PharmaTraining

GMP Auditor Training for Quality Systems

11 & 12 June 2013 *Amsterdam*
25 & 26 November 2013 *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"

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.

Train with the experts

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PROGRAMME:

Part 1: Auditing Basics
- Purpose of audits and audit models
- Role Characteristics of the Auditor
- Audit types and classification
- Audit methods
- General themes for audits

Part 2: Auditing Tools and Techniques
- Basic auditing tools
- Audit techniques
- Audit scheduling, planning and management

Part 3: The Audit Process
- Audit scheduling
- Conducting the audit
- Managing an audit team
- The Exit Meeting
- Audit Reporting and closeout

Part 4: Improving the Audit System
- Adding Value from the Audit programme
- Organisation of the internal audit programme (Self Inspections)

Part 5: How to Audit CAPA, OOS and QRM
- Necessity for structured investigation
- Corrective and Preventive Action procedures
- Out of Specification procedures
- Risk Assessment techniques

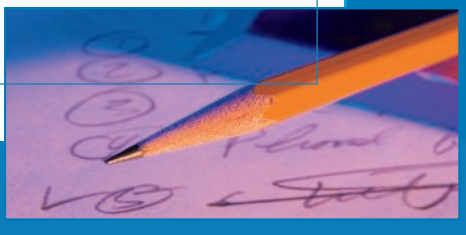
Part 6: Auditing API Manufacturers
- Why Audit API Manufacturers?
- Control of raw materials and process intermediates
- Handling Manufacturing Deviations
- QC Laboratories
- Distribution
- Computer systems
- QP Declaration

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

Part 7: Auditing Products Manufacturers

Oral solid and liquid dosage forms
- Packaging and labelling
- Distribution
- QC Laboratories
- Computer systems

Part 8: Auditing for Approval of Suppliers/Contractors
- Technical requirements (physical properties, purity, quantity, frequency, etc)
- Critical steps and controls.
- Preferred location (UK, EU, Far East, world-wide?)
- Key points of contract (Quality Technical Agreement)



Venues:

Amsterdam (Central) venue will be advised at a later date

Window Conference Venue 13 Windsor Street, Islington London, N1 8QG
convenient for central London, in a pleasant informal setting.

Accommodation and travel directions are available on our website

www.pharma-training-courses.com

For 5 or more staff requiring training it may be beneficial to run a course in-house.

The benefits of running a course in-house:

- Up to 70% savings on delegate fees
- Save on travel or accommodation costs
- Customised content to meet your requirements
- Big print savings on course material - especially with larger groups
- Courses arranged for large groups up to 24 staff
- Tutorials available for small groups of 2 or 3 staff
- Meet course speakers in advance to discuss design and content

Contact **Judy Callanan at any time to discuss**
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REGISTRATION DETAILS

GMP Auditor Training for Quality Systems 11 & 12 June 2013 *Amsterdam*:
Early-bird Fee: 2 day course £1062.00 (+ VAT **if applicable, see VAT NOTES)**
if booked and paid by 15 April 2013
Full Fee: 2 day course £1180.00 (+ VAT **if applicable, see VAT NOTES)**

GMP Auditor Training for Quality Systems 25 & 26 November 2013 *London*
Early-bird Fee: 2 day course £1062.00 (+ VAT **if applicable, see VAT NOTES)**
if booked and paid by 27 October 2013
Full Fee: 2 day course £1180.00 (+ VAT **if applicable, see VAT NOTES)**

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%

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT ***PROVIDED THAT*** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

☐ Cheque (**Please make payable to "PharmaTraining Ltd")**

☐ Bank transfer

☐ Credit/Debit Card (If paying by Credit Card please register online)

Please register online on our website:
www.pharma-training-courses.com

Data Protection
PharmaTraining Ltd 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.

Online Registration is available on our website:
www.pharma-training-courses.com

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

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