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 22 – Wednesday 24 February 2010
Moller Centre, Cambridge, UK

APS
apsgb.org

Honeywell
Main supporter

www.rpsgb.org/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.
- 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.

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.

PROGRAMME

MONDAY 22 FEBRUARY

08.00 Registration

09.00 Introductions
Kevin Ryan, Pfizer R&D and Andy Rignall, AstraZeneca R&D

09.15 Setting the scene
Kevin Ryan

9.45 Avoiding stability issues - chemical basis for the stability testing of pharmaceuticals
Andy Rignall

10.45 Coffee and networking

11.00 Physical aspects of product stability
Graham Leonard, GSL Pharma Consulting

12.00 Lunch

13.00 Characterising materials with respect to physical stability
Paul Royall, King's College London

14.00 Purposeful degradation studies and the development of stability-indicating methodology
Andy Rignall and Sue Smith, AstraZeneca R & D

15.00 Practical aspects of stability testing
Gerry Maxwell, NDA Analytics

16.00 Coffee and networking

16.15 Interactive workshop: the stability of 'profragilazone' – analytical & formulation development strategies
Andy Rignall, Gerry Maxwell, and Sue Smith

17.15 Interactive workshop: teams feedback and group discussion
Andy Rignall and Sue Smith

18.00 Workshop session report

18.15 Close of day

19.00 Welcome reception

20.00 Dinner and table debates

TUESDAY 23 FEBRUARY

8.30 Statistical intrepretation of stability data
Stan Altan, Johnson & Johnson

9.30 Stability testing of pharmaceutical delivery devices
Sue Smith

10.30 Coffee and networking

11.00 Stability testing of biotechnology products
Steve Flatman, Lonza Biologics

12.00 Product packaging and stability: an overview
TBD

13.00 Lunch

14.00 Show and tell – examples of packaging failures/ fixes
TBD

14.30 Workshop on devising appropriate development clinical stability protocol
TBD

15.30 Coffee and networking

15.45 QBD for stability and accelerated stability assessment program (asap): using science to set shelf life
Garry Scrivens, Pfizer

16.45 Stability testing - the UK and European regulatory perspective
Paul Marshall, Medicines and Healthcare products Regulatory Agency (MHRA)

17.45 Open forum - round table discussion
Paul Marshall

18.30 Close of session

19.30 Dinner and table debates

WEDNESDAY 24 FEBRUARY

09.00 Healthcare packaging that is value based
Thomas Dries, Honeywell

09.30 Registration stability testing for product
Allan Edwards, 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

12.30 Lunch

13.30 Feedback and workshop reports

14.00 Open forum – final round table discussion
Andy Rignall, Allan Edwards, Kevin Ryan

15.00 Close of course

WHAT PREVIOUS DELEGATES HAVE SAID:

"Thoroughly enjoyable course - organised to a high standard and open forum maintained throughout. Lecturers provided an extremely welcoming reception and gave good opportunities for relevant discussions."

"The course was thoroughly enjoyable, educational and pertinent to my current role."

"I thoroughly enjoyed the course. I do not rate anything highly unless it thoroughly meets my standards. This course definitely did. Thank you."

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

LEARN FROM A TEAM OF EXPERTS

Course directors

Kevin Ryan, Pfizer Global Research and Development
Andy Rignall, AstraZeneca Research and Development

Speakers

- Stan Altan, Johnson & Johnson
- Allan Edwards, Pfizer
- Steve Flatman, Lonza Biologics
- Graham Leonard, GSL Pharma Consulting
- Paul Marshall, MHRA
- Gerry Maxwell, NDA Analytics
- Andy Rignall, AstraZeneca
- Paul Royall, King's College London
- Gary Scrivens, Pfizer
- Susan Smith, AstraZeneca

This course is kindly supported by Honeywell (www.honeywell.com)

STABILITY TESTING OF PHARMACEUTICALS 22-24 FEBRUARY 2010

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. Fees inclusive of two nights accommodation, catering and course documentation.
Register before 18 December 2009 for an early bird discount. DELEGATE FEES FIXED AT 2009 PRICES.

	Early Bird before 18.12.09		Full Fee	
MEMBER OF RPSGB OR APS	£1,695	☐	£1,795	☐
NON -MEMBER	£1,745	☐	£1,865	☐
MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£1,410	☐	£1,510	☐
NON MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£1,460	☐	£1,580	☐

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

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