PharmaTraining

Tablet Process Development and Validation and the application of QbD

June 2014 — CANCELLED

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. He is a popular and highly respected presenter.

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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

- Principles of Quality by Design and the product development process
- Linking material properties to formulation and processing behaviour
- FDA Guidance on Process Validation

Workshop session - Understanding Quality by Design

Afternoon - Mixing, and dry granulation

- Identifying potential Critical Process Parameters.
- 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 - EFPIA Case study. Wet granulation

- The new regulatory landscape. Q8, Q9 and Q10 and their impact on product and process development.
- EFPIA case study - what would a QbD regulatory submission look like?
- Use of Process Matrices in process development
- Developing wet granulation processes
- Granulation endpoint control

Afternoon - Drying, compression and film coating

- Drying - techniques and process control
- Compression - opportunities and threats!
- Developing film coating processes
- Round-up session

Day 3: Practical

- Blending
- Granulation
- Drying
- Milling
- Sieving
- Compression
- Granule and product characterisation

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. Numbers are restricted to guarantee personal involvement.

The experts on tablets and tableting

Venue
London

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)

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends. *Please check our website for other courses added throughout the year.*

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:

- savings on delegate fees
- 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: ++44 20 7193 7703
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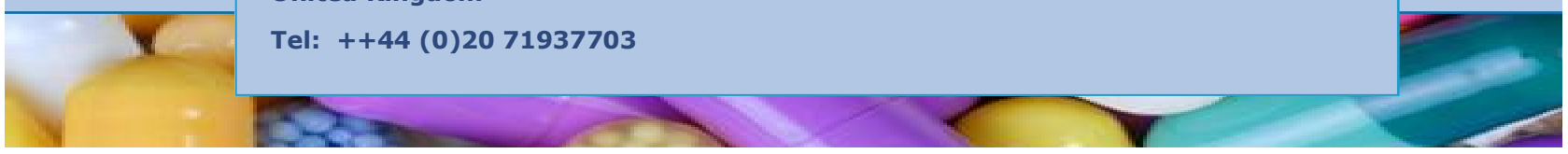

REGISTRATION DETAILS

Tablet Process Development, Validation and the application of QbD:
June 2014—CALCELLED

Early-bird fee: 3 day course £1593.00 (+VAT £318.60 if applicable, see notes on VAT)

Full Fee: 3 day course £1770.00 (+ VAT £354.00 if applicable, see notes on VAT)

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.

Methods of Payment available:

- **Cheque (Please make payable to "PharmaCourses Ltd")**
- **Bank transfer**
- **Credit/Debit Card**

Online Registration is available on our website:
www.pharma-training-courses.com

Data Protection

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Liability: 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.

Delegate fees : 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.