

the Joint Pharmaceutical Analysis Group  
**OUTLINE INFORMATION ON  
FORTHCOMING PROGRAMMES 2008**

**Th.3-Fr.4 April 2008** Univ.London School of Pharmacy  
2-day meeting: “Faster and smarter analysis” and **JPAG 38<sup>th</sup> AGM**

**Th.12 June** King’s College London, Waterloo campus  
“Combating counterfeit medicines – the challenge for the analyst”

**8-10 September** Manchester Conference Centre  
**JPAG contributions within British Pharmaceutical Conference 2008**

**within 28 Sep/2 Oct** Reno Hilton,Nevada, USA  
“Pharmaceutical applications of Near InfraRed Spectroscopy”  
**JPAG contribution within the F A C S S meeting**

### **2008 PROPOSALS UNDER DISCUSSION**

**Th/Fr 28/29 February** RPSGB, London  
“BioVal 2008”

**Th.16 October** RPSGB, London  
“Advances in pharmaceutical laboratory efficiency”

**We. 3 December** RPSGB, London  
“The current state of *in vitro* release assessment”

Information correct at 19 September 2007

For later information see <[www.jpag.org](http://www.jpag.org)>

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## **THE JOINT PHARMACEUTICAL ANALYSIS GROUP**

Chairman: Prof A C Moffat  
Hon Treasurer: Dr AH Andrews

Hon Secretary: Prof G F Phillips OBE  
website <[www.jpag.org](http://www.jpag.org)>

### **TRACE ANALYSIS & CHALLENGES for HIGH SENSITIVITY METHODS**

at  
**the University of London School of Pharmacy, Brunswick Square, London**  
**on Thursday 13<sup>th</sup> December 2007**

#### **SCOPE**

A major challenge faced by pharmaceutical analysts throughout the industry has always been the detection of substances present at very low concentration. Often the substances are impurities that may arise from the raw materials or be generated in the process and left behind as residuals. Increasingly these days, the drug product may be so potent that very small doses are required and these must be accurately assayed.

This symposium provides a unique opportunity to bring together the views of experts with particular interests in high sensitivity detection methods as well as regulators who have concerns for patient safety arising from such potent materials and so will be of wide interest within the pharmaceutical community and beyond.

#### **WHO SHOULD ATTEND**

- ✓ those involved in trace analysis or product development
- ✓ in setting or assessing specifications for trace compounds
- ✓ pharmaceutical analysts and QA scientists.
- ✓ regulatory affairs professionals and Qualified Persons

*A customised Certificate attesting 5-hours credit for Continuing Professional Development portfolios will be included in the delegate pack of all registrants.*

## PROGRAMME

10.15 Introduction : Chairman JPAG, **Prof Tony Moffat**

### 1 : The extent of the challenge – what the assessors are concerned about

10.20 **Malcolm Dash** (MHRA, London)

- Impurities control
- Pesticide residues (herbals) and Residual Proteins (biologicals)
- Extractables and cleaning validation
- Capability and validation of methods

### 2. What the technology can find – generic approaches and special applications

11.00 Application of Mass Spectrometry techniques for trace analysis

**Andrew Ray** (AZ, Loughborough)

- MS techniques available for trace analysis
- Different uses of MS in trace analysis
- Quantitation of genotoxic impurities by MS
- The future – analysis without sample pretreatment ?

11.35 Analytical strategies for the quantification of trace impurities

**Karen Taylor-Worth** (Pfizer, Sandwich)

### 3. When knowing what is there, and how much is there, could be critical!

12.10 Cleaning validation & Specification setting – How clean is clean?

**Tim Wood** (GSK, Harlow)

12.45 **LUNCH**

13.40 Case Study on the use of threshold levels for detection of leachables

**Arthur J Shaw** (Pfizer, USA)

- Why the need for leachable thresholds
- Technological justification for threshold levels
- Is standardized methodology for leachable determination practicable?

### 4. Trace Analysis in Practice

14.15 Analysis of Highly Potent Biological molecules - How 'trace' is 'trace'?

**Andy Pickett** (Ipsen Biopharm, Wrexham)

14.50 Complying with the CHMP Guideline on Limits of Genotoxic Impurities

**Andrew Teasdale** (AZ, Loughborough)

15.25 Statistical Challenges in Trace Analysis"

**Steve Ellison** (LGC, Teddington)

- the basics of recovery
- LoD/LoQ and how to treat an "ND" result
- sample homogeneity and inter-lab comparisons

16.00 Chairman's closure

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## REGISTRATION FORM

one form per person please : fax or photocopy forms will be accepted

Completed registration forms should be returned by **Wednesday 5<sup>th</sup> December** to **Julie Churchill**  
3<sup>rd</sup> floor, Royal Pharmaceutical Society of GB, 1 Lambeth High St., London SE1 7JN

Enquiries may be made to ☎ +44 (0)20 7572 2261 ; Fax +44 (0)20 7572 2506 ; E= < [science@rpsgb.org](mailto:science@rpsgb.org) >

### REGISTRATION FEES

Members JPAG	£ 105
other Members of RSC/RPSGB £105 rate if join JPAG before 6 <sup>th</sup> Dec., otherwise	£ 175
bona fide Retired/Student/Unemployed members of RSC/RPSGB	£ 25
Not a member of any of these bodies	£ 175

All fees include registration, symposium documentation, morning coffee and lunch

A block booking can be arranged for Students, including documentation but without lunch

**PLEASE NOTE that there is NO charge for VAT**

It is regretted that, once registration is accepted, fees cannot be waived but substitutions are allowed at any time

Cheques/BACS payment (in sterling) are payable to "JOINT PHARMACEUTICAL ANALYSIS GROUP"  
**NOT** to the Royal Pharmaceutical Society

===== **PLEASE COMPLETE AS APPROPRIATE** =====

I wish to attend the Symposium ULSoP. on **Thu.13<sup>th</sup> December 2007** and provide

a remittance for £\_\_\_\_\_ Payment must be made before the start of the symposium.

DELEGATE SURNAME \_\_\_\_\_ (BLOCK CAPITALS PLEASE)

TITLE (Miss/Mrs/Ms/Mr/Dr/Prof) \_\_\_\_\_ FORENAMES \_\_\_\_\_

ORGANISATION \_\_\_\_\_

ADDRESS \_\_\_\_\_

\_\_\_\_\_  
POSTCODE \_\_\_\_\_

Tel No \_\_\_\_\_ Fax no: \_\_\_\_\_ e-mail \_\_\_\_\_

**Method of payment** (please tick one box):

- Cheque in GB pounds sterling, made payable to "The Joint Pharmaceutical Analysis Group".
- Bank Transfer: use SortCode 30-99-93. Account Number: 00779842, at Lloyds TSB Bank, 41-43 South St., Worthing, West Sussex; BN11 3AU and **Quote ref: 1207**

### **Additional Information**

- I am a member of the **J P A G**
- While **not** a member of JPAG, I **am** a member of RSC or RPSGB
- I am currently a FULLY RETIRED or UNEMPLOYED member of RSC or RPSGB
- I am a bona fide STUDENT at [name INSTITUTION] \_\_\_\_\_  
[address] \_\_\_\_\_
- I would like to be sent **directions for travel** to Univ.London Sch.of Pharmacy, Brunswick Sq.

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