



Tablet Process Development and Validation and the application of QbD

14 & 15 June 2010

Window Conference Venue, London UK

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 tableting 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. He is a popular and highly respected presenter.



PharmaTraining

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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.

Numbers are restricted to guarantee personal involvement.



Venue

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

Course fee includes all course materials, refreshments, lunch and course dinner or social activity, accommodation is not included.

Accommodation and travel directions are available on our website www.pharmatrainingsservices.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)

Liability

PharmaTraining 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.

PharmaTraining will not be responsible for any airfare, accommodation or other travel costs incurred.

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.

We offer: *Moderate prices, small classes, interactive workshops given by knowledgeable speakers with many years of industry experience.*

Course Programme 2010

GMP Auditor Training 19 & 20 May 2010

How to Audit API Manufacturers 21 May 2010

Technology Transfer 19 & 20 May 2010

Integrated Tablet Formulation Development 10 & 11 June 2010

Process Development, Validation and QbD 14 & 14 June 2010

Stability Testing in Pharmaceutical Development 28 & 29 June 2010

Pharmaceutical Documentation—a practical approach 17 & 18 June 2010

An Integrated Approach to Pharmacokinetics in Drug Development—June 2010

GMP Auditor Training 10 & 11 November 2010

How to Audit API Manufacturers 12 November 2010

Technology Transfer 10 & 11 November 2010

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

We run our programmes in a variety of locations, throughout the year. All of our programmes can be run in-house.

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REGISTRATION FORM

Process Development and Validation and the application of QbD:

14 & 15 June 2010, London UK

2 day course £1160.00 + VAT £203.00

Total £1363.00

Process Development and Validation and the application of QbD:

14 & 15 June 2010, London UK

Discounted rate for registering and paying before **Friday 2 April 2010** -

2 day course £1044.00 + VAT £182.70 VAT

Total £1226.70

Integrated Tablet Formulation 10 & 11 June 2010 and Tablet Process Development and Validation and the application of QbD 14 & 15 June 2010

A discounted rate of £1972 + 345.10 VAT Total £2137.10 when booking both courses

Integrated Tablet Formulation Development 19 & 20 November 2009 and Tablet Process Development and Validation and the application of QbD 14 & 15 June 2010

A reduced rate of £1774.80 + £310.59 VAT (£2085.39) if booked and paid by Friday 2 April 2010

Title _____ First name _____

Surname: _____

Position: _____

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Address: _____

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Method of Payment

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