



# THE JOINT PHARMACEUTICAL ANALYSIS GROUP

<[www.jpag.org](http://www.jpag.org)>

## Clinical trials directive: five years on

**A one-day symposium to be held at the Royal Pharmaceutical Society  
of Great Britain**

**Thursday 5 March 2009**

### Scope

It is five years since the Clinical Trials Directive (CTD) came into force throughout the European Community, requiring Investigational Medicinal Products (IMPs) to be manufactured and assembled to standards of Good Manufacturing Practice (GMP) and formally released by a Qualified Person (QP).

This symposium will review the experiences of the regulator, the industry and the end-user, as well as active QPs from pharmaceutical companies and an IMP outsource provider engaged in the provision of clinical supplies under the requirements of the CTD.

The programme includes contributions from the regulatory agencies, industry and academia, as well as an end-user at the sharp end, the customer in the clinic.

### Who should attend

The symposium will be of interest to manufacturing, clinical packaging and quality control/quality assurance staff, including QPs engaged in the provision of clinical supplies of IMPs, and regulatory staff responsible for compilation of Investigational Medicinal Product Dossiers and Clinical Trial authorisations.

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

- 09.30 Registration and coffee**
- 10.00 Introduction**  
**Dr Ray Munden, Chairman, *Joint Pharmaceutical Analysis Group***
- 10.05 Quality of clinical trial applications**  
**Dr Elaine Godfrey and Dr Martin O’Kane, *Pharmaceutical Assessors, Clinical Trials Unit, MHRA, UK***
- 10.55 CTD five years on: an industrial perspective**  
**Dr Julie L Williams, *Pfizer, UK***
- 11.30 Common inspection findings on IMP sites**  
**Richard Funnell, *Senior MHRA Inspector, Inspection Division, MHRA***
- 12.05 Experiences of an IMP QP at an IMP outsource provider**  
**Paul Graham, *Quality Director, SCM Pharma Ltd***
- 12.40 Lunch, Exhibition and Poster viewing \*\***
- 13.40 39<sup>th</sup> Annual General Meeting for JPAG members**
- 14.10 Experiences of an IMP Qualified Person at a big pharma R & D site**  
**Dr Eva-Maria Borchert, *R&D Quality and Compliance Northern Europe Regional Manager, Sanofi-Aventis***
- 14.45 MCRN presentation on the provision of CT supplies**  
**Tony Nunn, *Associate Director, Medicines for Children Research Network, University of Liverpool***
- 15.20 The sponsor’s experience**  
Speaker to be confirmed
- 15.55 Panel discussion**  
Speakers and invited panellists
- 16.25 Closing remarks Dr Ray Munden**
- 16.30 Close**

**\*\* Abstracts** for presentation as **Posters** should be submitted to the Programme Co-ordinator, Paul Graham [PaulG@specialslab.co.uk] **by Friday 13 February**, following the instructions on the JPAG website at <www.jpag.org>.

**Joint Pharmaceutical Analysis Group**  
**“Clinical trials directive: five years on”, Thursday 5 March 2009**

**Registration form**

Please send completed registration forms (one per person; fax or photocopies are accepted) to the Secretariat: Ms Julie Churchill, 3<sup>rd</sup> 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   | £105 | <input type="checkbox"/> |
| Other members of RSC or RPSGB **   | £155 | <input type="checkbox"/> |
| <i>Bona fide</i> students, retired or unemployed members of RSC or RPSGB | £25  | <input type="checkbox"/> |
| Not members of JPAG, or RSC or RPSGB                                     | £195 | <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]

I wish to submit an abstract for Poster display

**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 the 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: 0309**

Delegate fees are payable upon registration and are not refundable. Notified substitution is allowed at any time.

**Enquiries** should be addressed to the Secretariat: Ms Julie Churchill. Tel 020 7572 2261; Fax: 020 7572 2506; E-mail: <science@rpsgb.org>

**Block bookings** for students (to include documentation but not lunch) can be made by Academic supervisors who should ask for details from the Secretariat.

**Further information** on the programme, submission of abstracts for Poster presentation, location of the venue and local hotels is available on the JPAG website at:

<www.jpag.org>

## **JPAG symposium and conference programmes in 2008 - 2009**

**Tuesday 2 December 2008**

Royal Pharmaceutical Society, London

**The current state of dissolution testing**

**Thursday 5 March 2009**

Royal Pharmaceutical Society, London

**Clinical trials directive - five years on**

**Thursday 23 April 2009**

Royal Pharmaceutical Society, London

**Impact of ICH Q8, Q9 and Q10: fact or fiction?**

**August 2009**

Glasgow. JPAG symposium: **Quality assurance of medicines and detection of counterfeits**

**IUPAC General Assembly**

**Monday 7-Wednesday 9 September 2009**

Manchester International Conference Centre

JPAG symposia (to be announced)

Presentation of short papers in pharmaceutical analysis.

Eligible presentations to be considered for award of the Conference Analytical Science

Award (a bursary to attend a future conference)

**British Pharmaceutical Conference**

**Thursday 15 October 2009**

Joint with Inhalation Focus Group of the Academy of Pharmaceutical Sciences

Royal Pharmaceutical Society, London

**Analysis of inhaled products**

**For current information see the JPAG website: <[www.jpag.org](http://www.jpag.org)>**