Tablet Process Development and Validation

Hotel Kong Frederick
Copenhagen Denmark
16 & 17 October 2007

Pharmaceutical Development Services

Workshop objectives

This goal of this highly successful course is to provide detailed information on the development and validation of manufacturing processes for tablets including Quality by Design, design space, process control, problem solving and documentation issues. The course includes workshops and the opportunity for participants to bring specific problems for review by the course leader.

By the end of the course, you will

1. Understand the purposes of tablet development and validation, and the relationship between tablet formulation, tablet process development and tablet process validation
2. Understand the processes commonly used to manufacture tablets 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 examine their influences on the manufacturing process

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 Control and Quality Assurance personnel responsible for the design or implementation of tablet process validation protocols

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.

Course Leader

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a Guildford-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.

Presented by

PharmaTraining Services

PharmaTraining Services
1st Floor
77 Leonard Street
London EC2A 4QS
UK

Tel: +44 20 7613 7232
Fax: +44 20 7681 3582

judy@pharmatrainingservices.com

www.pharmatrainingservices.com

Tablet Process Development and Validation

Hotel Kong Frederick
Copenhagen Denmark
16 & 17 October 2007

Course Outline

Day 1

8.45 Registration and coffee

9.15 **Introductions**
Tablet formulation development
- Understanding the relationship between manufacturing formula and process
- How are processes and formulas arrived at?
- How are they controlled?

10.45 Coffee

11.15 **Key manufacturing processes - purpose, equipment and control (1)**
- Blending and lubrication
- Dry Granulation—Roller compaction and slugging
- Wet Granulation

12.30 **Lunch**

14.00 **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. FDA requirements for blend uniformity assessment

15.00 **Blending scale-up and segregation**

15.30 Tea

16.00 **Key manufacturing processes - purpose, equipment and control (1)**
- Drying
- Sieving
- Tablet compression
- Film coating

17.00 End of Day 1

Day 2

9.00 **Process Control Case study - Granulation-end point control**
- How can we can we control granulation processes? End point selection
- How do granule properties relate to key processing parameters?

10.30 Coffee

11.00 **Scale up of high speed mixer granulation**
- Segregation
- Capping
- How to address these problems?
- Including mixing, granulation and compression problems

12.00 **Documentation of Process Development**

12.30 **Lunch**

14.00 **Quality control in tablet manufacture**
- Assuring tablet quality during and after manufacture

14.30 **Principles of validation**
- 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

15.30 Tea

16.00 **Developing process validation protocols**
- Planning and developing protocols based on process development data

16.30 Summary and Q&A

17.00 End of Course

Presented by:

PharmaTraining Services

Pharmaceutical Development Services

PharmaTraining Services
1st Floor
77 Leonard Street
London EC2A 4QS
UK

Tel: +44 20 7613 7232
Fax: +44 20 7681 3582

judy@pharmatrainingservices.com

www.pharmatrainingservices.com

Venue

Hong Kong Frederick, Vester Voldgade 25, Copenhagen

Hong Kong Frederick is a deluxe hotel with a unique atmosphere. It is perfectly situated by the Town Hall Square, next to Tivoli Gardens and the main pedestrian street, Strøget.

Hotel accommodation is not included in the course fee and should be booked and paid for separately.

Hotel details and booking information is available on the hotel website www.remmen.dk/kongfrederick

Additional Resources

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

Terms and conditions

Delegate fees

Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch as well as course dinner on the evening of 16 October.

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

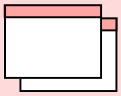
PharmaTrainingServices reserves the right to change the programme, speakers, date or venue without notice or to cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid.

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

Course Calendar Autumn 2007

- Molecules to Markets—London
- The Amorphous State and its Significance for Product Manufacturing—London
- Integrated Tablet Formulation and Development—Copenhagen Denmark
- Tablet Process Development and Validation—Copenhagen Denmark
- GMP Auditor Training—Ireland
- How to Audit API Manufacturers—Ireland
- The Challenges and Formulation Strategies for Poorly Soluble Drug Substances—London
- Strategic Marketing—London
- Customer Focused Project Management—London

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



www.pharmatrainingservices.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.

PharmaTraining Services
1st Floor
77 Leonard Street
London EC2A 4QS
UK

Tel: +44 20 7613 7232
Fax: +44 20 7681 3582

judy@pharmatrainingservices.com

www.pharmatrainingservices.com

PharmaTraining Services

REGISTRATION FORM

Please select the course you wish to book	Please tick
Tablet Process Development and Validation: 16 & 17 October 2007 2 day course £1160 + VAT (Danish) £290.00 Total £1450.00 €2120.00	☐
Integrated Tablet Formulation Development: 9 & 10 October 2007 *and* **Tablet Process Development and Validation** 16 & 17 October 2007 *At the reduced rate of* £1972.00+VAT(Danish) £493 Total £2465.00 €3600.00	☐

Total payable £_____

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

Surname: _____

Position: _____

Company: _____

Address: _____

_____

Post Code: _____ Country: _____

Email address: _____

Tel: _____ Fax: _____

Signature: _____

Method of Payment

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

☐ Bank transfer **Quoting Reference No. 714**
Bank Account Name: JA Conference Management
Barclays Bank, Muswell Hill & Crouch End Branch
Sort Code: 205851 **Account No:** 10245038

☐ Credit/Debit Card

Card Number: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Expiry Date: _ _ _/_ _ _/_ _ _

Cardholder: _____

Address: _____

_____

Signature: _____

For security purposes please supply Security Code separately (email)

Data Protection
PharmaTraining Services gathers personal data for the sole purpose of informing you about our products and services. We do not sell on or share this information with any other organisation.

w

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

PharmaTraining Services
1st Floor
77 Leonard Street
London EC2A 4QS
UK

Tel: +44 20 7613 7232
Fax: +44 20 7681 3582

judy@pharmatrainingservices.com

www.pharmatrainingservices.com

PharmaTraining Services