

Stability Testing of Pharmaceuticals

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

Monday 18 – Wednesday 20 February 2008
Moller Centre, Cambridge, UK

www.rpsgb.org/worldofpharmacy/events



**Royal
Pharmaceutical
Society**
of Great Britain



In this thoroughly updated and comprehensive course delegates will be provided with a detailed appraisal of the rationale and techniques associated with the stability testing of pharmaceuticals and related products. Aspects covered will include criteria for product stability, challenges associated with specific product types, including biotechnology products, complex formulations and devices, new technology for stability assessment, and the application and limitations of stability test procedures. UK and international regulatory aspects will be discussed, including the guidelines for stability testing within the EU, Japan and the USA introduced through the ICH (International Conference on Harmonisation). Workshop sessions will use practical examples to illustrate essential steps in the development of stability testing protocols. Sufficient time will be available for detailed discussion and questions during the lecture programme.

LEARN ABOUT

- Chemical and physical aspects of drug substance and drug product stability
- Development pharmaceuticals and stability testing
- Rational design of stability testing methods
- Selection and validation of stability-indicating analytical methods
- Stability testing of biotechnology products
- Product packaging and stability testing
- Application of statistical tools for the assessment and interpretation of stability data
- UK and European regulatory perspectives on stability testing
- International aspects of stability testing for product registration
- Characterising materials with respect to physical stability
- Practical aspects of finished product testing

CONTENT & OBJECTIVES

This successful and well established course, updated for 2008, is designed to be applicable to both experienced colleagues and those new to stability testing. The course is comprehensive and will provide a detailed appraisal of the rationale and techniques associated with the stability testing of pharmaceuticals and related products. Aspects covered will include 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.

UK and international regulatory aspects will be discussed, including the guidelines for stability testing within the EU, Japan and the USA introduced through the ICH. Workshop sessions will use practical examples to illustrate essential steps in the development of stability testing protocols. Sufficient time will be available for detailed discussion and questions during the lecture programme and delegate networking opportunities.

The course is based on a blend of current and informative presentations together with interactive workshops that allow discussion of real challenges encountered in day to day work. The highly participative workshops provide opportunities for informal discussions and problem-solving sessions with the course tutors. Delegates are encouraged to bring problems to discuss at the workshop sessions. This might be the design of a protocol for a difficult product, a difficult set of data to interpret or the design of an appropriate non-pharmacopoeial test for an unusual product.

The social programme includes an informal welcome reception and course dinners, arranged to maximise the opportunities for informal discussion and networking between delegates and the team of course experts. The resource pack supplied to each delegate includes a CD-ROM with relevant reference documents.

OUTLINE PROGRAMME

- Setting the stability scene
- Overview of stability testing
- Chemical and physical aspects of drug substance and drug product stability
- Development pharmaceuticals and stability testing
- Rational design of stability testing methods
- Selection and validation of stability-indicating analytical methods
- Stability testing of biotechnology products
- Stability assessment of complex formulations and devices
- Product packaging and stability testing
- Application of statistical tools for the assessment and interpretation of stability data
- UK and European regulatory perspectives on stability testing
- International aspects of stability testing for product registration
- Characterising materials with respect to physical stability
- New approaches to stability testing such as isothermal methods and PAT.
- Quality by design, Right first time and Bio-investment paradigm philosophies
- Practical aspects of finished product testing

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 delegates 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.

WHO SHOULD ATTEND

The course is designed to provide a programme for those involved in all stages of stability evaluation. It will be of value to all those involved in stability testing of pharmaceuticals and related products, including formulation and analytical scientists, those involved in regulatory affairs as well as recent graduates working in an R&D environment. Although relying on expertise within the pharmaceutical industry, the course will be equally relevant for workers in related fields such as food science and cosmetics.



LEARN FROM A TEAM OF EXPERTS

Course Director

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.

Dr Andy Rignall, AstraZeneca R&D

Dr Rignall is an Associate Director at AstraZeneca Charnwood and has worked as an Analytical Chemist in the Pharmaceutical Industry since 1987, after leaving the University of Bradford with a PhD (a study of the adsorption of organophosphorous compounds onto clays). Stability testing has formed a significant part of his career to date and he has been involved with projects at all stages of development from pre-clinical to registration. More recently, Andy has become involved with packaging and device development and is gaining a better understanding on how and where these aspects fit into the stability puzzle.

Dr Graham Leonard, GlaxoSmithKline

Dr Leonard is Director of Pharmaceutical Development, New Chemical Entities, Harlow. He graduated in 1967 from The School of Pharmacy, University of London and followed this with a PhD, working on research into properties of compressed tablets. He has worked in the Pharmaceutical industry for more than thirty years in the field of pharmaceutical development, with his first appointment being with Eli Lilly at the Lilly Research Centre Ltd., before joining Smith Kline & French Laboratories Limited in 1973. His career developed here through a series of posts (and company transformations) with increasing seniority, culminating in his present position at GlaxoSmithKline. He has experience of a wide range of dosage forms and lists Tagamet®, Seroxat®, Ridaura® and Avandia® amongst the successful products he has developed. In his current role he has prime responsibility for all pharmaceutical aspects in the selection of NCE development candidates in the areas of Neurology and GI and their subsequent development through clinical trials and registration to commercial production.

Dr Andrew Lipczynski, Pfizer Global R&D

Until recently, Dr Lipczynski was a Senior Director in Analytical R&D, Worldwide Pharmaceutical Sciences, Sandwich Laboratories, Pfizer Global R&D, responsible for providing all analytical support and stability studies for the development of human and veterinary medicinal projects, from late Discovery through Phase III studies to technology/knowledge transfer to manufacturing and to global registration and post-approval activities. His current role is Research Fellow, responsible for Intellectual Property Management and CMC review of Licensing & Development opportunities. He has experience in the pharmaceutical development of both conventional NCEs and biologic NMEs, a diverse variety of dosage formulations and associated specialised drug delivery technologies such as inhaled and oral modified release drug products. Andrew joined Pfizer in 1987 after PhD studies at the University of Bath researching the degradation and analysis of beta-lactam antibiotics.

Dr Paul Royall, King's College London

Dr Royall lectures in pharmaceuticals at King's College London. Paul Royall has many years of experience in applying thermal analysis and calorimetry to the characterisation of pharmaceutical materials. He has been on the committee of Thermal Analysis group of the Royal Society of Chemistry and is on the Editorial Board of *Thermochimica Acta*. Paul's first degree was Chemistry and his Ph.D. supervised by Prof A.E. Beezer was an investigation of the thermodynamics and kinetics of transfer across model biophases in particular DPPC SUV liposomes. Both of these degrees were awarded by the University of Kent at Canterbury. Since then Paul's area of research has progressed towards solid state issues, namely processed induced disorder, amorphous formulation and polymorph stability. These research themes were developed during his post-doctoral positions at the School of Pharmacy University of London and The Queen's University of Belfast.

Ms Sue Harris, Medicines and Healthcare products Regulatory Agency

Ms Harris graduated from the School of Pharmacy University of London in 1975. After completing her pre-registration year, she worked as a community pharmacist until 1986 when she changed direction completely and joined Licensing Division of the Department of Health as a Pharmaceutical Officer, assessing applications for parallel imports. Ms Harris obtained an MSc in biopharmacy from Chelsea College (now part of Kings College) in 1990 and on creation of the Medicines Control Agency (now the MHRA) moved across to assessing the chemistry and pharmacy dossiers for abridged applications. Since then she has been responsible for assessing new drug applications as well as abridged applications both nationally and through the mutual recognition and centralised procedures and is currently Unit Manager of the anti-infectives, genito-urinary and obstetrics and gynaecology product lifecycle assessment team.

Dr Jon Beaman, Pfizer

Dr Beaman is a Senior Director, Analytical R&D, Worldwide Pharmaceutical Sciences, and is based in Sandwich, Kent. He runs the Pfizer Global Stability Group, with teams based in both the UK and the US, responsible for designing and running all stability studies for Pfizer small molecule new chemical entities. He has 14 years experience in a variety of analytical roles including support for a wide variety of APIs and drug products at all stages of development, setting up and running a pilot plant analytical support unit, running a separation sciences group and being responsible for an analytical group supporting all aspects of the veterinary medicine portfolio covering a large number of products and dosage form types. Dr Beaman studied for his PhD in chromatography/mass spectrometry with Professor Dai Games at Swansea.

Mr Gerry Maxwell, NDA Analytics

Mr Maxwell graduated in Biochemistry from Queens University Belfast in 1982 and obtained his Masters degree in Analytical Chemistry from the same university in 1983. He has worked in pharmaceutical analysis for 20 years and is currently Head of Pharmaceutical Analysis & Quality Control at the contract laboratory, NDA Analytics. He is responsible for methods development and validation, compound and product characterisation, stability testing and QC release testing (both for marketed products and Investigational Medicinal Products, IMPs), undertaken on behalf of pharmaceutical and biopharmaceutical companies. He is a Qualified Person for release of IMPs in the EU. In his role, he has been the lead respondent during several MHRA and FDA PAI GMP inspections of his facility.

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.

Delegates are asked to arrive and register by 09.00 on Monday 18 February (the course will start promptly at 09.15). The course will end at approximately 15.00 on Wednesday 20 February.

DELEGATE FEES

FIXED AT 2007 RATES – Delegate fees for the 2008 course will remain at the 2007 rate of £1,760 or £1,690 for members of the Royal Pharmaceutical Society or the Academy of Pharmaceutical Sciences. The fees are inclusive of 2 nights' accommodation, meals and refreshments, a welcome reception and a resource pack with full course documentation and CD-ROM.

REGISTER BY 30 NOVEMBER 2007 FOR THE EARLY BIRD FEE OF £1,640

CANCELLATION & REFUND

Should you find that you are not able to attend the residential course 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.

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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."

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 CODETELEPHONE NUMBER.....

FAX NUMBEREMAIL 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)

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Registration fees: £1,690 for members of Royal Pharmaceutical Society or Academy of Pharmaceutical Sciences* or £1,760 for non-members (fees inclusive of 2 nights' accommodation, meals and refreshments, a welcome reception, and a resource pack with full course documentation and CD ROM.)

REGISTER BEFORE 30 NOVEMBER 2007 FOR THE REDUCED EARLY BIRD FEE OF £1,640

☐ I am registering before 30 November 2007 and enclose an early bird fee of £1,640

☐ I am a member of the Royal Pharmaceutical Society or Academy of Pharmaceutical Sciences* and registering after 30 November 2007 (£1,690)

☐ I am a non-member and registering after 30 November 2007 (£1,760)

*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/403
National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB

☐ Credit card Mastercard

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@rpsqb.org (Tel: 020 7572 2261)

Cancellation and refund

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