Hands-on Tablet Development
including principles of pre-formulation, formulation and process development
28, 29 & 30 September - London

Course overview

This unique 3 day course is designed to integrate the key elements of tablet development with hands-on, practical experience in a small scale, lab scale test facility. Each day will consist of lectures on aspects of tablet development, followed by linked sessions in which participants take part in related experimental work.

The course enables attendees to apply the theory learnt in the taught sessions, and also to directly observe the effect of formulation on product properties, and relate the theory to the practice of Quality by Design (QbD).

Who Should Attend?

- Newcomers to tablet formulation development and manufacturing
- Production operators who need a better understanding of their products and how they have been developed
- Analytical and QC staff who would benefit from understanding the tablet development and production process
- Experienced personnel in one area of product development who need a broader overview
- Project team members needing a broader insight into formulation development including preclinical, clinical, and project management representatives
- Regulatory staff who would benefit from brief practical experience of the processes for which they are compiling dossiers. Regulatory agency staff requiring practical experience

Numbers are restricted to 10 participants for maximum benefit

Learning outcomes

- Understanding of the relationship between Quality by Design, drug substance properties, formulation and process development
- Practical experience of small scale tablet manufacture with direct knowledge of the relationship between formulation properties and tablet compressibility
- Understanding of the roles of critical quality attributes, critical process parameters, and product control strategy in the application of the principles of QbD to formulation development

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Course Programme

Day 1 Theme - Quality by Design (QbD) - ICH Q8-10
- Material properties and their impact on processing.
- The role of excipients

8.30am	Registration and coffee/tea
9.00am	Welcome. Introductions. Plan for the day. Learning objectives for course
9.15am	Introduction to Quality by Design – a new pharmaceutical manufacturing system. Regulatory guidance.
10.45am	Coffee break
11.00am	Drug substance properties and their impact on formulation development. Part 1—physico-chemical properties
12.45pm	Lunch
1.45pm	Drug substance properties and their impact on formulation development. Part 1—physico-chemical properties
3.00pm	Tea break
3.15pm	Practical—impact of material properties on bulk powder behaviour • Flow • Bulk density • Compressibility • Particle size and shape
4.45pm	Wrap up
5.00pm	Close

Day 2 Theme - Formulating good products

9.00am	Consolidation. Plan for day. Learning objectives for day
9.15am	Approaches to formulation development using QbD principles. Manufacturing Process selection—applicability of wet granulation/roller compaction/direct compression. Unit processes 1—blending.
10.30am	Coffee break
10.45am	Unit processes 2—granulation and drying. Factors affecting granulation and drying behaviour. Critical Process Parameters for these processes. Impact of powder properties on manufacturing behaviour
12.15pm	Powder and granule characterisation—advanced techniques. Porosity, compressibility, surface area
12.45pm	Lunch
1.30pm	Granulation and drying practical
3.00pm	Tea break
3.15pm	Lubrication and compression practical
4.45pm	Wrap up
5.00pm	Close

Day 3—Theme - Process development and validation

9.00am	Consolidation. Plan for day. Learning objectives for day
9.15am	Principles of process development. FDA Process Validation Guidance 2011 and the impact of QbD
10.30am	Coffee
10.45am	Identifiying Critical Process Parameters and Critical Quality Attributes • Blending • Granulation • Drying • Lubrication • Compression
12.45pm	Lunch
1.45pm	Practical—Direct compression products Impact of excipient selection, grades, and processing on critical quality attributes— • Compressibility • Friability • Content Uniformity • Disintegration
4.00pm	Closing session with tea
5.00pm	Depart

Course Speakers:

Dr Michael Gamlen, Pharmaceutical Development Services

Michael is Managing Director of Pharmaceutical Development Services Ltd, a Guildford (UK) -based technical consultancy. Dr Michael 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 has since worked for Vanguard Medica Ltd and as a consultant. He 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 case.

Dr Dipankar Dey

Dipankar joined PharmaTraining Ltd from Oystar Manesty (Liverpool) where he was Head of Process Development. He has particular expertise in manufacturing of solid dose and bio-pharmaceuticals and has worked in a number of different functions including technology transfer, new product development, training and manufacturing. He also has experience in film coating and the implementation of PAT.

Dipankar is working with Michael to develop online tabletting training programs for future delivery.

Venue: County House, 221-241 Beckenham Road, Beckenham BR3 4UF **near London.** Delegates can stay locally to the course venue. Alternatively Beckenham is a short train ride from London Victoria station which is convenient for central London hotels

REGISTRATION FORM:
Hands-on Tablet Development including principles of pre-formulation, formulation and process development: √

28, 29 & 30 September 2011 - London
3 day course £1593.00 (+ VAT £318.60 if applicable, see notes on VAT)
if booked and paid by 2nd August 2011

28, 29 & 30 September 2011 - London
3 day course £1770.00 (+ VAT £354 if applicable, see notes on VAT)

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.

VAT ID No._____

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.

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%

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

Surname:

Company:

Job Title:

Address:

Post Code: Country:

Tel: Fax:

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☐ Cheque (**Please make payable to "PharmaTraining Ltd")**

☐ Bank transfer ☐ Credit/Debit Card (If paying by Credit Card please register online)

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

Course fee includes all course material, refreshments and lunch, accommodation is not included, details of nearby hotels are available on our website.

Terms and Conditions are available on our website:

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