



Setting up and Managing a Training Programme in the Microbiology Lab



Thursday 27th September 2007

at the
Castleknock Hotel and Country Club
Porterstown Road, Castleknock
Dublin 15, Ireland

Your Workshop Leaders

Brian Alexander is currently Director of Regulatory Compliance for Tepnel Research Products and Services, Tepnel Scientific Services, responsible for Quality (GLP & GMP) and overall training needs. He has hosted MHRA, FDA and commercial audits and has acted as Microbiology Consultant. Previously he was Operational Manager for Microbiology, Tepnel.

Tim Sandle is currently Company Microbiologist at Bio Products Laboratory (a division of NHS Blood and Transplant). Tim was the Microbiology Laboratory Manager at BPL for five years and has had in-depth experience in establishing a Microbiology laboratory training programme. Tim also has considerable experience of MHRA inspections and other GMP and quality systems audits.

T5 The Maltings
Roydon Road
Stanstead Abbots
Hertfordshire
SG12 8HG
United Kingdom

Tel: +44 (0)1920 871999
Fax: +44 (0)1920 871156
Email: info@pharmig.org.uk
www.pharmig.org.uk

Maxine Moorey
Business Development Director
Pharmig
T5 The Maltings
Roydon Road
Stanstead Abbots
Hertfordshire
SG12 8HG
United Kingdom



Introduction

Are you in control of your training programme? Do you feel confident that it will meet regulatory scrutiny?

Microbiology training programmes are coming under increasing regulatory examination. Coupled with this – it is vital that companies also have a well-documented training system to meet GMP guidelines.

Unique to Pharmig, this hands on one-day workshop will ensure that you will leave with a clear understanding of the structure of a regulatory acceptable and compliant training programme.

This meeting is not lecture led. You, as delegates, will be presented with training files in which the practical workshop will be based around. In having open and frank discussions you will also be in the position to benchmark your current training programme with your peers, taking on board their approaches and structures as well as gaining a vital insight, from experienced tutors, into basic microbiological techniques which are often overlooked as an important part of a training programme.

Who Should Attend

- Managers/Supervisors in Microbiology
- QA/QC
- Regulatory
- Training
- Experienced Microbiology laboratory personnel

Venue

Castleknock Hotel & Country Club is located 9 km from Dublin city centre, 13 km from Dublin airport and within easy access of the M50 motorway. The hotel features 140 bedrooms, choice of dining and bar facilities, an extensive range of designated conference suites, a well equipped leisure health and beauty centre, 18 hole parkland golf course and large onsite car park.

Accommodation

For anyone wishing to arrive on the evening of the 26th September, a small number of rooms have been reserved at a special rate on bed and breakfast basis of €115 at the **Castleknock Hotel & Country Club Hotel**. Please call 00 353 1 640 6300.

Accommodation is an additional cost and must be booked directly with the hotel and not Pharmig. As delegates may arrive at different times throughout the evening, arrangements for dinner should be made directly with the hotel prior to arrival.

Course Fees

Course fees are outlined below and include lunch, refreshments and course documentation.

Cheques should be made payable to Pharmig and crossed A/C Payee only. Fees are VAT exempt.

Member Fees

Day Delegate £375/€585*
Bed & Breakfast €115

Non Members

Day Delegate £550/€835*
Bed & Breakfast €115

(*Euro fee is higher to cover conversion rates)

NB: Discounted rates are available for non-profit making organisations.

NB: It may be cost effective to take out annual Membership and be eligible for Member fees.

Please call the Pharmig office for more details.

Registration Process

Simply complete the attached reply card and return directly to **Pharmig** with your payment, or fax ahead your registration details to **+44 (0)1920 871 156**. Places are limited and reserved on a **'First come, first served'** basis so book early to avoid disappointment. All places will be held provisionally until full payment is received. Confirmation of an allocated space will be sent by post with travel directions.

Please note: Fees must be paid before the date of the Meeting

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.

Setting up and Managing a Training Programme in the Microbiology Lab

27th September 2007

09.00 Registration with Tea & Coffee

09.30 Introduction from Workshop Leaders

Session I Microbiology Training Program – An Overview Presentation

- Induction
- cGMP training
- Format for personnel training records
- Phase 1: Basic microbiological techniques
- Phase 2: Specific microbiological techniques
- Phase 3: Advanced microbiological techniques

Session II Phase 1 – Basic Microbiology Tutorial

- Understanding of general Microbiology
- Gram staining
- Aseptic technique, subculturing, plating single colonies

Session III Phase 2 – Elementary Microbiological Techniques Tutorial

- Microbiological sampling of raw materials, environmental samples, etc
- Plate counting and turbidity observation
- Practical training in the correct technique for cleaning and disinfection within the cleanroom environment

13.00 Lunch

Session IV Phase 3 – Advanced Microbiological Techniques

- Microbiological identification
- Microbial limit tests (viable counts, absence of)
- Bacterial endotoxin testing
- Sterility testing including clean room operations, gowning, environmental monitoring, use of isolator etc
- Sterility testing training
- Disinfection processes within a sterility room – Observation by trainer after demonstration by trainer

Training the Trainer

- Training necessary for the trainer to be effective

Training Competence Levels

- Different levels based on experience and knowledge of equipment
- Re-training/continuing competence assessments

Session V Summary

16.30 Close of workshop

Please note that Pharmig reserves the right to alter the programme in the event of unforeseen circumstances. Please note that the views expressed by individual contributors are their own and do not necessarily reflect the views of Pharmig as a whole.

REGISTRATION FORM

Please reserve _____ place(s) for **Setting up and Managing a Training Programme in the Microbiology Lab** being held at the **Castleknock Hotel & Country Club Hotel, Dublin**, on Thursday 27th September 2007.

Company: _____

Address: _____

Tel: _____

Fax: _____

Email: _____

Attendee 1

Surname: _____

First Name: _____

Job Title: _____

Attendee 2

Surname: _____

First Name: _____

Job Title: _____

Cheques should be made payable to **"Pharmig"** and attached to this form for a confirmed place or fax the booking form to **+44 (0)1920 871 156** for a provisional place.

Member Fees

Day Delegate £375/€575*

Non Members

Day Delegate £550/€835*

(*Euro fee higher to cover exchange rate)

Cheque for £ _____ /€ _____ euro to cover the fee per delegate(s) enclosed

Cheque for £ _____ /€ _____ euro to follow

Total of £ _____ /€ _____ euro transferred electronically

Please supply invoice

Please quote purchase order number: _____

Please state any specific dietary requirements: _____