Stability Testing Of Pharmaceuticals

Royal Pharmaceutical Society of Great Britain

A three-day residential course organised by the Royal Pharmaceutical Society of Great Britain in partnership with the Academy of Pharmaceutical Sciences.

Monday 9 – Wednesday 11 February 2009
Moller Centre, Cambridge, UK

APS
apsgb.org

www.rpsgb.org/worldofpharmacy/events

OBJECTIVES:

An up-to-date and well-established residential course designed to:

- Provide delegates with a detailed appraisal of the rationale and techniques associated with the stability testing of pharmaceuticals and related products.
- Illustrate the essential steps in the development of stability testing protocols through practical examples.
- Inform delegates about all aspects of stability testing, including criteria for product stability, challenges associated with specific product types (including biotechnology products, complex formulations and devices), application of statistical tools and new technology for stability assessment, and the application and limitations of stability test procedures.

PROGRAMME
MONDAY 9 FEBRUARY

08.00	Registration (including coffee & networking)
09.15	Introduction by the course director Kevin Ryan, Pfizer
09.30	Setting the scene – Stability of materials we put on or in our bodies Kevin Ryan, Pfizer
10.00	The chemical basis for the stability testing of pharmaceuticals Andy Rignall, AstraZeneca R & D
11.15	Physical aspects of product stability Graham Leonard, GSL Pharma Consulting
12.30	Lunch
13.30	Purposeful degradation studies and the development of stability-indicating methodology TBD
14.30	Interactive workshop: the instability of 'profragilazone' – analytical & formulation development strategies TBD
15.30	Coffee and networking
15.45	Interactive workshop: teams feedback and group discussion TBD
16.45	Workshop session report
17.00	Close of day
18.00	Welcome drinks reception
19.15	Dinner

- Discuss UK and international regulatory aspects, including the guidelines for stability testing within the EU, Japan and the USA introduced through the ICH.
- Enable delegates to discuss real challenges faced in day-to-day work through a blend of interactive workshops and informative presentations.
- Provide delegates with opportunities for informal discussion and problem-solving sessions with the experts. Delegates are encouraged to bring problems to discuss at the workshop sessions.
- Allow delegates to network with course tutors and other delegates from the field through an informal welcome reception and course dinners.
- Provide reference material for use after the course through a full resource pack and CD-ROM with relevant reference documents.

TUESDAY 10 FEBRUARY

09.00	Characterising materials with respect to physical stability Paul Royall, King's College London
10.00	Statistical interpretation of stability data Stan Altan, Johnson & Johnson
11.00	Coffee and networking
11.30	Stability testing of pharmaceutical delivery devices Sue Smith, AstraZeneca
12.45	Lunch
13.45	Stability testing of biotechnology products Alison Sykes, Lonza Biologics
14.45	Product packaging and stability: an overview Roy Gray, Consultant
15.15	Coffee and networking
15.30	Workshop on product packaging Roy Gray, Consultant
16.30	Stability testing - the UK and European regulatory perspective TBD, Medicines and Healthcare products Regulatory Agency
17.30	Open forum - round table discussion TBD, Medicines and Healthcare products Regulatory Agency
18.15	Close of session
19.15	Dinner

WHO SHOULD ATTEND

The course is aimed at:

- Those involved in all stages of stability evaluation.
- All those involved in stability testing of pharmaceuticals and related products.
- Formulation and analytical scientists.
- Those involved in regulatory affairs.
- Recent graduates working in the R&D environment.
- Colleagues from related fields such as food sciences and cosmetics.

WEDNESDAY 11 FEBRUARY

08.30	International aspects of stability testing for product registration Jon Beaman, Pfizer
09.30	Workshops in parallel session Jon Beaman, Pfizer
	Workshop 1 - Stability testing by contract research organisations
	Workshop 2 - Establishment of stability testing criteria
	Workshop 3 - Minimal stability study design for worldwide filing
10.20	Coffee and networking
10.45	Feedback and workshop reports
11.45	Practical aspects of stability testing Gerry Maxwell, NDA Analytics
12.45	Lunch
13.45	Accelerated stability assessment program (ASAP): using science to set shelf life Garry Scrivens, Pfizer
15.00	Close of course

WHAT PREVIOUS DELEGATES HAVE SAID:

"An enjoyable course that I will recommend to colleagues."

"As a relatively inexperienced formulation chemist, this course provided me with essential knowledge that will be valuable for my career development."

"Would recommend that anyone in the stability industry should attend."

"An interesting and comprehensive course which has provided a good forum for open debate with issues surrounding stability testing."

LEARN FROM A TEAM OF EXPERTS

Course director

Kevin Ryan, Pfizer Global Research and Development

Speakers

- Stan Altan, Johnson & Johnson
- Jon Beaman, Pfizer
- Roy Gray, Consultant
- Graham Leonard, GSL Pharma Consulting
- Gerry Maxwell, NDA Analytics
- Andy Rignall, AstraZeneca
- Paul Royall, King's College London
- Susan Smith, AstraZeneca
- Alison Sykes, Lonza Biologics R & D

VENUE

The Moller Centre in Cambridge is a modern and comfortable purpose-built conference and training venue in the grounds of Churchill College - easily accessible by road, train and air. Car parking facilities are available.

THE MOLLER CENTRE CAMBRIDGE

STABILITY TESTING OF PHARMACEUTICALS - 9-11 FEBRUARY 2009
REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will liable to pay the fees. Payment must be made before the start of the course. **Register before 31 October 08 for reduced early bird fee**.

Early-bird (Before 31 Oct 08): £1,695 ☐

RPSGB or APS members: £1,795 ☐

Non-members: £1,865 ☐

Title	Forename	Surname
Job Title		Post code
Company		Email
Address		Telephone
		Membership No.

☐ 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 the mailing list.

Dietary Requirements	How did you hear about this event?

METHOD OF PAYMENT

☐ Bank transfer (Sort Code 60 60 04 Account Number: 70378193. National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB) Quoting ref **CAS/SPR/403**

☐ Debit/Credit card ☐ Maestro ☐ Mastercard ☐ Visa ☐ Amex

Card No.	Security No.
Card holder's name and address (if different from above)	Expiry
	Signed

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED
Please return this form with your payment to: Science Programme Admin Assistant,
Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: science@rpsgb.org (Tel: 020 7572 2640)

NB. IF YOU DO NOT RECEIVE A CONFIRMATION OF YOUR PLACE VIA EMAIL WITHIN 5 WORKING DAYS OF SUBMITTING YOUR REGISTRATION FORM PLEASE LET US KNOW

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 thedate of receipt of fax or letter. Substitution is permitted at any time if notified in writing.