

Integrated Tablet Formulation Development
9 & 10 October 2008
Tablet Process Development and Validation
13 & 14 October 2008
ISPE PQLI initiative. Putting QbD in practice
15 October 2008

This suite of courses offers intensive study on the pre-formulation, formulation, process development and validation of pharmaceutical tablet manufacture and also a one day seminar which will give an insight into the benefits of Process Analytical Technology and Quality by Design

The Window Conference Venue
Angel Islington, London UK

The venue is situated 10 minutes from St Pancras Eurostar Terminal providing easy access from Europe

Speakers:

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a Guildford-based technical consultancy. Dr 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. Dr Gamlen specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tableting courses for many years.

Eve Roodhouse is a Regulatory and Technical Affairs Advisor at Pharmaceutical Development Services Ltd. She has experience of

- Analytical method development and validation, in line with cGxP, using many instrumental/classical techniques
- stability assessment for new and existing products incl. protocol design/development and study management
- Technology transfer of analytical methods between testing laboratories
- Managing laboratory investigations and analytical technology transfers
- Development and rollout of equipment and process SOPs

Numbers will be limited to give participants the opportunity for thorough discussion of the issues to be covered by the programme and one on one consultation with speakers.



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Integrated Tablet Formulation Development

9 & 10 October 2008

Course content

This unique 2 day course introduces and integrates the key elements of tablet development:

- **Preformulation studies**
 - ◆ Material characterisation
 - ◆ Morphic form identification
 - ◆ Salt selection
 - ◆ Compressibility testing
 - ◆ Process and material compatibility testing
- **Formulation development**
 - ◆ Formula selection
 - ◆ Process selection
 - ◆ Optimisation and the formulation cycle
 - ◆ Intermediate and Product characterisation
 - ◆ Organisational influences
 - ◆ Stability testing for regulatory purposes

and explains the important links between each of these. Proper integration 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. Key process parameters and their control are identified.

Course Outline

This 2 day course will consist of:

Day 1: Preformulation

9.00	Welcome and Introductions
9.10	Introduction to preformulation for product development
10.00	Coffee
10.30	Preformulation studies in context <ul style="list-style-type: none">• Making use of your data
11.30	Material Characterisation techniques (1)
12.30	Lunch
14.00	Material Characterisation techniques (2)
14.45	Tablet components and their roles
15.30	Tea
16.00	Excipient compatibility testing
16.45	Case study—applying preformulation in tablet formulation
17.15	Course closes

Day 2: Tablet formulation—an introduction

09.00	Introduction to tableting operations
10.30	Coffee
11.00	Tableting operations (cont'd)
11.30	Tablet formulation development
12.30	Lunch
13.45	Formulation development case study
14.30	Formulation development case study 2
15.15	Compression testing and use of the Precision Compression Tester
16.30	Preparation for formal stability testing
17.00	Q and A
17.30	Course closes

Speaker

Dr Michael Gamlen

*Comments from previous attendees -
"Excellent course and well worthwhile"
"Very good course and highly informative"*

Who will benefit from the course?

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 processes can go wrong, and regulatory and quality personnel who need to understand the development process.

Additional Resources

An extremely comprehensive memory stick will be provided containing extensive resources on preformulation and tablet formulation, as well as colour copies of all presentations and case studies

Tablet Process Development and Validation

13 & 14 October 2008

Workshop objectives

The goal of this workshop is to provide detailed information on the validation and qualification of manufacturing processes for tablets and capsules including process control, problem solving and documentation for FDA and other regulatory inspection.

By the end of the workshop, you will

1. Understand the purpose of tablet process validation, and the relationship between tablet formulation, tablet process development and tablet process validation
2. Understand the processes commonly used to manufacture tablets and capsules, and the factors which affect them
3. Gain practical guidance on how and why Quality Assurance and Quality Control functions should be involved in tablet process validation
4. Know how to identify critical processing parameters and how to control the process

Course Outline

Day 1

- 8.30 Registration and Coffee
9.00 Workshop introduction
9.20 **Validation and the quality system**
- Regulatory guidance on validation—FDA and EU
 - What is the purpose of Process Validation and where does it fit in the quality system, and production transfer
 - PreApproval Inspections (PAIs) and process qualification
 - Who is responsible for what?
 - Documentation – protocols and reports
- 11.00 Coffee
11.30 **Tablet formulation development**
- Understanding the relationship between manufacturing formula and process
 - How are processes and formulas arrived at?
 - How are they controlled?
- 12.15 **Discussion**
Review and Q&A
12.30 **Lunch**
14.00 **Key manufacturing processes - purpose, equipment and control (1)**
- Blending and lubrication
 - Dry Granulation—Roller compaction and slugging
 - Wet Granulation
 - Granulation end-point control
- 15.00 Tea
15.30 **Case study – blending for direct compression**
We follow the development of a formulation from hand filled capsules to production tablet manufacture, reviewing blending options and actual results
16.30 **FDA guidance on blend sampling**
17.30 End of Day 1

*Comments from previous attendees -
"The Lecturers knowledge exceeded expectations"
"Well planned and delivered"
"Good environment for open discussion"*

Day 2

- 9.00 **Key manufacturing processes - Purpose, Equipment and Control (2)**
- Drying
 - Sieving
 - Tablet compression
 - Film coating
- 10.00 **Process Control Case study - Granulation-end point control**
- How can we evaluate granules?
 - How do granule properties relate to key processing parameters?
- 10.30 Coffee
11.00 **Manufacturing problems**
- Segregation
 - Capping
 - How to address these problems?
Including mixing, granulation and compression problems
- 12.00 **Principles of scale-up**
12.30 **Lunch**
14.00 **Identifying key processing parameters**
How you can identify parameters, which must be controlled in, order to control your process.
15.00 Tea
15.30 **Quality control in tablet manufacture**
16.30 **Developing process validation protocols**
17.00 Summary and Q&A
17.30 End of Workshop

Who will benefit from the course?

Tablet formulation and process development staff and those involved in commissioning products into production.
Regulatory Affairs staff preparing dossiers for tablet products.
Quality Assurance personnel responsible for the design or implementation of tablet process validation protocols

Additional Resources

An extremely comprehensive memory stick will be provided containing extensive resources on preformulation and tablet formulation, as well as colour copies of all presentations and case studies

ISPE PQLI initiative. Putting QbD in practice

15 October 2008

Building quality into a product should start in the research and development phase. Considering and implementing product quality requirements early will lead to an increased efficiency in the manufacturing process with real business benefits.

The Product Quality Lifecycle Implementation (PQLI) initiative was launched in June 2007 by ISPE to help industry find practical, global approaches to implementing ICH guidances.

Objective of the seminar

This one day course of lectures and case studies will provide an overview of the benefits of applying Process Analytical Techniques (PAT) principles and Quality by Design (QbD) to achieve process optimisation and process understanding.

Who will benefit from the seminar

This course will benefit tablet formulation and process development staff and those involved in commissioning products into production. Regulatory affairs staff preparing dossiers for tablet products and quality assurance personnel responsible for the design and implementation of tablet process validation protocols

Programme

- 9.00am **Putting QbD into context**
- 9.30am Defining criticality -
 How to establish assess critical process and product attributes based on development data
- 10.30 Break
- 11.00am Establishing design space -
 Use of DOE and possible statistical approaches to ensure product quality
- 11.45am Control strategy model and concepts -
 Bringing together development data and up to date process control techniques to assure product quality on completion of processing
- 12.30 Lunch
- 13.30 **Process Analytical Technology (PAT)**
- Principles and purpose
 - Key techniques. Continuous vs Batch Process
 - Real-time blend monitoring
 - NIR spectroscopy
- 15.30 Break
- Raman spectroscopy
 - Controlling drying by NIR
 - Particle size measurement and control
 - Bringing it all together – PAT and QbD
- 17.00 Close

Speakers

Dr Michael Gamlen, Pharmaceutical Development Services

Eve Roodhouse, Pharmaceutical Development Services

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Venue

The Window Conference Venue, Angel Islington, London UK

A specialist conference and training venue in the heart of Islington within easy reach of the sights of London. Situated only 10 minutes from the Eurostar terminal at St Pancras makes travelling from Europe a breeze.

Terms and conditions

Delegate fees

Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments, lunch and course dinner on the evening of 9 and 13 October 2008

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 Services 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.

PharmaTrainingServices will not be responsible for any airfare, accommodation or other travel costs incurred.

Course Calendar Autumn 2008

- Integrated Tablet Formulation and Development—London
- Tablet Process Development and Validation—London
- ISPE PQLI initiative. Putting QbD in practice
- Active Pharmaceutical Ingredients—Development, Supply and Commercial Manufacture
- GMP Auditor Training—London
- How to Audit API Manufacturers—London
- Stability Testing in Pharmaceutical Development and Manufacturing
- An Integrated Approach to Pharmacokinetics in Drug Development

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www.pharmatrainingervices.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** by email or telephone at any time to discuss

REGISTRATION FORM

Please select the course you wish to book:	<input checked="" type="checkbox"/>
Integrated Tablet Formulation Development: 9 & 10 October 2008 2 day course £1160 + VAT £203 Total £1363.00 (€1725.00)	<input type="checkbox"/>
Tablet Process Development and Validation 13 & 14 October 2008 2 day course £1160 + VAT £203 Total £1363.00 (€1725.00)	<input type="checkbox"/>
ISPE PQLI initiative. Putting QbD in practice 15 October 2008 1 day course £500 + £87.50 Total £587.50 (€745.00)	<input type="checkbox"/>
Integrated Tablet Formulation Development: 9 & 10 October 2008 <i>and</i> Tablet Process Development and Validation 13 & 14 October 2008 <i>4 days at the reduced rate of</i> £1972.00 + VAT £345.10 Total £2317.10 (€2965.00)	<input type="checkbox"/>
Tablet Process Development and Validation 13 & 14 October 2008 and ISPE PQLI initiative. Putting QbD in practice , 15 October 2008 <i>3 days at the reduced rate of</i> £1580.00 + VAT £276.50 Total £1856.50 (€2345.00)	<input type="checkbox"/>
Integrated Tablet Formulation Development: 9 & 10 October 2008 <i>and</i> Tablet Process Development and Validation 13 & 14 October 2008 <i>and</i> ISPE PQLI initiative. Putting QbD in practice , 15 October 2008 <i>5 days at the reduced rate of</i> £2392.00 + VAT £418.60 Total £2810.60 (€3550.00)	<input type="checkbox"/>

I would like to claim a 10% discount for booking before Friday 8 August 08

Total payable £_____

Title (Mr/Mrs/Ms/Dr/Prof): _____ First name _____

Surname: _____

Position: _____

Company: _____

Address: _____

Post Code: _____ Country: _____

Tel: _____ Fax: _____

Email address: _____

Signature: _____

**Please send completed registration forms and payment to:
Judy Callanan at:**

Method of Payment

Cheque **(Please make payable to "JA Conference Management")**

Bank transfer **Quoting reference: 805**
Bank Account Name: JA Conference Management
 Barclays Bank, Muswell Hill & Crouch End Branch
Sort Code: 205851 **Account No:** 10245038
IBAN: GB05 BARC 2058 5110 2450 38 **SWIFT:** BARCGB22
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For security purposes please supply Security Code separately (email)