Integrated Tablet Formulation Development

7 & 8 April 2011 - New Jersey USA

9 & 10 June, 24 & 25 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:

The Product Development Lifecyle

- Making sense of ICH Q8, 9 and 10
- Identifiying the material properties which will become Critical Quality Attributes at an early stage

Preformulation studies

- Material characterisation
- Morphic form identification Salt selection
- Compressibility testing
- Excipient and Process compatibility testing
- Applications of advanced techniques to aid development including AFM

Formulation development

- Formula selection
- Process selection
- Product Optimisation and the formulation cycle
- Advanced Intermediate and Product characterisation
- Develping Product Control Strategies at the formulation development phase

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 development at the preformulation and formulation development phases as well 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 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. 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.

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 a copy of all notes and guidance used.

He is a very popular presenter.

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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 outline

This 2 day course will consist of:

Day 1: Preformulation

Morning
Developing a Target Product Profile
The product development process
What are "Preformulation studies"
Linking material properties to formulation and processing behaviour

Afternoon
Identifying potential Critical Product Attributes related to the drug substance
Advanced material characterisation
Linking material properties to formulation requirements

Practical
Effect of material properties on powder mixing behaviour

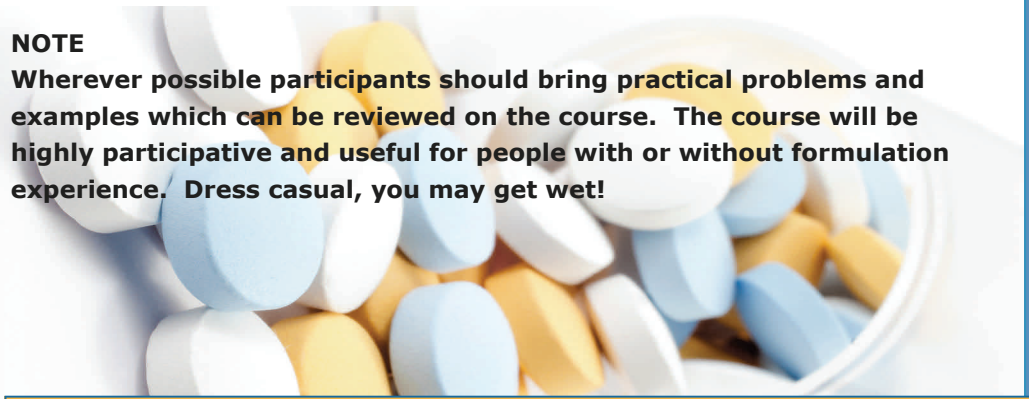
Day 2: Tablet formulation—an introduction

Morning
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
Putting it altogether—building a coherent manufacturing process

Afternoon
Case studies, workshops
Use of the Precision Compaction Tester
Participants open forum and Question and Answer session.

Practical
How do tablets stick together? Developing a "fair test" to evaluate 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. Dress casual, you may get wet!



The experts on tablets

Venue

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

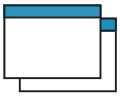
New Jersey USA - The Commercialization Center for Innovative Technologies, The Technology Centre of New Jersey , 675 US Highway One, North Brunswick, New Jersey 08902

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

2011 Course Programme

Planning for Commercial Launch: *29 & 30 March 2011*
GMP Auditor Training*: New Jersey USA - 11 & 12 April 2011*
London - 9 & 10 May, 7 & 8 November 2011
How to Audit API Manufacturers: *New Jersey USA - 13 April 2011*
London - 11 May, 9 November 2011
Supply Chain Management in Pharma/Biotech: *5 & 6 May 2011*
Technology Transfer: *London - 9 & 10 May, 7 & 8 November 2011*
Integrated Tablet Formulation Development: *New Jersey USA - 7 & 8 April*
London - 9 & 10 June, 24 & 25 November 2011
Tablet Process Development, Validation and the application of QbD:
New Jersey USA - 11 & 12 April, London - 13 & 14 June, 28 & 29 November
Pharmacokinetics in Drug Development - an Integrated Approach:
9 & 10 June 2011
An Introduction to LC/MS: *19 September 2011*
Quantitative Analysis: *20 & 21 September 2011*
Writing effective SOPs in a GMP Environment: *13 & 14 October 2011*
OOS investigations in a GMP Environment: *18 & 19 October 2011*
Stability Testing in Pharmaceutical Development: *16 & 17 May 2011,*
12 & 13 December 2011
Introduction to Photostability: *14 December 2011*
HPLC Analytical Method Development and Validation: *22 & 23 November*
Oral Solid Dosage Manufacturing Technology: *28 November 2011*
Development and Manufacture of Effervescent Tablets: *30 November 2011*
Pharmaceutical Packaging - an Introductory Course: *14 December 2011*
Hands-on tabletting *- tba*

Check out the benefits, content, details, dates and times of our range of training programmes:



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Email: judy@pharma-training-courses.com

PharmaTraining

Please check our website for courses added throughout the year

REGISTRATION FORM

Integrated Tablet Formulation Development: √

7 & 8 April 2011, New Jersey USA - (No VAT or Sales Tax required)

9 & 10 June, 2011 - London

24 & 25 November 2011—London

Integrated Tablet Formulation Development:
2 day course £1062.00 + VAT £232.40 **Total £1294.40**
if booked and paid eight weeks prior to course commencement

Integrated Tablet Formulation Development:
2 day course £1180.00 + VAT £236.00 **Total £1416.00**

Integrated Tablet Formulation Development *and* Tablet Process Development, Validation and the application of QbD:
A reduced rate of £2124.00 + VAT £424.80 **Total £2548.80**
If booking both courses

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%

ALL EU delegates are liable for VAT irrespective of country

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

Terms and Conditions are available on our website:

Data Protection
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