GMP Auditor Training

The Baltic Exchange
London UK
20 & 21 November 2007

This 2 day course is aimed at Quality Assurance auditors and production management for Level 2 internal audits and supplier auditing.

To be a business benefit rather than a drain on resources, your auditing programmes must be integral to continuous improvement. The key to effective internal auditing and auditing of suppliers is the training of both auditors and auditees in the purpose and relevant techniques of the audit and how these techniques can be channeled to achieve business and compliance improvements.

Participants will learn about the key techniques and thought processes which may be used by auditors to maximize the benefits of each type of audit. These include planning and preparation, the audit team, structuring the audit, close out, CAPAs and follow up.

Who should attend

- QA auditors and trainees
- Production managers who receive internal QA and corporate GMP audits
- Engineering managers who receive internal QA and corporate GMP audits
- Production supervisors who lead Self Inspection audits
- Auditors of suppliers and contractors

How to Audit API Manufacturers

The Baltic Exchange
London UK
22 November 2007

This one day seminar is aimed at QA staff in drug products manufacturers and especially their QPs who have specific responsibilities under directive 2004/27/EC.

QPs are required to declare that the active materials used in each of their products have been manufactured to GMP as interpreted by the EU.

Participants will learn about the legislators' perspectives and the key differences between APIs and products, which lead to different audit techniques and thought processes when auditing API manufacturers.

The seminar includes:

- the background to current GMPs for APIs
- FDA and EU interpretation of GMPs for APIs
- specific opportunities from the guidelines that API manufacturers may exploit
- specifics of what to look for when auditing an API site.

Who should attend

- Supplier auditors for drug products manufacturers
- QPs in manufacture of drug products
- QA managers who support the QP / declaration
- QC managers of drug products manufacturers
- Production managers of drug products manufacturers

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

Course Programmes

GMP Auditor Training
20 & 21 November 2007

Day 1

Auditing Basics

- Reasons for audits and audit models (overview)
- The Purpose of Audits
- Role Characteristics of the Auditor
- Audit Types
- Audit Classification
- Audit Methods
- General Themes for All Audits

Auditing Tools and Techniques

- Basic tools
- Audit Techniques
- Audit Planning

The course will include three or four Workshops on specific aspects of the programme

DAY 2

The audit process

- Audit scheduling
- Conducting the audit
- Managing the Audit Team
- The Exit Meeting
- Audit Reporting
  Audit Closeout

Improving the audit system

- Adding Value from the Audit programme

Added Value from Self Inspections (Level2 – QA Led)

- A practical Level 2 inspection programme (based on Auditor Training)
- Purpose of the self inspection programme
- Establishing the programme
- Setting up and training the inspection team

How to Audit API Manufacturers
22 November 2007

Why audit API Manufacturers?

EU Directive 2004/27/EC (Regulator's view)
What are the requirements?
What are the similarities with the FDA GMP requirements for APIs?
What are the expectations from API Manufacturers?
What role should secondary manufacturers play?
How will regulators assess compliance with these requirements?

Background to ICHQ7a and EU Guide Part II (formerly Annex 18)

History of GMP for APIs
What role these documents play
How they will be enforced
GMP expectations outlined
How to go about implementing the requirements

FDA GMP expectations of API manufacturers

FDA draft guidance
Legal basis of ICH Q7a
Details of what is required
How is it enforced?
Differences and similarities with EU requirements
How would manufacturers comply with both regulators' requirements?

Workshop I:
How to identify and select a GMP compliant API supplier

Preparing for GMP assessment of an API site

- identifying the GMP relevant activities
- assessing the rational for GMP relevance of activities
- identifying the processing steps
- list of key documentation
- identifying the critical steps impacting your secondary product

Lunch

Implications of EU Directive 2004/27/EC on Drug Manufacturers

- what role manufacturers of the secondary products should play on enforcing these requirements
- what is the impact on manufacturers?
- how to apply the requirements to non EU API sites
- what impact this will have on cost of APIs?

Workshop 2:
Handling Manufacturing Deviations

Basis of proactive deviation management
Identifying and documenting GMP non-compliance incidents
Monitoring and reporting
Key aspects of knowledge management
Framework of critical deviation management
Continuing governance of critical deviations management

Auditing of an API site (I)

Documentation and systems review
Facilities and support services
Validation
Materials control

Auditing of an API site (II)

SOPs and SOP training
Calibration
Testing laboratories
Packaging and labelling
Storage and distribution

Summary of Key Issues

Close of Seminar

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

Course Speaker

DR DAVID INGLIS is director of Ulverston GMP Consulting Ltd, specialising in GMP/Quality Assurance for the manufacturing sectors of the pharmaceutical and consumer healthcare industry. He has extensive experience in assessment and improvement of QA/GMP systems, auditing, GMP training, inspection preparation and plant cleaning / decontamination, especially in bulk intermediates and APIs. He has a Ph.D. degree in enzyme chemistry (affinity chromatography).

During more than 29 years in Quality Assurance in the pharmaceutical industry, Dr Inglis has gained extensive experience of Quality Management, through roles in QA laboratories, GMP compliance and regulatory compliance. He successfully pioneered automated HPLC methods, then managed all aspects of QC laboratories before spending the following 11 years managing and developing Quality Assurance, including documentation, control of change, auditing and routine regulatory compliance to cGMP. He is a Qualified Person under EU Regulations, formerly for bulk sterile antibiotics and now for bulk product intermediates for use in clinical trials.

Dr Inglis is an experienced international auditor of suppliers and contractors and has successfully prepared several sites for FDA/MHRA inspections, including FDA "Systems" based inspections. He has extensive experience of being the lead spokesman during major regulatory audits.

Dr Inglis is a specialist in cGMP training and QA system improvement. His flagship improvement package details a system of secure GMP compliance at competitive cost. For conceiving and developing this package, Dr Inglis received the highest level of recognition for excellence from a global pharmaceutical manufacturing company.

Venue

The Baltic Exchange, 38 St Mary Axe, London EC3A 8BH

The Baltic Exchange is situated within a five minute walk to Liverpool Street Station in the heart of the City of London with easy access to all the well known sights.

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

Accommodation

A list of local hotels is available on request.

Terms and conditions

Delegate fees

Fees for this suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch as well as course dinner.

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

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

I wish to register for the following 2 day course	Please tick
GMP Auditor Training **20 & 21 November 2007:** £1160 + VAT £203 £1363.00	☐
I wish to register for the following 1 day course	
How to Audit API Manufacturers **22 November 2007:** £600 + VAT £105 £705.00	☐
I wish to register for both the following courses	
GMP Auditor Training *and* **How to Audit API Manufacturers** ***at the reduced rate of*** £1584 + VAT £277.20 £1861.20	☐

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. 718**
JA Conference Management
Barclays Bank, Muswell Hill & Crouch End Branch
Sort Code: 205851 **Account No:** 10245038
VAT Reg. GB 876952267

☐ Credit/Debit Card _____

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

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

Cardholder: _____

Address: _____

Signature: _____

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