GMP Auditor Training for Quality Systems

7, 8 & 9 November 2018 London UK

This 2.5 day course is aimed at Quality Assurance auditors and production management for Level 2 internal audits and supplier auditing.

Current GMP legislation requires that there are internal and external audit programmes operating as part of an integrated quality system. Effective auditing should provide evidence of operational compliance status and identify opportunities for continuous improvement and improved supply chain control and relationships. Both internal auditors and supplier auditors need to have in-depth, interactive training in audit techniques and understand how audit activities complement quality and risk management processes to ensure business compliance and identify quality improvements.

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

The course includes role play sessions to practice auditor/auditee communications. There is also a session on Data Integrity and implications of the US—EU MRA

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 -

"Fantastic course which gave a good overview of what is required"
"an excellent technical auditing course which was delivered in a proactive and enjoyable style"

Course Speaker — Susan Rocca

Susan is a Chemist who has held senior QA roles with fine chemical companies and latterly with GlaxoSmithKline.

Site roles included qualification of a new purified water system, design of a new archive building, redesign of a suite of laboratories to incorporate 'Smart' instrumentation, plus day-to-day quality management and inspection preparation.

Head office roles included quality strategy development, interaction with commercial companies across the world, supply chain management, distribution quality risk management and cold/cool chain quality issue management.

Areas of Expertise

- Active pharmaceutical manufacturing: complying with cGMP requirements
- Experienced auditor for APIs, distribution and cold chain, in the UK, Europe, India, Singapore, Dubai, Mexico, Panama, Costa Rica, Puerto Rico and the USA
- Auditing specialisation in good laboratory practice, distribution and cold chain
- Incident management: troubleshooting and problem solving to 'root cause'. Rapid response to global quality issues
- Quality management systems: development through simplification
- Quality leadership: promoting that quality makes sense for a better business and helping quality departments integrate their plans with site business plans
- Application of lean sigma tools to reduce errors and continuously improve processes
- Application of quality procedures to non-manufacturing areas: eg logistics, commercial operations and regulatory processes
- Inspection preparation, including one-to-one preparation clinics
- Group training and one-on-one coaching for quality management understanding and application
- Cold/cool chain processes for quality assurance
- Preparation of sites for FDA, MHRA and other agency inspections, with successful outcomes

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PROGRAMME:

The course will commence at 9.00am on Day 1

Part 1: Auditing Basics
- Purpose of audits
- Justification for Quality, Compliance and Improvement
- Role Characteristics of the Auditor
- Desirable Audit Behaviours

Part 2: Auditing Types and Models
- Audit types and themes
- General model for audits
- Quality Systems – a short history

Part 3: Audit Methods, Tools and Techniques
- Basic auditing tools
- Audit methods and techniques
- Audit scheduling, planning and management

Part 4: The Audit Process
- Audit scheduling
- Conducting the audit
- Managing an audit team

Part 5: Developing and Audit Plan for the Opening Meeting
- Workshop to develop audit plans and aide memoires
- Conducting the Opening Meeting: role play exercise.

Part 6: Internal Auditing and Improving the Audit System
- Organisation of the internal audit programme (Self Inspections)
- Adding Value from the Audit programme

Part 7: How to Audit CAPA, OOS, OOT and QRM
- Necessity for structured investigation
- Corrective and Preventive Action procedures
- Out of Specification and Out of Trend procedures
- Risk Assessment techniques

Part 8: Auditing Products Manufacturers
- Oral solid and liquid dosage forms
- Packaging and labelling
- Distribution
- QC Laboratories
- Computer systems

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

Part 9: Data Integrity
- 2015 MHRA Guidance and Definitions
- Corporate Culture and Integrity
- Examples of Data Integrity Issues
- Types of Data Fraud

Part 10: Classification of Observations
- Audit Reporting
- Typical observation classification schemes
- Workshop to classify a selection of typical observations

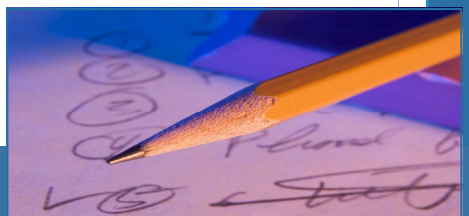
Part 11: Plan for the Closing Meeting
- The Exit Meeting and close-out
- Consideration of timing to prepare for and deliver the closing meeting
- Audit Follow-up
- Conducting the Closing Meeting and presentation of observations: role play workshop

Part 12: 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)

Part 13: Auditing API Suppliers
- Why Audit API Manufacturers?
- What is different about API operations?
- Control of raw materials and process intermediates
- Manufacturing Deviations
- QC Laboratories
- Distribution
- Computer systems
- QP Declaration

Part 14: Q&A, Course Review, Key Messages
- Review of the course
- Issue of certificates and course closure

The course will finish at 12.30pm on Day 3



Venue:

London: DoubleTree Hilton, (formerly Jury's Inn) 60 Pentonville Road, Islington London N1 9LA
Website: www.doubletree3.hilton.com

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:

- 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**
Ph: 0044 (0)20 7193 7703, Email: **judy@pharma-training-courses.com**

COURSE PROGRAMME 2018

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 March 2018
Croydon Greater London

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Stability Testing in Pharmaceutical Development and Manufacture
17 & 18 May 2018 London

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Pharmaceutical Dissolution Testing – a 2 day course
21 & 22 May 2018 London

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Pharmacokinetics in Drug Development - an integrated approach
18 & 19 June 2018 London

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Pharmaceutical Packaging – an introductory course
25 June 2018 London

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Powder Technology for Pharmaceutical Development and Manufacturing
26, 27 & 28 September 2018 London

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Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
September 2018, London

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Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs
September 2018, London

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Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 June, 5, 6 & 7 December 2018
Croydon Greater London

View Course Calendar on our website www.pharma-training-courses.com

REGISTRATION DETAILS:
GMP Auditor Training for Quality Systems:

7, 8 & 9 November 2018 London UK

Early-bird Fee: 2.5 day course £1215.00 (+ VAT **if applicable, see VAT NOTES) if booked and paid by 28 September 2018**
Full Fee: 2.5 day course £1350.00 (+ VAT **if applicable, see VAT NOTES)**

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 "PharmaCourses Ltd")**

☐ Bank transfer

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

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

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