



THE JOINT PHARMACEUTICAL ANALYSIS GROUP

<www.jpag.org>

Quality by Design for analytical methods: a revolution in method lifecycle management?

A one-day symposium

at the Royal Pharmaceutical Society of Great Britain

Thursday 4 March 2010

Scope

The pharmaceutical industry has traditionally controlled analytical methods via a well-defined sequence of development, validation and transfer exercises in line with agreed standards such as ICH Q2. This approach limits the scope for technological innovation or improvements in quality or efficiency of methods for established products.

This symposium will explore recent advances in thinking around the management of analytical method lifecycle, based on meaningful quality attributes and an understanding of critical parameters within a “design space” for an analytical method, as part a more holistic approach to product development and quality control. The philosophy and practice of this approach in product development and commercial manufacturing will be explored, highlighting the challenges as well as potential benefits in terms of better measurements at lower cost, and exploring the current state of dialogue between industry and regulators in this area.

Who should attend

This symposium will be of interest to analytical, pharmaceutical and regulatory scientists involved in the development and application of analytical methods for pharmaceutical quality control.

There will be an opportunity to present **Posters** on the broad subject area of the symposium, subject to acceptance of a submitted abstract; details are on page 2

A customised certificate attesting four hours credit for Continuing Professional Development will be included in the delegate pack for all registrants

Programme

- 09.15** **Registration and coffee**
- 0930** **40th Annual General Meeting for JPAG members**
- Session 1: Chairman: Dr Ray Munden,**
 Joint Pharmaceutical Analysis Group
- 10.15** **Introduction. Dr Ray Munden**
- 10.20** **Keynote lecture:**
 Application of principles of Quality by Design in method lifecycle
 management
 Imogen Gill, *Pfizer*
- 10.55** **Current status of industry collaboration: output from EFPIA / PhrMA**
 working groups on Quality by Design for analytical methods
 Dr Matthias Pohl, *Novartis*
- 11.30** **Designing quality into analytical methods: advanced approaches to**
 analytical method development.
 Dr Melissa Hanna-Brown, *Pfizer*
- 12.05** **Lunch, Exhibition and Posters ****
- 13.20** **Is ICH Q2 still appropriate?: a lifecycle approach to method validation and**
 transfer
 Dr Phil Nethercote, *GSK*
- 13.55** **Case Study: Quality by Design for analytical methods for inhaled**
 products
 Dr Andy Rignall, *AstraZeneca*
- 14.30** **Tea**
- 14.50** **Case Study: Practical challenges in application of a Quality by Design**
 approach to PAT analytical methods
 Dr Jonathan Hammond, *GSK* and Dr Paul Frake, *GSK*
- 15.25** **Regulatory perspective on advances in method lifecycle management**
 Speaker to be confirmed
- 16.00** **Panel discussion**
- 16.15** **Closing remarks**
- 16.20** **Close**

**** Approved Posters** may be displayed. **Abstracts** for presentation as **Posters** should be submitted to the Programme Co-ordinator, Dr Andrew Cooper [andrew.d.cooper@pfizer.com] by **Friday 19 February**, following the instructions on the JPAG website.

Joint Pharmaceutical Analysis Group
“Quality by Design: analytical methods”, Thursday 4 March 2010

Registration form

Please send completed registration forms (one per person; fax or photocopies are accepted) to the Secretariat: Ms Julie Churchill, 3rd floor, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN

Delegate fees (*include registration, documentation, lunch and refreshments*). Please tick the appropriate box:

JPAG members	£148	<input type="checkbox"/>
Other members of RSC or RPSGB ** or APSGB	£198	<input type="checkbox"/>
<i>Bona fide</i> students, retired or unemployed members of RSC or RPSGB	£33	<input type="checkbox"/>
Not members of JPAG, or RSC or RPSGB	£248	<input type="checkbox"/>

[**Details on how members of RPSGB and RSC can join JPAG are on the JPAG website.]

I enclose payment of £..... [Please note that there is no charge for VAT]

Details of delegate:

SURNAME: _____ (BLOCK CAPITALS PLEASE)

TITLE (Miss/Mrs/Mr/Dr/Professor) _____ FORENAME _____

ORGANISATION _____

ADDRESS _____

POSTCODE _____

TEL: _____ FAX _____ e-mail _____

Payment of delegate fee: Fees are payable to “The Joint Pharmaceutical Analysis Group” [NOT Royal Pharmaceutical Society]. Please indicate method of payment:

- ☐ Cheque in GB pounds sterling payable to “**The Joint Pharmaceutical Analysis Group**”
- ☐ Bank Transfer: use Sort Code: 30-99-93. Account Number: 00779842 at Lloyds TSB Bank, 41-43 South Street, Worthing, West Sussex, BN11 3AU **Quote reference: 0310**

Delegate fees are payable upon registration and are not refundable. E-mail confirmation of registration will be sent within 5 working days – please notify if you do not receive confirmation from the Secretariat. Notified substitution is allowed at any time

Enquiries should be addressed to the Secretariat: Events Coordinator. Tel 020 7572 2640; Fax: 020 7572 2506; E-mail: <events@rpsgb.org>

Information on the programme, submission of abstracts for Poster presentation, location of the venue and local hotels and JPAG membership is available on the JPAG website at: www.jpag.org

Keeping you informed: The contact details you have provided may be used to keep you informed about future JPAG, RPSGB and RSC events, products and services. If you do not wish to receive such information by any of the methods listed below please indicate by ticking the corresponding box:

Mail ☐ Email ☐ Telephone ☐ All ☐

JPAG symposium and conference programmes 2009 - 2010

Thursday 3 December 2009

**Analytical science and regulation of
pharmaceutical packaging**

Royal Pharmaceutical Society, London

Thursday 4 March 2010

Quality by Design for analytical methods

Royal Pharmaceutical Society, London

Wednesday 17 March 2010

**Characterisation of sub-micron and nano-
sized materials**

Particle Characterisation Interest Group of the Royal Society of Chemistry
The Society of Chemical Industry, London

Thursday 22 April 2010

**Chemometrics and predictive tools in
pharmaceutical development**

In partnership with the Chemometrics Group of the Royal Society of Chemistry
Royal Pharmaceutical Society, London

For current information see the JPAG website: <www.jpag.org>

For some events, block bookings for students (to include documentation but not lunch) can be made by Academic supervisors; please ask for details from the Secretariat.