Gamlen Tableting Ltd.

PharmaTraining

Gamlen Tableting Ltd and PharmaCourses Ltd present

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

Croydon, Greater London

22, 23 & 24 March 2017
14, 15 & 16 June 2017

Croydon, Greater London UK

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).

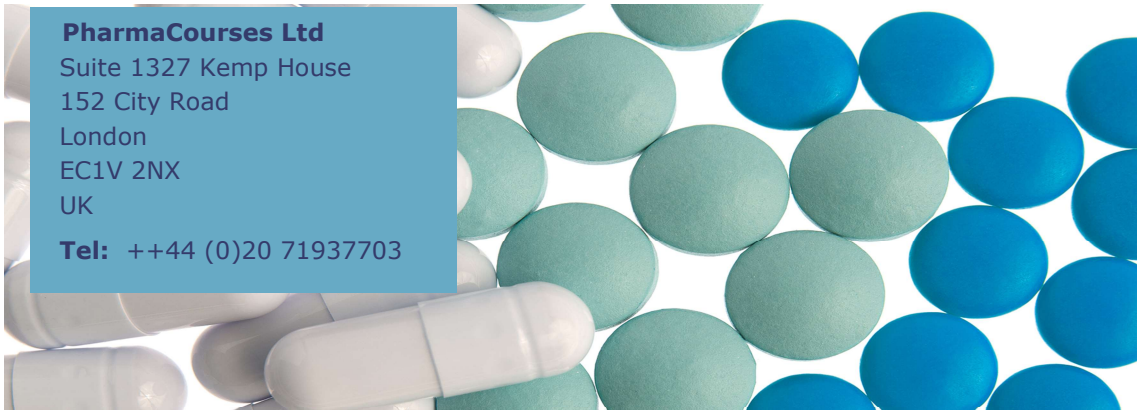
Who Should Attend?

- 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



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

Tel: ++44 (0)20 71937703

Course Programme

Croydon Park Hotel, Croydon Greater London

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	Approaches to formulation development using QbD principles. Manufacturing Process selection—applicability of wet granulation/roller compaction/direct compression. Unit processes 1— blending.
3.00pm	Tea break
3.15pm	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
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	Powder and granule characterisation — advanced techniques. Porosity, compressibility, surface area Identifiying Critical Process Parameters and Critical Quality Attributes • Blending • Granulation • Drying • Lubrication • Compression
10.30am	Coffee break
10.45am	Principles of process development. FDA Process Validation Guidance 2011 and the impact of QbD
12.45pm	Lunch and travel to **Yeoman House**
2.00 pm	Practical—impact of material properties on bulk powder behaviour • Flow • Bulk density • Compressibility • Particle size and shape
3.00pm	Tea break
3.15pm	Wet Granulation and drying practical Lubrication and compression practical
5.00pm	Close

Yeoman House, 61-63 Croydon Road, Penge (London)

9.00am	Consolidation. Plan for day. Learning objectives for day
9.15pm	Dry Granulation practical Lubrication and compression practical PracticaDirect compression products Impact of excipient selection, grades, and processing on critical tablet quality attributes— • Compressibility • Friability • Disintegration
12.45pm	Lunch
1.45pm	Practical—Direct compression products Impact of excipient selection, grades, and processing on critical tablet quality attributes— • Compressibility • Friability • Disintegration
4.00pm	Closing session with tea – comparing data
5.00pm	Depart

Course Speaker:

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.

Michael has been teaching professional tabletting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many case.

Venue:

Days 1 & 2
Croydon Park Hotel, 7 Altyre Road Croydon Greater London CR9 5AA

Days 2 & 3
Yeoman House 61-63 Croydon Road, Penge SE20 7TS

Accommodation:
Croydon Park Hotel, 7 Altyre Road Croydon Greater London CR9 5AA
Website: http://www.croydonparkhotel.com/

Alternatively if you wish to stay in Central London the venues are easily accessible by train from London Victoria or London Bridge

Accommodation is not included in the fees, please make your own arrangements, if you have any questions please email: info@pharma-training-courses.com

REGISTRATION DETAILS:
Hands-on Tablet Development including principles of pre-formulation, formulation and process development: ***Remember to book early—numbers are limited***

22, 23 & 24 March 2017 — Croydon, Greater London
Early-bird fee: 3 day course £1593.00 (+ VAT £318.60 if applicable, see notes on VAT)
if booked and paid by 14 February 2017
Full Fee: 3 day course £1770.00 (+ VAT £354.00 if applicable, see notes on VAT)

14, 15 & 16 June 2017 — Croydon, Greater London
Early-bird fee: 3 day course £1593.00 (+ VAT £318.60 if applicable, see notes on VAT)
if booked and paid by 19 April 2017
Full Fee: 3 day course £1770.00 (+ VAT £354.00 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.

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.

Reduced fees available for multiple bookings:

Contact Judy Callanan to discuss a bulk booking
Phone: ++44 20 71937703 Email: info@pharma-training-courses.com

Methods of Payment available:

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

☐ Bank transfer ☐ Credit/Debit Card

Please register online at:
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:

Data Protection
PharmaCourses Ltd gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

PharmaCourses Ltd is registered in England and Wales No. 08509096

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Course Programme Spring/Summer 2017

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Stability Testing in Pharmaceutical Development and Manufacture - an update for the 21st Century
18 & 19 May London

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Pharmaceutical Dissolution Testing - a 2 day course
22 & 23 May London

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Development of Stability-Indicating HPLC Methods
21 June London

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HPLC Analytical Method Development and Validation
22 & 23 June London, 20 & 21 November London

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Pharmaceutical Packaging – an introductory course
26 June London

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Pharmacokinetics in Drug Development - an integrated approach
November London

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GMP Auditor Training for Quality Systems
November London

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