

REGISTRATION DETAILS:

Stability Analysis for the Pharmaceutical Industry 10 & 11 October 2017, Reading:

2 day course £930.00 (+ VAT if applicable, see VAT NOTES)

Reduced fees available for multiple bookings:

- 15% 2 courses or 2 delegates
 - 20% for 3 courses or 3 delegates or any combination thereof
 - 25% for 4 courses or 4 delegates or any combination thereof
 - 30% for 5 or more courses or 5 or more delegates or any combination thereof
- Payment to be made in a timely manner**

Contact Judy Callanan to discuss bulk bookings

Phone: ++44 20 71947703 Email: info@pharma-training-courses.com

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Please register online on our website:
www.pharma-training-courses.com

Delegate fees Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you. PharmaCourses Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid. PharmaCourses Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

Cancellation Policy Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

Stability Analysis for the Pharmaceutical Industry 10 & 11 October 2017—Reading UK

This 2-day course is designed for anybody concerned with stability testing who wants to know how to design trials and how to analyse them efficiently. No prior knowledge of statistics is required.

By the end of the 2-day course you will be able to:

- Understand what the regulatory Authorities require
- Know how to implement statistical analysis as given in the WHO Technical Report No. 953
- Understand the technical requirements of ICH Q1A and Q1E
- Know how to obtain a representative sample so that your results are valid
- Determine if there are real differences between two sets of results using significance testing
- Evaluate the relationship between two variables using regression analysis
- Improve the precision of a stability trial by changing the design

Speakers:

Dick Boddy

Dick is the MD and founder of s4i. His mission is to help companies use statistics to solve real life business problems. Enabling them to make informed decisions to increase efficiency, drive their company forward and generate greater profit.

After working as a process development chemist for one of the UK's largest manufacturers, Dick retrained as a statistician and spent several years as a senior lecturer in statistics. He realised that there was a huge gap between theoretical statistics taught in higher education and the practical application of statistics needed to give companies a competitive edge. And so s4i was born.

Michael Gamlen

Michael is Managing Director of Pharmaceutical Development Services Ltd, a pharmaceutical consultancy based in Nottingham (UK). Dr Gamlen has over 30 years experience of tablet development. Awarded a First Class Honours degree in Pharmacy, specialising in Pharmaceutical Engineering, he studied for a PhD at Nottingham University.

Michael was Head of Tablet Development at the The Wellcome Foundation for 15 years, and worked as an outsourcing manager before starting his consultancy business in 2000.

PharmaCourses Ltd
Suite 1327, Kemp House
152 City Road
London EC1V 2NX

Tel: ++44 (0)20 71937703

Email: info@pharma-training-courses.com



Programme

Introduction to Stability Testing: Why is it necessary? Who uses it? What do the Regulatory Authorities require?

What is the True Mean?: Highlighting vagaries within data using diagrams. Summarising data using an average - mean or median and a measure of variability - standard deviation or range. Obtaining a confidence interval for the true mean based on the sample mean and standard deviation. Estimating the sample size necessary to obtain a required width of confidence interval.

Samples and Populations: Conclusions are generally drawn about a population from data obtained from a sample. What is a population? What is a sample? How should the sample be selected?

Introduction to Significance Testing: The significance testing procedure using the one sample t-test for the mean and the F-test for comparison of standard deviations. Formulation of hypotheses and the use of statistical tables. When to choose significance tests or confidence intervals. Choice of sample size and the need for a relevant design if valid conclusions are to be drawn from a significance test.

Significance Tests for Comparing Two Means: The importance of designs involving two groups (e.g. control and treatment). Analysis using the two-sample t-test for independent samples and the one-sample t-test for paired samples. Sample size required to detect a difference.

The Normal Distribution: The use of the Normal Distribution. Obtaining probability values and percentage limits from statistical tables. The circumstances for which the distribution of data is likely to be Normal. Problem solving using normal probability plots.

Outliers: The assumptions behind outlier tests. The importance of the Normal distribution. Applying Grubbs' test. The circumstances in which Grubbs' test is unsuitable.

Regression Analysis: Fitting a straight line to data by least-squares regression. Assessing the variability about the line using the residual standard deviation. Determining the goodness of fit of the line using the correlation coefficient and percent fit. Confirming that a relationship exists between two variables using the correlation coefficient. Trending and extrapolation of data - obtaining predicted values and confidence intervals.

Regression in Stability: Estimating the uncertainty in the response factor. Improving the precision of a stability estimate by changing the design. Checking on validity of assumptions using residuals.

Combining Standard Deviations: The need to improve the accuracy of an estimate of precision (standard deviation) by combining standard deviations from relevant sets of data.

Analysis of Variance and Pooling: Examining overall variability within a batch. Understanding an Analysis of Variance table. Comparing Estimating within-batch SD and batch-to-batch SD from an investigation. Determining whether several groups are significantly different.

Review of ICH Q1A and Q1E: A detailed review of the technical requirements of ICH Q1A and Q1E.

Stability Testing - How to Apply the Standard: A statistician's view of the guidance as written. What are its limitations and consequences? How to implement statistical analysis as given in the WHO Technical Report No. 953 "Stability Testing of pharmaceutical ingredients and finished pharmaceutical products".

Interactive Case Exercise: Interactive case exercises, based on real industrial problems, are a feature of the course.

Tutorials: Tutorials follow each lecture. Course members, under the guidance of experienced tutors, learn how to apply newly-found knowledge by solving realistic problems from industry.

Problem Seminars: Problem Seminars and additional tutorials are held in the evenings, when extra help and guidance are available.

Free Consultancy Service: A free consultancy service is available to course members which allows for practical problems to be presented for advice and help.

The course will commence at 9.00am and finish at 5.00pm

Book online—www.pharma-training-courses.com

Venue:

Reading West Holiday Inn, Padworth Lane, Bath Road, Reading RG7 5HT

Website: www.ihg.com

Accommodation, if required, is £95 + VAT per night on a bed & breakfast basis, please advise when booking your place on the course whether you require accommodation.

Accommodation and travel directions are available on our website

Register online

www.pharma-training-courses.com

For 5 or more staff requiring training it may be beneficial to run a course in-house.

The benefits of running a course in-house:

- Save on travel or accommodation costs
- Customised content to meet your requirements
- Big print savings on course material - especially with larger groups
- Courses arranged for large groups up to 24 staff
- Tutorials available for small groups of 2 or 3 staff
- Meet course speakers in advance to discuss design and content

Contact **Judy Callanan at any time to discuss**

Ph: 0044 (0)20 7193 7703, Email: judy@pharma-training-courses.com

UPCOMING COURSES

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs

11th and 12th September 2017, London

Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs

13th and 14th September 2017, London

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development

27, 28 & 29 September, 6, 7 & 8 December Croydon Greater London

Stability Analysis for the Pharmaceutical Industry

10 & 11 October 2017, Reading UK

Pharmaceutical Dissolution Testing - a Hands-on course

24, 25 26 & 27 October London

GMP Auditor Training for Quality Systems

1, 2 & 3 November London

HPLC Analytical Method Development and Validation

20 & 21 November 2017 London

Online Registration is available on our website: