Tablet Process Development and Validation and the application of QbD

11 & 12 April 2011, New Jersey USA
13 & 14 June, 2011 - London
28 & 29 November 2011—London

Course objectives

This interactive workshop provides up-to-date, relevant and detailed information on the impact of Quality by Design (QbD) on the Development and Validation of tablet manufacturing processes. It will also study the identification and evaluation of Critical Product Attributes and Critical Process Parameters for tablets, and their implications for process control. We develop new concepts including the use of risk and process matrices for risk management. The latest ICH and FDA guidance on Quality by Design and Process Development, published in 2009, will be comprehensively reviewed.

By the end of the course, you will

- Understand the relationship between the principles of QbD and tablet development and process validation in generic and new product development
- Understand the relationship between material properties, formulation development and process development
- Understand the processes commonly used to manufacture tablets and the factors which affect them
- Recognise how to identify critical processing parameters, and how to incorporate into a process validation program
- Understand the principles of PAT, how and where it can be most effectively deployed
- Know the latest FDA thinking on Process Development including the three key steps of validation

Course Speaker

Dr Michael Gamlen 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. He 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.

Dr Gamlen specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tabletting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many cases.

Michael continually updates the content of his courses with the latest guidance and extracts of up-to-the minute scientific papers. He provides a substantial body of relevant literature to all course participants as well as copies of all notes and guidance used and a workbook.

PharmaTraining
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF
United Kingdom

Tel: 0044 (0)115 9124249
Fax: +44 115 912 4278
info@pharma-training-courses.com

www.pharma-training-courses.com

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Who should attend?

The course is designed for people new to Process Development, and those requiring a refresher in the area. It will also benefit Process Development experts wishing to extend their understanding of why products processes can go wrong, and regulatory and quality personnel who need to understand the development process better. The course will include the latest FDA guidance on the development of generic products under QbD.

Course outline:

Day 1:

Morning—Product development

- The new regulatory landscape. Q8, Q9 and Q10 and their impact on product and process development
- Principles of Quality by Design and the product development process
- Linking material properties to formulation and processing behaviour
- **Workshop session**—Understanding Quality by Design

Afternoon—Mixing and blending

- Identifying potential Critical Process Parameters. Use of Process Matrices in process development.
- Unit processes 1—Mixing and blending
- Assessing blend uniformity. Sampling problems and practice
- **Workshop session**—blend assessment practical. Effect of material properties on powder mixing behaviour

Day 2:

Morning—Granulation—wet and dry

- Why granulation matters—good and bad
- Critical granulation process parameters and their impact
- Optimising granulation processes
- **Workshop session**—granulation practical. Effect of binder volume on product properties

Afternoon—Process Control and Process Analytical Technology (PAT)

- Principles of process control—feedback and feed forward
- Use of advanced techniques—limitations and applicability
- Case studies—what has been done? What is possible?
- Continuous processing
- Participants open forum and Question and Answer session.

NOTE

Wherever possible participants should bring practical problems and examples which can be reviewed on the course. The course will be highly participative and useful for people with or without experience.

Dress casual, you may get wet or dusty.

The experts on tablets

Venue

London -Window Conference Venue 13 Windsor Street, Islington London, N1 8QG convenient for central London, in a pleasant informal setting.

New Jersey USA - The Commercialization Center for Innovative Technologies, The Technology Centre of New Jersey , 675 US Highway One, North Brunswick, New Jersey 08902

Course fee includes all course materials, refreshments and lunch, accommodation is not included.

Accommodation and travel directions are available on our website
www.pharma-training-courses.com

Numbers are limited to give participants the opportunity for thorough discussion of the issues to be covered by the programmes and one-to-one consultation with speaker(s)

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Delegate fees

Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments, lunch and evening reception or social programme.
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.

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.

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REGISTRATION FORM

Tablet Process Development, Validation and the application of QbD: √

11 & 12 April 2011, New Jersey USA (early-bird date 11 February 2011)

13 & 14 June, 2011 - London (early-bird date 11 April 2011)

28 & 29 November 2011—London (early-bird date 30 September 2011)

Tablet Process Development, Validation and the application of QbD:
2 day course £1062.00 + VAT £232.40 **Total £1294.40**
if booked and paid eight weeks prior to course commencement

Tablet Process Development, Validation and the application of QbD:
2 day course £1180.00 + VAT £236.00 **Total £1416.00**

Tablet Process Development, Validation and the application of QbD *and* Integrated Tablet Formulation Development: If booking both courses
A reduced rate of £2124.00 + VAT £424.80 **Total £2548.80**

Discount of 10% applies for booking 8 weeks in advance

Discount of 10% applies for booking more than 1 delegate

Discount of 10% applies for booking more than 1 course

Maximum discount received is 15%

ALL EU delegates are liable for VAT irrespective of country

Title (Mr/Mrs/Ms/Dr/Prof): First Name:

Surname:

Company:

Job Title:

Address:

Post Code: Country:

Tel: Fax:

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Signature:

Method of Payment:

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Fax: +44 (0)20 7681 3582
Email: info@pharma-training-courses.com

PharmaTraining
BioCity Nottingham
Pennyfoot Street
Nottingham NG1 1GF
United Kingdom