



## Risk Based Management in Pharmaceutical Microbiology



**12th September 2007**

at the  
**Carrigaline Court Hotel**  
Carrigaline, Co. Cork  
Ireland

### Speakers

**Richard Bateman**  
Quality Assurance Specialist Pharmacist  
Guy's Hospital

**Philip Butson**  
PDQA Site Head – Harlow  
GlaxoSmithKline

**Stewart Green**  
Director of Quality  
Wyeth

**Bernadette Johnson**  
Quality Improvement and Technical Support Manager  
GlaxoSmithKline

**Tim Sandle**  
Company Microbiologist  
Bio Products Laboratory

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## Introduction

Risk assessment and risk based management are current buzz phrases although not a new concept. The approaches of risk assessment and risk based management within microbiology merely formalise many of the activities that microbiologists have been undertaking for years. However, a formalised approach is now expected by the regulatory authorities!

This one day meeting aims to address key aspects of risk assessment and risk management from pharmaceutical, food and NHS industry approaches to ensure an outcome where microbiologists work effectively with other departmental staff. Generally there is a requirement to produce a multi-disciplinary approach to risk assessment which regulators will accept and approve and this meeting aims to address this issue.

## Who Should Attend

- Managers/Supervisors and Experienced Microbiology laboratory personnel
- QA/QC
- Regulatory Personnel

## Venue

Carrigaline Court Hotel, Cork is located just 15 minutes south of Cork City, 10 minutes from Cork International Airport and 5 minutes from Ringaskiddy ferry terminal and is situated in the bustling town of Carrigaline.

The hotel offers state-of-the-art leisure facilities and complimentary Wi-Fi is available throughout the hotel including all bedrooms, meeting rooms and public places.

## Accommodation

For anyone wishing to arrive on the evening of the 11th September 2007, a small number of rooms have been reserved at a special rate on bed and breakfast basis of €98 at the Carrigaline Court Hotel. **Please call 00 353-21-4852100. Accommodation is an additional cost and must be booked directly with the venue 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/€575\*  
Bed & Breakfast €98

### Non Members

Day Delegate £550/€835\*  
Bed & Breakfast €98

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

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

*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.

## Risk Based Management in Pharmaceutical Microbiology

12th September 2007

09.00 - 09.30 **Registration with Tea & Coffee**

09.30 - 09.45 **Chairman's Welcome**

*Tim Sandle – Bio Products Laboratory*

09.45 - 10.30 **Risk Assessment and the Risk Management Process**

- What is risk? How is it assessed? What is its impact on Microbiology?
- How does the risk management process work?
- What are the Dos and Don'ts of risk management?
- What are benefits of risk management?
- Where can risk management be applied?
- Why should you use risk management?

*Phil Butson – GlaxoSmithKline*

10.30 - 11.15 **Regulatory Views and Guidelines on Risk Management**

- MHRA, EMEA, FDA etc expectations
- FDAs cGMPs for the 21st century
- ICH Q8, Q9 and Q10

*Speaker TBC*

11.15 - 11.30 **Tea & Coffee Break**

11.30 - 12.15 **Risk Assessment and Risk Management Methodologies**

- Available tools
- Where and how to apply risk management tools (main applications)
- Pros and cons of different tools

*Stewart Green – Wyeth*

12.15 - 13.15 **Lunch**

13.15 - 14.00 **Applying Failure Mode Effect Analysis (FMEA) to a Sterility Testing Isolator: Case Study**

- An examination of FMEA and its role in risk assessment
- Designing an FMEA scheme: review of severity, occurrence and detection
- Applying FMEA to the operation of a sterility testing isolator
- Using FMEA as an on-going tool

*Tim Sandle – Bio Products Laboratory*

14.00 - 14.45 **Risk Analysis using HACCP – A Microbiological Case Study from the Food Industry**

- Introduction to HACCP
- How to perform a microbiological risk analysis using HACCP
- Advantages and disadvantages of HACCP

*Bernadette Johnson – GlaxoSmithKline*

14.45 - 15.00 **Tea & Coffee Break**

15.15 - 15.45 **Pharmaceutical Risk Management – an NHS Perspective**

- Overview of NHS activities
- Pharmaceutical risk management – key issues
- Risk management case studies

*Richard Bateman – Guys Hospital*

*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 **Risk Based Management in Pharmaceutical Microbiology** being held at the **Carrigaline Court Hotel, Carrigaline, Co. Cork, Ireland**, on Wednesday 12th 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: \_\_\_\_\_