Thirteenth Arden House European Conference

Driving innovation, control and performance improvement on the critical path - the pivotal role of particle and powder technologies in dosage form manufacture

A 3-day conference presented by the Royal Pharmaceutical Society of Great Britain, in partnership with the Academy of Pharmaceutical Sciences and the American Association of Pharmaceutical Scientists.

Monday 31st March – Wednesday 2nd April 2008
Royal Pharmaceutical Society of Great Britain, London

www.rpsgb.org/worldofpharmacy/events

Royal Pharmaceutical Society of Great Britain

aaps

APS
apsgb.org

The 2008 Arden House European conference is a three-day conference presented by the Royal Pharmaceutical Society of Great Britain (RPSGB), the Academy of Pharmaceutical Sciences (APS) and the American Association of Pharmaceutical Scientists (AAPS).

The drive for significant step change in the industry's manufacturing performance continues to highlight the limited understanding and critical importance of the physical characteristics of both APIs and excipients, and their process interactions, on manufacturing and ultimately clinical performance. The introduction of ICH guidelines Q8 and Q10 indicate that quality cannot be tested into products and provide the necessary driver to ensure processes are under control and the concept of "quality by design" will become commonplace in the industry.

There is now no doubt that particle and powder technologies will play an increasingly key role in bridging the current process understanding and performance gap that exists between API and Drug Product Manufacture and the even more complex processing requirements of combination presentations predicted in the future.

TOPICS

This conference will review:

- The drivers for a step change in the engineering and production of pharmaceutical particles and powders
- The impact of recent scientific innovations in crystal engineering and particle technologies on the functionality, understanding, control and processing of pharmaceutical dosage forms.
- The effect on manufacturing - overcoming the inefficiencies in the manufacturing of particulate based dosage forms via continuous processing, monitoring and control.
- The improvement of product quality through the design and in-situ monitoring of material processing technologies.
- The legal, regulatory, and skill base challenges for their implementation.

CONFERENCE FORMAT

The conference format follows that of the widely recognised Arden House Conference, held annually in the USA since 1968. It combines didactic presentations on fundamentals and state-of-the-art technical information, with the presentation of workshops and case-studies, to challenge delegates in problem-solving through the application of knowledge gained during the conference. Combined with presentations by leading scientists in their fields from industry, academia and government service, there will a series of interactive round table sessions and ample opportunity time for discussions. A full social programme will provide opportunities for informal discussion and networking between delegates and the team of experts.

WHO SHOULD ATTEND

The conference will provide an essential and intensive course of study for global pharmaceutical scientists working in all aspects of the production of pharmaceuticals including R&D, product development, process engineering, manufacture, QA/QC, regulatory affairs, and senior staff from the regulatory agencies.

PROGRAMME

See www.rpsgb.org/worldofpharmacy/events for the latest version of the programme.

LEARN FROM A TEAM OF EXPERTS

Programme Committee

Conference chairs: Richard Storey (Associate Principle Scientist, AstraZeneca, UK) and Rob Price (Reader in Pharmaceutical Technology, University of Bath, UK)
Alastair Florence (University of Strathclyde, UK), Ken Leiper (Benson Associates, UK), Claire Madden-Smith (Molecular Profiles, UK), David Morton (Victorian College of Pharmacy, Monash University, Australia), Bill Jones (University of Cambridge, UK), Tom Sam (Organon, Netherlands)

Many thanks to colleagues from the Joint Pharmaceutical Analysis Group for their help in setting the programme.

Contributors

Lars-Erik Briggner, AstraZeneca, Sweden
Roland Boese, University of Duisburg-Essen, Germany
Scott Childs, Aptuit, USA
Gerard Coquerel, University of Rouen, France
Aurora Cruz Cabeza, University of Cambridge, UK
Roger Davey, University of Manchester, UK
Marc Descamps, University of Lille, France
Sarah Dilworth, AstraZeneca, UK
Robert Docherty, Pfizer, UK
Alastair Florence, University of Strathclyde, UK
Jim Fox, GlaxoSmithKline, UK
Angelo Gavezzotti, University of Milan, Italy
Amy Gillon, AstraZeneca, UK
Ken Leiper, Benson Associates, UK
Ivan Marziano, Pfizer, UK
David Morton, Victorian College of Pharmacy, Monash University, Australia
Gordon Munroe, Watson Pharma, USA
Fernando Muzzio, Rutgers University, USA
Wolfgang Peukert, University of Erlangen, Germany
Rob Price, University of Bath, UK
Gavin Reynolds, AstraZeneca, UK
Dave Rudd, GlaxoSmithKline, UK
Graham Ruecroft, Prosonix, UK
Tom Sam, Organon, Netherlands
Jonathan Seville, University of Birmingham, UK
Martyn Ticehurst, Pfizer, UK
Andrew Trask, Jonesday, USA
Neil Wilkinson, AstraZeneca, UK
Janet Woodcock, FDA, USA

VENUE

The Royal Pharmaceutical Society is conveniently located in central London with easy access from Waterloo, Vauxhall and Victoria rail and tube stations (for directions see http://www.rpsgb.org/pdfs/rpsgbmap.pdf). Delegates should expect to register from approximately 09.00 on Monday 31st March and the meeting should end at approximately 16.00 on Wednesday 2nd April.

Delegates are responsible for arranging their own accommodation. For more information on hotels in the area, please contact RPSGB on 020 7572 2261 or email science@rpsgb.org.

DELEGATE FEES

Delegate fees are £950 for members of RPSGB, APS or AAPS or £995 for non-members. Fees are inclusive of lunches and refreshments, a full social programme (including dinner on the last evening) and comprehensive course documentation.

REGISTER BEFORE 30 NOVEMBER 2007 FOR THE EARLY BIRD FEE OF £895

PROGRAMME

MONDAY 31 MARCH

SESSION 1: The drivers for change
Moderators: Richard Storey, AstraZeneca, UK and Rob Price, University of Bath, UK

What are the shortfalls of the current approaches to powder technology?
Fernando Muzzio, Rutgers University, USA

The current manufacturing environment
Neil Wilkinson, AstraZeneca, UK

Pharmaceutical powders: Why do we need enhanced control in particle formation?
Robert Docherty, Pfizer, UK

Continuous processes and life cycle management - the factory of the future
Jim Fox, GlaxoSmithKline, UK

Creating a regulatory environment to encourage innovation and change
Janet Woodcock, FDA, USA (via video conference)

Lunch

SESSION 2: Engineering and control of particle formation 1
Moderator: Alastair Florence, University of Strathclyde, UK

Nucleation simulation: what do we know about nucleation on the molecular scale?
Angelo Gavezzotti, University of Milan, Italy

Crystallisation engineering to aid drug product processing or performance
Amy Gillon, AstraZeneca, UK

Control of polymorphic systems during crystallization
Roger Davey, University of Manchester, UK

The use of ultrasonic crystallisation in providing a level of control in crystallisation procedures
Graham Ruecroft, Prosonix, UK

Round table discussion

Wine Reception

TUESDAY 1 APRIL

SESSION 2: (continued) Engineering and control of particle formation 2
Moderators: Rob Price, University of Bath, UK and Claire Madden - Smith, Molecular Profiles, UK

Particle formation and technologies, particle size optimization
Wolfgang Peukert, University of Erlangen, Germany

Novel methodologies for the production of material for particulate systems
Ivan Marziano, Pfizer, UK

Surface interactions and their importance in performance of pharmaceutical formulations
Rob Price, University of Bath, UK

Excipient variability and its impact on a drug product manufacture
Sarah Dilworth, AstraZeneca, UK

Investigating powder processing
David Morton, Victorian College of Pharmacy, Monash University, Australia

Lunch

SESSION 3: Opportunities for optimizing particulate properties using crystal modifications
Moderator: Bill Jones, University of Cambridge, UK

The salt-cocrystal continuum
Scott Childs, Aptuit, USA

The use of solvates and hydrates as pharmaceutical forms
Gerard Coquerel, University of Rouen, France

The issue of cocrystal formation by grinding and the possible role of amorphous intermediates
Marc Descamps, University of Lille, France

Obtaining cocrystals and using synthons in the design of cocrystals
Roland Boese, University of Duisburg-Essen, Germany

Crystal structure prediction, an introduction and the potential for predicting cocrystals
Aurora Cruz Cabeza, University of Cambridge, UK

Round table discussion

Social programme with dinner

WEDNESDAY 2 APRIL

SESSION 4 Control of processes for particulate-based systems
Richard Storey, AstraZeneca, UK and David Morton, Victorian College of Pharmacy, Monash University, Australia

Aspects of control in the formulation of particulate products
Jonathan Seville, University of Birmingham, UK

Characterization of materials for formulation control - oral & inhaled
Martyn Ticehurst, Pfizer, UK

Use of Design of Experiments in identifying design space
David Prime, Glaxosmithkline

Understanding particle surfaces/conditioning
Lars-Erik Briggner, AstraZeneca, Sweden

Understanding processes using PAT, case studies
Gavin Reynolds, AstraZeneca, UK

The criticality of sampling and relevance of measurement in process control
Dave Rudd, GlaxoSmithKline, UK

Lunch

SESSION 5: The intellectual property, regulatory and educational success factors for facilitating this paradigm shift
Tom Sam, Organon, Netherlands and Ken Leiper, Benson Associates, UK

The intellectual property challenges arising from enhanced knowledge of powders, processability and isolation
Andrew Trask, Jonesday, USA

A regulatory perspective of the related challenges for industry, agencies, pharmacopoeias and the qualified person
Gordon Munro, Watson Pharmaceuticals, USA

The adoption of new technologies requires new skills – how will the global challenge be facilitated?
Fernando Muzzio, Rutgers University, USA

Close of conference

CHANGES TO THE PROGRAMME

The Royal Pharmaceutical Society will endeavour to present the programme as described. However, it reserves the right to make changes to the programme or speakers but will advise delegates of changes in advance. Should it be necessary to cancel the event, delegates will be advised as soon as possible and will receive a full refund of fees paid. The Royal Pharmaceutical Society does not accept liability for any expenses incurred by delegates, including advance purchase travel tickets.

CANCELLATION AND REFUND

Should you find that you are not able to attend the conference after booking a place, please advise us in writing as soon as possible. If a colleague is able to attend in your place and you notify us in writing, we are pleased to accept the substitution at no charge. In the event that it is necessary to cancel a registration, please notify us in writing. A processing fee is payable. For cancellations, the following refunds will apply: Over 14 days: 90% of the fee; less than 14 but over 3 working days: 50% of the fee; three or less working days: nil. The time of notification is taken at the date of receipt of fax or letter. Substitution is permitted at any time if notified in writing.

REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will be liable to pay the fees. Payment must be made before the start of the course.

PLEASE WRITE CLEARLY IN BLOCK CAPITALS

SURNAME …….. ....

TITLE (Miss/Mrs./Ms./Mr./Dr./Prof) ……..FORENAME……

ORGANISATION ……..

ADDRESS …….

……

……..

POST CODE ……...TELEPHONE NUMBER……..……..

FAX NUMBER ……EMAIL ADDRESS.....

MEMBERSHIP NUMBER (if applicable)……..

By giving us your details you are agreeing to be added to our electronic and postal mailing list and receive information on our events. Please note that your information will not be sold and will be handled in accordance with the Data Protection Act and the Society's Privacy Policy

☐ Tick here if you do not wish to be added to our mailing list

I have specific dietary requirements (please detail).....

.....

Registration fees: £950 for members of Royal Pharmaceutical Society, Academy of Pharmaceutical Sciences or American Association of Pharmaceutical Scientists or £995 for non-members (fees inclusive of meals and refreshments, a welcome reception, social programme, and course documentation.)

REGISTER BEFORE 30 NOVEMBER 2007 FOR THE REDUCED EARLY BIRD FEE OF £895

☐ I am registering before 30 November 2007 and enclose an early bird fee of £895

☐ I am a member of RPSGB, APS* or AAPS and registering after 30 November 2007 (£950)

☐ I am a non-member and registering after 30 November 2007 (£995)

*Academy of Pharmaceutical Sciences. Members of the Academy of Pharmaceutical Sciences qualify for reduced fees to a number of scientific meetings, including residential courses. The cost of membership is £60 per annum. For further information and a membership application form please contact us at the address over the page.

METHOD OF PAYMENT (Payment must be made before the start of the course)

PLEASE DO NOT INCLUDE ANY OTHER PAYMENTS TO RPSGB

☐ Cheque in GB pounds sterling, made payable to “The Royal Pharmaceutical Society”

☐ Bank Transfer:

Sort Code 60 60 04. Account Number: 7037 8193. Quote ref no: CAS/SPR/400
National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB

☐ Credit card ☐ Mastercard ☐ Visa ☐ Amex

Card Number - - - - - - - - - - - - - - - - Security Number - - -

Expiry Date ...../...../.....

Signed .....

VAT registration number GB 233 0296 92 (A VAT receipt will be issued upon request)

CARDHOLDER’S NAME.....

ADDRESS .....

.....

.....

POST CODE .....

PLEASE COMPLETE THE REVERSE SIDE OF THIS REGISTRATION FORM

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED
Please return this form with your payment to: Science Programme Manager, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: science@rpsgb.org (Tel: 020 7572 2261)

Cancellation and refund
Should you find that you are not able to attend the event after booking a place, please advise us in writing as soon as possible. If a colleague is able to attend in your place and you notify us in writing, we are pleased to accept the substitution at no charge. In the event that it is necessary to cancel a registration, please notify us in writing. A processing fee is payable. For cancellations, the following refunds will apply: Over 14 days: 90% of the fee; less than 14 but over 3 working days: 50% of the fee; three or less working days: nil. The time of notification is taken at the date of receipt of fax or letter. Substitution is permitted at any time if notified in writing.