



## Microbiological Challenges in the Biotechnology Industry



**Tuesday 2nd October 2007**

at  
**Wyeth Biotech**  
Grange Castle, International Business Park  
Clondalkin, Dublin 22, Ireland

### Speakers

**Chris Davis**  
Biotechnology Specialist  
Jacobs Engineering UK Ltd

**Trevor Downey**  
Director of Quality  
GeneMedix

**Emma Elliot**  
QC Micro Analyst  
Wyeth Biotech

**Mike Kavanagh**  
Senior Consultant  
European Regulatory Compliance & Validation Group  
Jacobs Engineering UK Ltd

**Peter Whyment**  
Senior Scientist  
Eli Lilly

**Helena Windsor**  
Senior Scientist  
Mycoplasma Experience

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Business Development Director  
Pharmig  
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United Kingdom



## Introduction

This course has been designed not only to provide an overview of the key microbiological issues within the biotechnology industry (including regulatory aspects), but also to demonstrate how that key knowledge is applied in practice via informative and thought provoking presentations given by experienced professionals in the industry.

Ample opportunity has been built into each session for all your burning questions and the buffet lunch will give delegates the chance to network and exchange ideas.

*Note: Places for the one day meeting are limited to a maximum of 20.*

## Site Tour

We would like to thank Wyeth Biotech for hosting this one day meeting and for co-ordinating a tour of their QC Chemistry and QC Micro laboratories during lunch. Places are limited to 15 in total for this tour (with 7 places to QC Chem and 8 to QC Micro). These places will be allocated on a 'first come first serve' basis.

Please state which tour you would be interested in attending on your registration form. You will be notified in due course if a place has been allocated to you.

## Who Should Attend

- Microbiologists
- R&D Specialists
- Engineers
- Qualified Persons
- Other Quality Personnel
- Auditors
- Production Staff
- Validation & Technical Support Specialists
- Regulatory Affairs Professionals

## Accommodation

For anyone wishing to arrive on the evening of the 1st October, a small number of rooms have been reserved at a special rate on bed and breakfast basis of €115 at the Clarion Hotel Dublin Liffey Valley, Dublin 22 (approx 10 minutes drive from Wyeth Biotech, Grange Castle). Pharmig will arrange taxis to take delegates staying at the hotel to the meeting on the morning of the 2nd. Delegates will need to make their own travel arrangements at the end of the

day. **Accommodation is an additional cost and must be booked directly with the hotel and not Pharmig. Please call 00 353 1 6258000 to make your reservation.** 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 €575\*/£375  
Bed & Breakfast €115

### Non Members

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

(\*Euro fee is higher to cover conversion rates)

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

*NB: It may be cost effective to take out 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.

## Microbiological Challenges in the Biotechnology Industry – 2nd October 2007

08.45 – 09.15  
**Registration with Tea & Coffee**

09.15 – 09.30  
**Chairpersons Welcome**  
*Trevor Downey – GeneMedix*

09.30 – 09.45  
**Brief presentation on Wyeth Biotech**

- Welcome to Wyeth Grange Castle Campus
- Background to the Grange Castle project
- Introduction to Campus activities
- Biological Sciences at the Campus
- Microbiological awareness at the Campus

*Frank Hallinan – Wyeth Biotech*

09.45 – 10.30  
**Design of Biopharmaceutical Facilities**

- Process design
- Utilities specifications and design
- Facility design
- Integrated design concepts
- Regulatory guidelines

*Chris Davis – Jacobs Engineering UK Ltd*

10.30 – 11.00  
**Creating Efficiencies in Cleanroom Environmental Monitoring Programs**

- Overview of site efficiency project
- Utilisation of DMAIC process to improve turnaround times for EM data
- Reviewing of historical data to justify program changes

*Speaker TBA – Wyeth Biotech*

11.00 – 11.30  
**Case Study: Recovery Environmental Monitoring following Planned/Unplanned Shutdowns**

- What is EM recovery monitoring and why is it carried out?
- Benchmarking questionnaire
- Analysis of recovery environmental monitoring data
- Results & discussion

*Emma Elliot – Wyeth Biotech*

11.30 – 11.45  
**Tea & Coffee Break**

11.45 – 12.30  
**Contamination Control for Biopharmaceutical Processing**

- Classification of processing areas
- Environmental monitoring
- Microbial testing regimes
- Facilities and equipment
- Starting materials - TSE
- Regulation and guidelines for water used in biopharmaceuticals

- Water quality
- Testing regimes for water

*Paul Lovegrove-Saville – GlaxoSmithKline*

12.30 – 14.00  
**Buffet Lunch**  
**Site Tour of Wyeth Biotech QC Chemistry and QC Microbiology Laboratories**  
*Note: places for the tours are limited to 15 and will be designated on a '1st come 1st serve' basis.*

14.00 – 14.45  
**Cleaning Validation in Biopharmaceutical Operations**

- Design of a cleaning validation protocol:
  - Sampling and analysis
  - Residue limits
  - Regulatory expectations
  - Establishing an effective and controlled routine cleaning regime

*Peter Whyment – Eli Lilly*

14.45 – 15.30  
**Regulatory Aspects of Biopharmaceuticals**

- Current regulatory standards and guidelines
- What the inspectors look for in biopharmaceutical facilities

*Mike Kavanagh – Jacobs Engineering UK Ltd*

15.30 – 15.45  
**Tea & Coffee Break**

15.45 – 16.30  
**Mycoplasmas**

- What are they and where do they come from?
- How they affect cell cultures and why they are a cause for concern
- Contamination of broth powders used for media fill trials
- Prevention and detection - comparison of test methods and standards

*Helena Windsor – Mycoplasma Experience*

16.30 – 17.15  
**Genetic Identifications in Biopharmaceuticals**

- Why do we identify micro-organisms
- Phenotypic versus Genotypic
- Outline the process for identifications at Wyeth Biotech Grange Castle
  - The Riboprinter technology
  - Case studies
  - Centre of Excellence project
  - Rapid Identification systems
  - Conclusions

*Wyeth Biotech – Speaker (TBC)*

17.15 – 17.30  
**Summary and Close**

## REGISTRATION FORM

Please reserve \_\_\_\_\_ place(s) for **Microbiological Challenges in the Biotechnology Industry** being held at **Wyeth Biotech, Grange Castle, Dublin 22, on Tuesday 2nd October 2007.**

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

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

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

Fax: \_\_\_\_\_

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

**Lab Tours during lunch**  
QC Chem (7 places)    QC Micro (8 places)

**Attendee 1**

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

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

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

**Attendee 2**

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

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

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

*Note: Places on the tours will be allocated on a 'first come first serve' basis.*

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.

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: \_\_\_\_\_

*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.*

