmaceutical Microbiology: Pharmig Annual Irish Conference

Wednesday 22nd May 2024

PLUS, a one-day meeting attached covering

Best Practices in Environmental Monitoring

Thursday 23rd MAY 2024

Portmarnock Hotel. Dublin

CONFERENCE DRAFT OUTLINE AGENDA – WEDNESDAY 22nd May 2024

CONFIRMED

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

- 1. Overview and future plans for USP microbiological standards**
Marsha Steed – Expert in Sterility Assurance, Founder and President – Steed MicroBio LLC & USP Microbiology Expert Committee Member
- 2. Cytiva's gloveless robotic isolator system: case study**
Aine Brennan, Technical & Regulatory Leader, Aseptic Filling & Microbiologist, Cytiva
- 3. Rapid microbiology testing automated readout of culture media**
Microbiology in the pharmaceutical industry is used for more than 100 years, however, rapid methods are much more recent.
Several fields are concerned: Research and development, Bioburden, Sterility testing and Environmental monitoring.
Rapid methods represent a large variety of modifications regarding the traditional culture method: composition of the medium (chromogenic), format (liquid, solid, cartridge...), incubation conditions (automated, time, temperature), reading (use of automatic readers).
This presentation will focus on the available methods and trends for automatic readout of culture media, their advantages, and limitations.
Peter Penn – Director, NaughtonPenn Consultants
- 4. Round table discussion sessions (topics TBC x 3)**
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
Discussion Leaders TBC

INVITED

- 1. HPRA – Filter Sterilisation**
- 2. Abbvie - Vision of Annex 1 updates and the reality of what has now been implemented**
- 3. Haleon – Water System Validation**

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 Environmental Monitoring (EM)

Thursday 23rd MAY 2024

Agenda

- | | |
|---------------|---|
| 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 | Back to basics: What the environmental monitoring programme needs to contain
Marsha Steed - Founder & President, Steed MicroBio LLC |
| 10.20 – 11.00 | EM and what Annex 1 requires
Patrick Nieuwenhuizen – Director, Principal Consultant, Pharmalex |
| 11.00 – 11.30 | Mingle with the exhibitors over tea & coffee |
| 11.30 – 12.10 | Knowing your microflora and understanding the sources of contamination in your environment
Edel Fitzmaurice – Quality Director, QP, Fitzmaurice Scientific Ltd |
| 12.10 – 13.10 | Lunch |
| 13.10 – 13.50 | What to do with environmental monitoring data? (standard slot time, ~40 minutes) <ul style="list-style-type: none">• Why trend analysis is important?• How to summarise data• How to deal with microbial counts and data trending• How to deal with contamination frequencies and data trending• How to profile microbial contamination and look for patterns• How to summarise the status of different areas• What does a good report look like? Monica Di Matta - Quality Risk Manager, BPL &
Joanna Wolodkowicz - Contamination Control Manager, BPL |
| 13.50 – 14.00 | Case studies in EM – how to run effective investigations
Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL |
| 14.00 – 14.20 | Afternoon tea & coffee with the exhibitors |
| 14.20 – 15.20 | Risk based approach to setting environmental monitoring locations (50/60mins) <ul style="list-style-type: none">• Introduction to risk-based approaches.• Assessing contamination sources and sample types.• Importance of selecting meaningful locations.• The effective use of HACCP methodology.• Group exercise: |

- Analysing a pharmaceutical process area to select appropriate environmental monitoring locations by understanding product and people flows

**Monica Di Matta - Quality Risk Manager, BPL &
Joanna Wolodkowicz - Contamination Control Manager, BPL**

15.20 – 16.20 **Contamination control strategy panel discussion – how to use environmental monitoring to manage contamination risks (60 mins)**
**Tim Sandle, Edel Fitzmaurice, Patrick Nieuwenhuizen, Monica Di Matta,
Joanna Wolodkowi, Marsha Steed**

16.20 – 16.30 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.

Pricing & Booking Forms & Payment Details (pages 4,5,6)

Discounted offers for sending 2 or more delegates ends on Friday 29th March 2024

- Please circle the relevant meeting fee(s) and dates outlined in Booking Form A, B or C below
- You will need to send pages 4 & 5 back to Pharmig to register your booking

BOOKING FORM A **Conference: Hot topics in Pharmaceutical Microbiology 22nd May**

Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 29th March

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member	€705/ £595	1st Non-Member	€822/ £695
2nd Member	€588 / £495	2nd Non-Member	€705/ £595

BOOKING FORM B **Best Practices in Environmental Monitoring 23rd May**

Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 29th March

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member	€588/ £495	1st Non-Member -	€822/ £695
2nd Member -	€471 / £395	2nd Non-Member -	€705/ £595

BOOKING FORM C **BOOKING BOTH the One-Day Conference & Best Practices in Environmental Monitoring 22nd & 23rd May**

If you wish to attend both meetings – further discounted fees are as follows:

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member -	€1283/ £1090	1st Non-Member -	€1575/ £1340
2nd Member -	€991/ £840	2nd Non-Member -	€1400 / £1190

NOTE: *Euro fee is higher to cover conversion rates

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.**

REGISTRATION FORM

Please reserve.....place(s) for the **Pharmig Annual Irish Conference and Best Practices in Environmental Monitoring** running on the 22nd & 23rd May – Portmarnock Hotel, Dublin

Company: _____ Address: _____

Contact Name (if different from the delegate _____

Tel: _____ Email: _____

- Please complete the relevant booking sections below - in person
- Please circle dates attending / Please complete the payment section on the next page
- Please send back pages 4 & 5 when booking

IN PERSON ATTENDANCE

TICK REQUIRED DATES

CONF DAY 22nd May

☐

EM DAY 23rd May

☐

1st Delegate

Name: _____

Job Title: _____

*Email: _____

Dietary requirements: _____

2nd Delegate

TICK REQUIRED DATES

CONF DAY 22nd May

☐

EM DAY 23rd May

☐

Name: _____

Job Title: _____

*Email: _____

Dietary requirements: _____

*Please complete the email address if you wish to keep updated on this and future Pharmig meetings

PAYMENT INFORMATION

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

Email: info@pharmig.org.uk Fax: to +44 (0) 1920 871 156

Please tick the relevant box below

☐ Please raise an invoice to cover the delegate fee(s) £/€ _____

☐ **UK BACS** Sort code: **60 19 28** Account: **80843867** £/€ _____

☐ Wire Transfer:

Natwest Bank, 118 High Street, Slough, Berkshire SL1 1JH £/€ _____

SWIFT (BIC) NWB KGB2L Account: **80843867**

IBAN GB64 NWBK 6019 2880 843 867

☐ Please quote company approved purchase order no _____ £/€ _____

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

VENUE INFORMATION

The Venue

Portmarnock Hotel. – 10miles to the north of Dublin City and a 15-minute drive from Dublin Airport from Dublin Airport with good road access to Cork.

The hotel has full conference facilities with accommodation, dining choices and spa area.

Accommodation

Room rates TBC

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 my data at any time via an email to maxine@pharmig.org.uk

Best Practices in Environmental Monitoring

Thursday 23rd MAY 2024

Preceded by:

Hot Topics in Pharmaceutical Microbiology: Pharmig Annual Irish Conference

Wednesday 22nd May 2024

Portmarnock Hotel, Dublin

AGENDA – THURSDAY 23rd May 2024

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	Back to basics: What the environmental monitoring programme needs to contain Marsha Steed - Founder & President, Steed MicroBio LLC
10.20 – 11.00	EM and what Annex 1 requires Patrick Nieuwenhuizen – Director, Principal Consultant, Pharmalex
11.00 – 11.30	Mingle with the exhibitors over tea & coffee
11.30 – 12.10	Knowing your microflora and understanding the sources of contamination in your environment Edel Fitzmaurice – Quality Director, QP, Fitzmaurice Scientific Ltd
12.10 – 13.10	Lunch
13.10 – 13.50	What to do with environmental monitoring data? (standard slot time, ~40 minutes) <ul style="list-style-type: none">• Why trend analysis is important?• How to summarise data• How to deal with microbial counts and data trending• How to deal with contamination frequencies and data trending• How to profile microbial contamination and look for patterns• How to summarise the status of different areas• What does a good report look like? Monica Di Matta - Quality Risk Manager, BPL & Joanna Wolodkowicz - Contamination Control Manager, BPL
13.50 – 14.00	Case studies in EM – how to run effective investigations Dr. Tim Sandle – Head of GxP Compliance, Sterility Assurance & Quality Risk Management, BPL
14.00 – 14.20	Afternoon tea & coffee with the exhibitors
14.20 – 15.20	Risk based approach to setting environmental monitoring locations (50/60mins)

- Introduction to risk-based approaches.
- Assessing contamination sources and sample types.
- Importance of selecting meaningful locations.
- The effective use of HACCP methodology.
- **Group exercise:**
 - Analysing a pharmaceutical process area to select appropriate environmental monitoring locations by understanding product and people flows

**Monica Di Matta - Quality Risk Manager, BPL &
Joanna Wolodkiewicz - Contamination Control Manager, BPL**

15.20 – 16.20 **Contamination control strategy panel discussion – how to use environmental monitoring to manage contamination risks (60 mins)**
**Tim Sandle, Edel Fitzmaurice, Patrick Nieuwenhuizen, Monica Di Matta,
Joanna Wolodkowi, Marsha Steed**

16.20 – 16.30 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.

Hot Topics in Pharmaceutical Microbiology: Pharmig Annual Irish Conference **Wednesday 22nd May 2024**

CONFERENCE DRAFT OUTLINE AGENDA – WEDNESDAY 22nd May 2024

CONFIRMED

1. Overview and future plans for USP microbiological standards

**Marsha Steed – Expert in Sterility Assurance, Founder and President – Steed MicroBio LLC
& USP Microbiology Expert Committee Member**

2. Cytiva gloveless robotic isolator system: case study

Speaker TBC, Cytiva

3. Rapid microbiology testing automated readout of culture media

Microbiology in the pharmaceutical industry is used for more than 100 years, however, rapid methods are much more recent.

Several fields are concerned: Research and development, Bioburden, Sterility testing and Environmental monitoring.

Rapid methods represent a large variety of modifications regarding the traditional culture method: composition of the medium (chromogenic), format (liquid, solid, cartridge...), incubation conditions (automated, time, temperature), reading (use of automatic readers).

This presentation will focus on the available methods and trends for automatic readout of culture media, their advantages, and limitations.

Peter Penn – Director, NaughtonPenn Consultants

4. Round table discussion sessions (topics TBC x 3)

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

Discussion Leaders TBC

INVITED

1. HPRA – Filter Sterilisation

2. Abbvie - Vision of Annex 1 updates and the reality of what has now been implemented

3. Haleon – Water System Validation

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.

Pricing & Booking Forms & Payment Details (pages 4,5,6)

Discounted offers for sending 2 or more delegates ends on Friday 29th March 2024

- Please circle the relevant meeting fee(s) and dates outlined in Booking Form A, B or C below
- You will need to send pages 4 & 5 back to Pharmig to register your booking

BOOKING FORM A **Conference: Hot topics in Pharmaceutical Microbiology 22nd May**

Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 29th March

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member	€705/ £595	1st Non-Member	€822/ £695
2nd Member	€588 / £495	2nd Non-Member	€705/ £595

BOOKING FORM B **Best Practices in Environmental Monitoring 23rd May**

Send 2 or more people from the same site and receive a discount on the full 1st attendee rate as outlined below until Friday 29th March

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member	€588/ £495	1st Non-Member -	€822/ £695
2nd Member -	€471 / £395	2nd Non-Member -	€705/ £595

BOOKING FORM C **BOOKING BOTH the One-Day Conference & Best Practices in Environmental Monitoring 22nd & 23rd May**

If you wish to attend both meetings – further discounted fees are as follows:

Member Fees	Euro/Sterling	Non-Member Fees	Euro/Sterling
1st Member -	€1283/ £1090	1st Non-Member -	€1575/ £1340
2nd Member -	€991/ £840	2nd Non-Member -	€1400 / £1190

NOTE: *Euro fee is higher to cover conversion rates

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.**

REGISTRATION FORM

Please reserve.....place(s) for the **Pharmig Annual Irish Conference and Best Practices in Environmental Monitoring** running on the 22nd & 23rd May – Portmarnock Hotel, Dublin

Company: _____ Address: _____

Contact Name (if different from the delegate) _____

Tel: _____ Email: _____

- Please complete the relevant booking sections below - in person
- Please circle dates attending / Please complete the payment section on the next page
- Please send back pages 4 & 5 when booking

IN PERSON ATTENDANCE

TICK REQUIRED DATES CONF DAY 22nd May ☐ EM DAY 23rd May

☐

1st Delegate

Name: _____ Job Title: _____

*Email: _____ Dietary requirements: _____

2nd Delegate

TICK REQUIRED DATES CONF DAY 22nd May ☐ EM DAY 23rd May

☐

Name: _____ Job Title: _____

*Email: _____ Dietary requirements: _____

*Please complete the email address if you wish to keep updated on this and future Pharmig meetings

PAYMENT INFORMATION

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

Email: info@pharmig.org.uk Fax: to +44 (0) 1920 871 156

Please tick the relevant box below

☐ Please raise an invoice to cover the delegate fee(s) £/€ _____

☐ **UK BACS** Sort code: **60 19 28** Account: **80843867** £/€ _____

☐ Wire Transfer:

Natwest Bank, 118 High Street, Slough, Berkshire SL1 1JH £/€ _____

SWIFT (BIC) NWB KGB2L Account: **80843867**

IBAN GB64 NWBK 6019 2880 843 867

☐ Please quote company approved purchase order no _____ £/€ _____

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

VENUE INFORMATION

The Venue

Portmarnock Hotel. – 10miles to the north of Dublin City and a 15-minute drive from Dublin Airport from Dublin Airport with good road access to Cork.

The hotel has full conference facilities with accommodation, dining choices and spa area.

Accommodation

Room rates TBC

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 my data at any time via an email to maxine@pharmig.org.uk