

Tablet Formulation Development

21 & 22 November 2011 - London

Course content:

This unique 2 day course introduces and integrates the key elements of tablet development with the principles of Quality by Design (QbD). It will include experimental, hands-on experience of formulation development using the Gamlen Tablet Press. Topics include:

Day 1 The Product Development Lifecycle

- Making sense of ICH Q8, 9 and 10—moving from theory to practice
- Designing formulations and processes to meet the Target Product Profile

Formulation development

- Formula selection
- Process selection
- Product Optimisation and the formulation cycle
- Developing Product Control Strategies at the formulation development phase
- Coating polymers

Day 2 Advance characterisation and development techniques

- Formulation mapping using X-ray and Raman spectroscopy
- AFM in formulation development
- Real time particle size analysis
- Dryer control using NIR
- Blend uniformity assessment using NIR and other techniques
- Compressibility comparison using the Gamlen Tablet Press
- Characterisation of tablet coats using THz spectroscopy

Proper integration of all of these elements is essential to achieve “Quality by Design” because data from each phase is used to control the next step in the development process. By achieving proper integration based on sound scientific principles, many development and production problems can be avoided. The course includes case studies of tablet formulation development and a detailed step by step analysis of all elements of the tablet manufacturing process. Hands on, practical studies will underpin the scientific learning in this participative course.

Course speakers:

Dr Michael Gamlen, Pharmaceutical Development Services

Michael is Managing Director of Pharmaceutical Development Services Ltd, a Guildford (UK) -based technical consultancy. He has over 35 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 tableting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many case.

Michael continually updates the content of his courses with the latest guidance and extracts of up-to-the minute scientific papers.

Dr Dipankar Dey, PharmaTraining Ltd

Dipankar Dey recently joined PharmaTraining Ltd as Training Manager. A graduate of Oxford University and with a PhD from Birmingham University, he was until recently Head of Process and Validation at OYSTAR Manesty, a well known tablet equipment manufacturer. Dipankar has experience in both sterile and solid dose pharmaceuticals, particularly in tablet coating and compression and is interested in PAT techniques to extract useful online information.

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Who should attend?

The course is designed for people new to tablet 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.

Numbers are restricted for maximum benefit to participants

Course Programme:

This 2 day course will consist of:

Day 1: Introduction to formulation development

Morning

- Linking material properties to formulation and processing behaviour. Selecting the right formulation for the drug and target product profile based on the properties of the drug substance
- Key unit operations and their Critical Process Parameters
- Formula selection
- Process selection

Afternoon

- Putting it altogether—building a coherent manufacturing process
- Product Optimisation and the formulation cycle
- Developing Product Control Strategies at the formulation development phase
- Coating polymers

Day 2 Advanced techniques in formulation

Morning

- Formulation mapping using X-ray and Raman spectroscopy
- AFM in formulation development
- Real time particle size analysis
- Dryer control using NIR
- Blend uniformity assessment using NIR and other techniques

Afternoon

- Compressibility comparison using the Gamlen Tablet Press
- Characterisation of tablet coats using THz spectroscopy
- Case studies, workshops
- Use of the Precision Compaction Tester
- Participants open forum and Question and Answer session.

Practical

Effect of formulation and process parameters on material compressibility

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 formulation experience.



The experts on tablets and tableting

Venue

London - Window Conference Venue, 13 Windsor Street, London N1 8QG

The venue is convenient for central London, in a pleasant informal setting.

Travel directions and accommodation details are available on our website www.pharma-training-courses.com

Terms and Conditions:

Delegate fees: Delegate fees are inclusive of course documentation, refreshments and lunch. 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. **Liability:** PharmaTraining 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. PharmaTraining Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

COURSE PROGRAMME 2011:

An introduction to LC-MS: 19 September 2011, London

Quantitative BioAnalysis using LC-MS: 20 & 21 September 2011, London

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

Writing effective SOPs in a GMP environment: 13 & 14 October 2011, London

OOS investigations in a GMP environment: 18 & 19 October 2011, London

GMP Auditor Training: 7 & 8 November 2011, London

How to Audit API Manufacturers: 9 November 2011, London

Technology Transfer: 7 & 8 November 2011, London

Preformulation Studies for Tablet Development: 17 & 18 November 2011, London

Tablet Formulation Development: 21 & 22 November, London

HPLC Analytical Method Development and Validation: 21 & 22 November, London

Oral Solid Dosage Manufacturing Technology: 28 November 2011, London

Tablet Process Development, Validation and the application of QbD:
28 & 29 November 2011, London

Development and Manufacture of Effervescent Tablets: 30 November 2011, London

Stability Testing in Pharmaceutical Development and Manufacture:
12 & 13 December, London

Stability Testing in Biological Product Development and Manufacture:
12 & 13 December, London

Introduction to Photostability: 14 December 2011, London

Pharmaceutical Packaging - an introductory course: 14 December 2011, London

Introduction to Sterile Products Manufacture for those with a cGMP basic understanding: date to be advised

Introduction to Sterile Product Manufacture for New Starters and Junior Staff: date to be advised

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. Our speakers/trainers are carefully chosen for their high degree of expertise.

All of our programmes can be run in-house, if you are interested please contact **Judy Callanan** to discuss your requirements:

Ph: 0044 20 7193 7703, Fax: 0044 20 7681 3582

Email: judy@pharma-training-courses.com

PharmaTraining Ltd is registered in England and Wales No. 4235908

REGISTRATION FORM:**Tablet Formulation Development, 21 & 22 November 2011, London**

2 day course £1062.00 (+ VAT £232.40 if applicable see VAT NOTES)
if booked and paid eight weeks prior to course commencement

Total £1294.40

Full fee: 2 day course £1180.00 (+ VAT £236.00 if applicable see VAT NOTES) **Total £1416.00**

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%**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.

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

First Name:

Surname:

Company:

Job Title:

Address:

Post Code:

Country:

Tel:

Fax:

Email address:

Signature:

Method of Payment: 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

Data Protection

PharmaTraining 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.

Please send completed forms to →

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