Course

ROYAL PHARMACEUTICAL SOCIETY

In association with

APS

Stability testing of pharmaceuticals

The Møller Centre, Cambridge
Monday 28 January – Wednesday 30 January 2013

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.

WHO SHOULD ATTEND

- Those involved in all stages of stability evaluation.
- 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.

COURSE DIRECTORS

Kevin Ryan

Pfizer Global Research and Development

Kevin Ryan is an Associate Director, Analytical R&D, Worldwide Pharmaceutical Sciences (WWPS), and is based in Sandwich, Kent. He currently runs a clinical stability team and dissolution development team. He has 19 years experience in several analytical roles including support for a wide variety of Human and veterinary APIs and drug products at all stages of development from discovery through to registration, and has led a team delivering global method validation guidance to WWPS.

Kevin joined Pfizer in 1987 after successful completion of studies at the University of Strathclyde in Forensic science and Irish technical colleges in applied toxicology and biology.

Andy Rignall

AstraZeneca Research and Development

Andy Rignall is an Associate Director in the Analytical Sciences group at AstraZeneca UK and manages a section accountable for analytical support to a range of projects at various stages of development. Understanding the stability behaviour of each product and its ingoing active pharmaceutical ingredient remains an important element of this role. Involvement with the development and commercialization of pressurized metered dose inhalers (MDIs) has emphasised the need to understand the impact of the container closure system on product stability. The experience gained has also highlighted the importance of developing capable measurement systems to monitor stability performance and ensure optimal stability data packages. Andy received his PhD from Bradford University where he studied the adsorption of organo-phosphorous compounds onto clays and has worked in the Pharmaceutical Industry for 22 years.

DAY 1

MONDAY 28 JAN

08.00 Registration and coffee

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

09.00 Setting the scene
Kevin Ryan, Pfizer R&D

10.00 Using chemical knowledge to avoid stability issues
Andy Rignall, AstraZeneca R&D

11.00 Coffee and networking

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

12.30 Lunch

13.30 Predicting stability issues and how to control them in DP based on knowledge of specific API/DP properties
Andy Rignall, AstraZeneca R&D

14.30 Chem Deg - How to predict deg in my API/DP and strategy for GTI's
Andy Rignall, AstraZeneca R&D

15.30 Coffee and networking

16.00 ASAP - What it is and how I can use it to rapidly predict stability of API/DP
Garry Scrivens, Pfizer R&D

17.00 Regulatory perspectives on Clinical and Registration Stability
Paul Marshall, Medicines and Healthcare products Regulatory Agency

18.00 Close of day

18.30 Welcome reception

19.30 Dinner and table debates

TUESDAY 29 JAN

08.30 **Best practices in pack-stability trials - from primary packaging selection to pack-integrity testing**
Thomas Dries, Honeywell

09.00 **Interactive workshop 1:The stability of 'fragilazole' - analytical & formulation development strategies**
Andy Rignall, AstraZeneca R&D, Kevin Ryan, Pfizer R&D and Gerry Maxwell, NDA Analytics

10.00 **Coffee and networking**

10.30 **Interactive workshop 1:Teams feedback and group discussion**
Andy Rignall, AstraZeneca R&D, Kevin Ryan, Pfizer R&D and Gerry Maxwell, NDA Analytics

11.30 **Packaging**
- introduction/principles and strategy
- show and tell -
examples of packaging failures/fixes
David Pethick, DPPK Consulting

12.30 **Lunch**

13.30 **Stability of complex products (biologics and Devices) including extractables/leachables considerations**
Andy Rignall, AstraZeneca R&D

14.30 **Stability of complex products (biotechnology products) Specific issues associated with these products**
Andy Rignall, AstraZeneca R&D

15.30 **Coffee and networking**

16.00 **Interactive workshop 2: Design an appropriate development clinical stability protocol based on product knowledge building in QRM and**

TUESDAY 29 JAN (contd)

QbD concepts, and regulatory arena
Andy Rignall, AstraZeneca R&D, Kevin Ryan, Pfizer R&D

17.00 Practical aspects of doing protocols (OOS, dealing with CRO's)
Gerry Maxwell, NDA Analytics

18.00 Open forum - round table discussion
All presenters and attendees

18.30 Close of day

19.30 Dinner and table debates

WEDNESDAY 30 JAN

08.30 Registration stability - strategy and requirements
Kevin Lord, GSK

09.30 Application of statistical design to ICH programmes and statistical interpretation of data and strategies
Mark Whitlock, Pfizer/ Neusentis

10.30 Coffee and networking

11.00 Interactive workshop 3:
A - Design an appropriate minimal design registration programme for a worldwide filing based on product knowledge building in QRM and QbD concepts, regulatory arena and cost
B - Establishing commercial stability testing criteria based on product knowledge build in QRM and QbD concepts and regulatory arena

12.30 Lunch

13.30 Feedback and workshop reports
Kevin Lord, GSK, Andy Rignall, AstraZeneca R&D, Kevin Ryan, Pfizer R&D

14.30 Close of course

For more information or to register, visit

www.rpharms.com/events

WHAT PREVIOUS DELEGATES SAID ABOUT OUR COURSES

"Excellent and well balanced course. Would definitely recommend it to others."

"This was an excellent and informative course. The content had clearly been put together with a lot of thought from the organisers. "

"All presentations were delivered in an interesting and interactive manner. I would definitely recommend attending this course to other people in the industry."

"Extremely relevant and useful lectures"

VENUE AND ACCOMMODATION

The Møller Centre is a modern and 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 Møller Centre
Storey's Way, Cambridge, CB3 0DE

Two ways to register

- Visit **www.rpharms.com/events** and pay with credit/debit card or request an invoice.
- Complete this form and post, email or fax it back to us. You will be registered upon receipt of the completed form and payment must be made before the start of the course.

What's included in the fees?

- Course documentation
- Social programme
- Meals and refreshments throughout the day
- Fees with accomodation include two nights at the Møller Centre and evening meals

N.B. Please contact us if you haven't received an email confirmation of your booking within 5 working days of submitting your form.

MEMBERS RPS	Early bird fee (before 3.12.12)	Full fee
Course only	☐ £1,410	☐ £1,555
Course + accommodation + evening meals	☐ £1,700	☐ £1,845

NON-MEMBERS	Early bird fee (before 3.12.12)	Full fee
Course only	☐ £1,485	☐ £1,630
Course + accommodation + evening meals	☐ £1,775	☐ £1,920

PAYMENT AND DETAILS

Method of payment ☐ Debit/credit card (someone will contact you to obtain your card details)

☐ Bank transfer (Sort code **60 60 04** Account number **45130574**
National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB)
Quoting reference: **MMS EVT 403**

Title Firstname	Surname
Job title	Company
Address	
	Postcode
Telephone	Membership number
Email	
Dietary requirements	

PLEASE RETURN THIS FORM TO:

Events Coordinator, Royal Pharmaceutical Society, 1 Lambeth High Street, London SE1 7JN
Telephone: 0845 257 2570 **Fax:** 020 7572 2506 **Email:** events@rpharms.com **Web:** www.rpharms.com/events

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