How to Audit API Manufacturers

13 April 2011, New Jersey, USA
11 May 2011 - London
09 November 2011 - London

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

PROGRAMME

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- FDA draft guidance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)

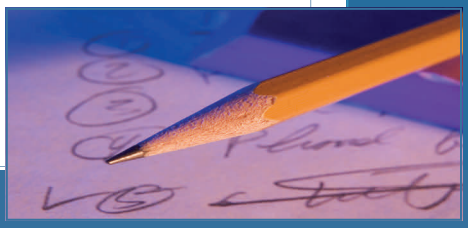
- Documentation and systems review
- Facilities and support services
- Validation
- Materials control

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



GMP Auditor Training

11 & 12 April 2011, New Jersey, USA
9 & 10 May 2011 - London
8 & 9 November 2011 - London

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

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

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

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

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

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Course Speaker

DR DAVID INGLIS is a consultant specialising in GMP/Quality Assurance for the manufacturing sectors of the pharmaceutical and consumer healthcare industry.

David 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.

David 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.

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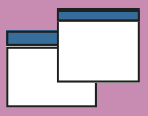

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Contact **Judy Callanan** by email or telephone at any time to discuss

Tel: 0044 20 71937703 Email: judy@pharma-training-courses.com

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www.pharma-training-courses.com

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Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. 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.

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REGISTRATION FORM

How to Audit API Manufacturers:
1 day course £610.00 + VAT £122.00 **Total £732.00** √

13 April 2011 - New Jersey USA *(early-bird date 15 February 2011)*	
11 May 2011- London *(early-bird date 15 March 2011)*	
9 November 2011 – London *(early-bird date 9 September 2011)*	

How to Audit API Manufacturers: *(No VAT for USA course)*
1 day course £549.00 + VAT £109.80 **Total £658.80**
if booked and paid eight weeks prior to course commencement (see above)

How to Audit API Manufacturers *and* GMP Auditor Training
3 day course — ***discounted rate of 10%***

Discounted rate of 10% for booking 8 weeks in advance	
Discounted rate of 10% for booking more than 1 delegate	
Discounted rate of 10% for booking more than 1 course	
Maximum discount received is 15%	

Title (Mr/Mrs/Ms/Dr/Prof): First Name:

Surname:

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