



## Integrated Tablet Formulation Development 10 & 11 June 2010 Window Conference Venue, 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 Lifecycle

- Making sense of ICH Q8, 9 and 10
- Identifying 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
- Developing 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 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.

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.



#### PharmaTraining

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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!**



## Venue

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.pharmatrainingsservices.com](http://www.pharmatrainingsservices.com)

## 2010 Course Programme

*GMP Auditor Training 19 & 20 May 2010*

*How to Audit API Manufacturers 21 May 2010*

*Technology Transfer 19 & 20 May 2010*

*Integrated Tablet Formulation Development 10 & 11 June 2010*

*Process Development, Validation and QbD 14 & 14 June 2010*

*Stability Testing in Pharmaceutical Development 28 & 29 June 2010*

*Pharmaceutical Documentation—a practical approach 17 & 18 June 2010*

*An Integrated Approach to Pharmacokinetics in Drug Development—June 2010*

*GMP Auditor Training 10 & 11 November 2010*

*How to Audit API Manufacturers 12 November 2010*

*Technology Transfer 10 & 11 November 2010*

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[www.pharmatrainingsservices.com](http://www.pharmatrainingsservices.com)

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a new range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

We run our programmes in a variety of locations, throughout the year. All of our programmes can be run in-house.

Contact **Judy Callanan** Ph: 0044 20 7193 7703, Fax: 0044 20 7681 3582  
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<b>REGISTRATION FORM</b>	✓
<b>Integrated Tablet Formulation Development: 10 &amp; 11 June 2010, London</b> 2 day course £1160.00 + £203 VAT      Total £1363.00	
<b>Integrated Tablet Formulation Development: 10 &amp; 11 June 2010, London</b> <i>Discounted rate if booked and paid by Friday 2 April 2010</i> £1044.00 + £182.70 VAT                      Total £1226.70	
<b>Integrated Tablet Formulation 10 &amp; 11 June 2010 and Tablet Process Development and Validation and the application of QbD 14 &amp; 15 June 2010</b> <i>A discounted rate of £1972 + 345.10 VAT Total £2137.10 when booking both courses</i>	
<b>Integrated Tablet Formulation Development 19 &amp; 20 November 2009 and Tablet Process Development and Validation and the application of QbD 14 &amp; 15 June 2010</b> <i>A reduced rate of £1774.80 + £310.59 VAT (£2085.39) if booked and paid by Friday 2 April 2010</i>	

Title \_\_\_\_\_ First name \_\_\_\_\_

Surname: \_\_\_\_\_

Position: \_\_\_\_\_

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**Method of Payment**

- Cheque **Please make payable to: "Pharmaceutical Assurance Services"**
- Lloyds Bank  
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**Delegate fees**

Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments, lunch and reception/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.

**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.

**Please send completed forms to:**

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