

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 38th 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>

[page 4]



**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>

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

at
the University of London School of Pharmacy, Brunswick Square, London
on Thursday 13th 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

[page 2]

REGISTRATION FORM

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

Completed registration forms should be returned by **Wednesday 5th December** to **Julie Churchill**
3rd 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 >

REGISTRATION FEES

Members JPAG	£ 105
other Members of RSC/RPSGB £ 105 rate if join JPAG before 6 th Dec., otherwise	£ 175
<i>bona fide</i> 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.13th 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.

[page 3]