



GMP Auditor Training **19 & 20 May 2010—London UK** **10 & 11 November 2010—London UK**

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 channelled 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 **21 May 2010—London UK** **12 November 2010—London UK**

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

www.pharmatrainingsservices.com

PharmaTraining

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Programme – GMP Auditor Training

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
- Conducting the inspection and reporting

Comments from previous attendees -

**“very informative and the pace was excellent”
“an excellent technical auditing course which was delivered in a proactive and enjoyable style”**

Programme – How to Audit API Manufacturers

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

Comments from previous attendees -

“a very interesting technical course, full of appropriate information—I feel I have learnt a great deal”

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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.

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

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



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** by email or telephone at any time to discuss

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REGISTRATION FORM

I wish to register for the following:

GMP Auditor Training – 19 & 20 May 2010—London
2 day course £1160.00 + VAT £203.00 **Total £1363.00**
£1044 if booked and paid by Friday 12 March 2010

How to Audit API Manufacturers – 21 May 2010—London
1 day course £600.00 + VAT £105.00 **Total £705.00**
£540 if booked and paid by Friday 12 March 2010

GMP Auditor Training and How to Audit API Manufacturers
3 day course — **19, 20 & 21 May 2010—London**
at the reduced rate of £1584 + VAT £277.20 **Total £1861.20**
£1425.60 + £249.48 VAT Total £1675.00 if booked and paid by
Friday 12 March 2010

GMP Auditor Training – 10 & 11 November 2010—London
2 day course £1160.00 + VAT £203.00 **Total £1363.00**
£1044 if booked and paid by Friday 3 September 2010

How to Audit API Manufacturers – 12 November 2010—London
1 day course £600.00 + VAT £105.00 **Total £705.00**
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Friday 3 September 2010

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

Surname: _____

Position: _____

Company: _____

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Method of Payment

- Cheque **Please make payable to: "Pharmaceutical Assurance Services"**
- Lloyds Bank
IBAN: GB58LOYD 30928901751981
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Delegate fees

Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch as well as course dinner or evening reception.

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 cancel The event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid.

Data Protection

PharmaTrainingServices gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us

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

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