



PHARMACEUTICAL DOCUMENTATION – a practical approach 17 & 18 June 2010 Central London UK (venue tba)

Course Objectives

Documentation is the key to GMP compliance and traceability of all development, manufacturing and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final product.

This course provides explanation and examples of the key documents, required for pharmaceutical development, manufacturing processes, laboratory testing and also those required for CRM sections of a regulatory dossier. It illustrates how the documents are linked and controlled through the quality management system and provides useful tips for document control and management to keep them current. The course provides a practical approach to master formula, batch records and laboratory controls and validation requirements. Documentation requirements for the qualification of instrumentation and equipment are also discussed; including validation protocols and validation reports.

The course material is presented in a dynamic environment by means of slides, handouts and participation of the attendees through discussion and hands on exercises. Who knew - documentation can be fun!

Note: Participants are asked to bring an example of a document related to their work for the final session on Day 2)

The workshop emphasizes practical issues such as:

- A hands on exercise to experience the document flow of the manufacturing process
- Design a User Requirement Specification (URS)
- Determine the specification for a drug product
- Define an IQ/OQ protocol for analytical instrumentation

This course will deliver the tools to enable you to

- Understand the importance of good documentation and how to apply it
- Recognise and understand the key documents involved in Chemical and Manufacturing Control (CMC) processes.
- Understand the role of these key documents and how they link together within the Quality Management System
- Understand how product specifications are determined
- Gain the skills and knowledge necessary to meet current regulatory expectations.
- Understand the documentation requirements with regards to storage of materials, sampling procedures, stability testing and qualification and training of personnel
- Know the key documents associated with laboratory controls
- Feel more comfortable with documentation on a daily basis
- Improve the current approach to documentation within your company

During the course, the Good Products document management system will be available for review by the participants. This fully validated system offers a wide range of support systems for document management in the pharmaceutical development and manufacturing areas.

Questions and answers will be taken throughout the duration of the course.

PharmaTraining

County House
221-241 Beckenham Road
Beckenham
BR3 4UF

Tel: +44 20 7193 7703
Fax: +44 20 7681 3582
info@pharmatrainingsservice



PHARMACEUTICAL DOCUMENTATION – a practical approach
17 & 18 June 2010
Central London UK (venue tba)

PROGRAMME

Day 1

8.30 Registration and Coffee

Morning Session 1 - 9.00 to 10.30am

- Introduction – Why Document?
- Quality management Systems

10.30 Morning refreshments

Morning Session 2 - 10.45 am to 12.45pm

Introduction to key documents and their relationships

- SOPs
- Protocols
- Master Formulae

Exercise "Tasty Tablets"

Master production documents

- Manufacturing Record
- Packaging Record
- Batch Records
- Specifications

12.45 Lunch

Afternoon Session 1 - 13.45 to 15.15pm

Additional Manufacturing documents

- Warehousing
- Sampling
- Weighing/dispensing
- Batch Manufacturing records
- Product testing and release

Training and qualification of personnel

15.15 Afternoon refreshments

Afternoon Session 2 - 15.30 to 17.30pm

Validation Documentation

- Validation overview
- Validation master plans

17.30pm End of day

Day 2

Morning Session 1 - 9.00 to 10.30am

Validation Documentation (continued)

- User Requirement Specification (URS)

Exercise

- Validation protocols
- Equipment/Instrument Qualification (IQ/OQ/PQ)
- Validation report

10.30 Morning refreshments

Morning Session 2

10.45 am to 12.30pm

Documentation in the Laboratory

- GMP requirements of Laboratory notebooks, raw data and log books
- SOPs
- Certificate of Analysis
- Test methods
- Protocols and Reports

12.30 Lunch

Afternoon Session 1 - 13.30 to 15.15pm

Documentation Control

- Common elements and standards
- Generation, review, approval
- Numbering systems
- Document Management
- Summary to success

Product development documentation in practice

- Determining the specifications for drug product (case study)

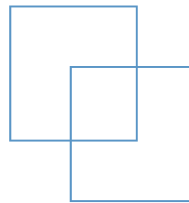
15.15 Afternoon refreshments

Afternoon Session 2 - 15.30 to 17.00pm

Stability testing and documentation

Individual documents (participants are asked to bring an example of a document related to their work for this segment)

17.00 Finish



Course Speakers

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 very popular presenter.

Dr Pauline McGregor, PMcG Consulting

Twenty years in the pharmaceutical industry has included working for pharmaceutical companies and Contract Testing Laboratories in Canada and the UK.

Pauline completed her honours degree in Scotland on a part time basis while employed full time. She left the industry to pursue her PhD in photo organic chemistry where she also taught analytical techniques to undergraduate students. On completing her PhD in 1995, she travelled to UWO in London, Ontario, Canada to complete her post doctoral studies. She is an experienced trainer and has been delivering analytical R& D, method validation, GMP and related Quality Systems courses across Canada, in the US, the UK and China . She is a very highly rated presenter.

Throughout her career, Pauline has identified a lack of shared knowledge between Manufacturing, Quality Control, R & D and Quality Assurance sectors in the Healthcare Industries. She believes there is a need for cross education and training to allow the different disciplines to communicate with each other so that realistic objectives can be met by all in a timely manner with a harmonised understanding.

COURSE PROGRAMME 2010

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 & 15 June 2010
Pharmaceutical Documentation—a practical approach 17 & 18 June 2010
Stability Testing in Pharmaceutical Development 28 & 29 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

PharmaTraining is a trading name of Pharmaceutical Assurance Services Ltd
Registered in England and Wales No. 4235908



REGISTRATION FORM

Pharmaceutical Documentation—a practical approach:

17 & 18 June, London UK

2 day course £1160.00 + VAT £203.00

Total £1363.00

Pharmaceutical Documentation—a practical approach:

17 & 18 June, London UK

Discounted rate for registering and paying before **Friday 2 April 2010**

2 day course £1044.00 + VAT £182.70

Total £1226.70

Title _____ First name _____

Surname: _____

Position: _____

Company: _____

Address: _____

Post Code: _____ Country: _____

Tel: _____ Fax: _____

Email address: _____

Signature: _____

Method of Payment

Cheque - **Please make payable to "Pharmaceutical Assurance Services"**

Bank transfer
Lloyds Bank
IBAN: GB58LOYD 30928901751981
BIC: LOYDGB21393

Credit/Debit Card

Delegate fees

Delegate fees are inclusive of course documentation, refreshments, lunch and evening reception or 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 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 will not be responsible for any airfare, accommodation or other travel costs incurred.

Please send completed forms to:

PharmaTraining

County Hall
221-241 Beckenham Road
Beckenham
BR3 4UF
UK

Tel: +44 20 7193 7703
Fax: +44 20 7681 3582
info@pharmatraining.com

www.pharmatraining.com