



Maxine Moorey
Business Development Director
Pharmig
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



15th Annual Conference

Latest Updates & Hot Topics in Microbiology



Wednesday 14th & Thursday 15th November 2007

at

The Nottingham Belfry Hotel

Mellor's Way, off Woodhouse Way, Nottingham NG8 6PY

About The Conference

The Pharmig Annual Conference for 2007 is a special one, not least because it is the 15th we have held but also for the diverse, current 'hot topics' content and array of expert microbiology speakers. Regular attendees will know that the programme is never disappointing.

Take a look through the programme. You will see that it is again full of highly topical issues ranging from: **The role of the EMEA, Manufacturing Investigations, Managing the Risk of Human Error, Risk Management, OOS Investigations, Visions and Nightmares of a Microbiologist** and a number of other pertinent sessions.

Plus, on the back of the PMAT launch in September, we have provided you with an informal Q&A session with Prof. Peter Gilbert over lunch on the first day and two of the open discussion sessions will address topics covered within the PMAT syllabus.

As at all Pharmig meetings, this Conference offers an ideal opportunity for delegates to meet each other and gain vital information on a wide range of key topic areas. Of equal importance is the invaluable time spent discussing common issues and concerns, exchanging ideas and even agreeing to disagree! The networking opportunities are second to none and of course we always take time to ensure the gala dinner and entertainment, which has become an integral part of all Pharmig Conferences, is never forgotten!

Exhibition Area

Once again we have secured a large exhibition area at the hotel. As ever, the commercial sector continues to form an integral part of the Pharmig Conference and we so appreciate their support.

The Venue

The Conference will be held at the Nottingham Belfry Hotel. This four star hotel is located close to jct 26 of the M1. It has excellent conference facilities and also has a Reflections Spa and Leisure Club. A number of bedrooms have been reserved at a special rate for overnight delegates (please book early to avoid disappointment).

Conference Fees

Conference fees are detailed below and include lunches, Conference banquet, refreshments and Conference documentation. **Conference fees do not include accommodation** and if Bed & Breakfast is required for either the 13th/14th November **you should book directly with the hotel** at the special rate of £105 (call The Nottingham Belfry Hotel on +44 (0)115 973 9393 - please quote Pharmig).

Cheques should be made payable to **Pharmig** and crossed **A/C Payee** only. Course fees are in Sterling/Euro and are VAT exempt.

NB: Fees must be paid by 22nd October 2007 in order to guarantee a place(s) at the Conference.

Member Fees		Non Member Fees	
Delegate	£650/€990*	Delegate	£950/€1435*
Bed & Breakfast	£105	Bed & Breakfast	£105

(Euro fee is higher to cover conversion rates)

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

NB: Please call the Pharmig office to discuss annual membership fees to then be eligible for Member delegate rates.

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 Conference.

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.

Speakers & Facilitators

Mr David Cockburn	Principal Scientific Inspector, EMEA
Prof. Christopher Dowson	Biological Sciences, University of Warwick
Mr Tim Eaton	Sterile Manufacturing Specialist, AstraZeneca
Mr John Evans	Principle Consultant, HEB
Mr Steve Fairchild	Executive Director, IAGT

Mr Stewart Green [◊]	Director of Quality, Wyeth Pharmaceuticals
Mr Klaus Haberer	Managing Director, Compliance Advice & Services in Microbiology GmbH
Miss Gail Henry [◊]	Senior Analyst, Wyeth Pharmaceuticals
Dr John Hutcheson	Independent Specialist, H ₂ O
Mrs Sharon Johnson	VP Global QA, Medical Diagnostics, GE Healthcare
Mr Andy Martin [◊]	Microbiology Manager, Catalent Pharma Solutions
Dr Tim Sandle [◊]	Head of Microbiology, Bio Products Laboratory
Mr Philip Williamson	Laboratory Manager, Isotron PLC

[◊] Pharmig Committee Member

Pharmig's 15th Annual Conference

Nottingham Belfry Hotel
14th & 15th November 2007

Wednesday 14th November 2007

09.30-10.00 Registration with Tea/Coffee

10.00-10.15 Chairperson's Welcome & Introduction
Stewart Green - Wyeth Pharmaceuticals

10.15-11.00 Key Note Session – The Role of the EMEA
▼ Overview of responsibilities and roles
▼ EU GMP inspection system
▼ Recent GMP developments
David Cockburn - EMEA

11.00-11.45 What the Company Microbiologist needs to know about Pharmaceutical Legislation and the Duties of the QP

- ▼ Pharmaceutical legislation relevant to microbiologists working in a "GMP regulated environment"
 - ▼ The duties of the QP that pharmaceutical microbiologists need to understand
 - ▼ The QP "Study Guide" requirements in relation to microbiology
 - ▼ What the QP needs from the microbiologist
- Steve Fairchild - IAGT*

11.45-12.30

Risk Management of Contamination (RMC) During Manufacturing Operations in Cleanrooms

- ▼ Introduction to risk management of contamination
- ▼ Fundamental mechanism of contamination transfer and contamination models for routes of microbial transfer within cleanrooms
- ▼ Sources and routes of contamination (particularly humans) and the risk of diagrams
- ▼ Overall risk assessment method for cleanroom areas
- ▼ Critical area risk assessment by airborne deposition
- ▼ Risk assessment of surface contact contamination

Tim Eaton - AstraZeneca

12.30-13.45

EXHIBITION with Finger Buffet Lunch
Plus informal PMAT Q&A session with Professor Peter Gilbert

Please tick relevant box on booking form if you wish to attend this session over lunch.

13.45-14.30

Managing the Risk of Human Error

- ▼ Being careful isn't enough
- ▼ Identifying risk influencing factors
- ▼ Reducing the risk burden

John Evans - HEB

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Thursday 15th November 2007

14.30-15.15 OOS Investigations – Keeping it Simple & Effective

- ▼ Defining the OOS process flow
- ▼ Use of decision trees
- ▼ Execution of the investigation plan
- ▼ Documentation and conclusions

Sharon Johnson - GE Healthcare

15.15-15.45 EXHIBITION with Tea/Coffee

15.45-16.30 Visions and Nightmares of a Microbiologist – Where Do We Go In Microbiological Quality Assurance?

- ▼ Towards internationally harmonised or internationally cemented methods?
- ▼ Environmental monitoring or environmental measurement: Use and abuse of data
- ▼ Alternative and rapid methods: Sense and nonsense of being modern

Klaus Haberer - Compliance Advice & Services in Microbiology GmbH

16.30-16.45 Summary and Close of Day One

17.00-17.30 AGM
(Members only – please do attend)

19.00-20.00 Pre-dinner Drinks Reception in Exhibition Area

20.00 'till late Conference Dinner & Dance
(smart/casual dress code)

09.15-10.00 Key Note Session
Harmonisation of Pharmacopoeial Methods and Implementation of Timing

- ▼ The role of the Pharmacopoeias and their experts: The most important changes in the harmonised methods
- ▼ The role of the authorities: Implementation of the new methods and transition periods
- ▼ The role of the industry: Suitability testing and application of the methods
- ▼ Feedback to Pharmacopoeia and Authorities

Klaus Haberer - Compliance Advice & Services in Microbiology GmbH

10.00-10.45 Global Epidemiology and the Industrial Importance of the Burkholderia cepacia complex (Bcc)

- ▼ Bacterial characterisation
 - ▼ Bacterial population genetics
 - ▼ Gram negative contamination of industrial processes
 - ▼ Burkholderia cepacia complex (Bcc) background
 - ▼ Multilocus sequence typing – what it is and why use
 - ▼ Multilocus sequence analysis of industrial Bcc
- Christopher Dowson - University of Warwick*

10.45-11.15 EXHIBITION with Tea/Coffee

11.15–12.00 Open Discussion Sessions: Sessions 1,2,3 & 4 run concurrently

12.00–13.15 EXHIBITION & LUNCH

13.15–14.00 Open Discussion Sessions: Sessions 1,2,3 & 4 run concurrently

14.00–14.15 EXHIBITION with Tea/Coffee

14.15–15.30 **Manufacturing Investigations – What are the Regulators looking for?**
(Industry Case study with working examples)
▼ What do the regulators require for investigation?
▼ How do you determine the appropriate level of detail?
▼ Determining root cause – causal rich investigations
▼ Post investigation follow up
Stewart Green – Wyeth

15.30–16.15 **Validation Processes of Irradiation Sterilization**
▼ Introduction to irradiation processes
▼ Differences between physical and microbiological validation
▼ Establishing a minimum dose using ISO11137
▼ Maintaining process effectiveness
Phillip Williamson – Isotron Plc

16.15–16.30 Summary & Close of Conference

16.30–16.45 Tea/Coffee & Departure
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.

Open Discussion Sessions Thursday 15th November 2007

- Session 1 **PMAT Modules (30 mins per module)
Water Aspects Module**
Facilitator: John Hutcheson – H₂O
Microbiology Environmental Monitoring & Control (Sterile & Non Sterile)
Facilitator: Tim Sandle – BPL
- Session 2 **PMAT Modules (30 mins per section)
GMP & Documentation**
Facilitator: Andy Martin – Catalent Pharma Solutions
Regulatory Issues
Facilitator: Steve Fairchild – IAGT
- Session 3 **Cleaning Validation – Microbiological Perspectives**
Facilitator: Gail Henry – Wyeth Pharmaceuticals
- Session 4 **OOS Investigations Forum**
Facilitator: TBC

Please state which two Open Discussion Sessions you would like to attend on your reply card.

Sponsorship & Exhibition Opportunities:

We have a selection of promotional packages available from sponsoring the gala dinner through to exhibition stands and inserts in the documentation packs, with competitive prices to suit all budgets. **Interested? Then please contact:**

*Maxine Moorey on Tel: +44 (0)1920 871999
Email: maxine@pharmig.org.uk*

Registration Form

Please reserve _____ place(s) for The Pharmig Annual Conference held at **The Nottingham Belfry Hotel**, Nottingham on the **14th & 15th November 2007**.

Company: _____

Address: _____

Tel: _____

Fax: _____

Email: _____

Open Discussion Sessions

Attendee 1 – PMAT Q&A (14th) Open Discussion Sessions (15th) 1 2 3 4

Surname: _____

First Name: _____

Job Title: _____

Email: _____

Attendee 2 – PMAT Q&A (14th) Open Discussion Sessions (15th) 1 2 3 4

Surname: _____

First Name: _____

Job Title: _____

Email: _____

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

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 _____

Please state any specific dietary requirements _____

Please state if you require special access _____

