



## How To Do Effective Internal Quality Audits

A TWO DAY COURSE SPECIFICALLY DESIGNED FOR THE PHARMACEUTICAL INDUSTRY AND ITS SUPPLIERS

### Course Description

Audits (self assessments) are a routine part of today's quality management. Because of the regulatory regime of the pharmaceutical industry, auditors frequently focus on non-compliance. Whilst essential to retaining the marketing authorisation, this approach often misses the important improvement opportunities which may benefit the business.

In this course, which is designed specifically for pharmaceutical companies and their suppliers, delegates are shown how to carry out quality system audits which:

- **Are effective and efficient**
- **Look for improvement opportunities as well as compliance**
- **Are value adding**

The standards against which the quality management systems are audited and on which the course is based can include:

- The PS 9000 series (the Application Standards for pharmaceutical suppliers based on ISO 9001: 2000 and including GMP)
- ICH Q7A
- ISO 15378 – Primary packaging GMP standard
- EU Good Manufacturing Practice (GMP)
- Good Laboratory Practice (GLP)
- ISO 17025 (replacement to NAMAS 10 laboratory standards)
- ISO 13485 (medical devices)
- ISO 9001: 2008
- Others (e.g. internal company standards)

### Course Structure

The course is structured in modules which provide flexibility to meet individual client needs. The programme is designed to fit in with individual client working times and other operational requirements and can be tailored to the needs of the client.

The two-day programme can be run consecutively or split to meet the client needs.

**J E M O Limited**

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A heavy emphasis is placed on practical application of what has been taught and the second day is devoted to practical auditing in the client's facility.

#### Who Should Attend

This workshop is designed for people who have some practical experience of auditing to a base-line standard such as ISO 9001. It is also applicable to people who operate in the support role during audits (e.g. technical specialists). It can also provide a useful foundation for internal auditors who plan to make the transition to pharmaceutical supplier auditors.

#### Learning Objectives

At the conclusion of the course, attendees should be able to:

- Understand the principles and application of the standards and regulations used in the course for auditing purposes
- Use the ask-look-check-record technique for seeking the true state of the quality management system
- Use forward and trace-back techniques for auditing a process based system
- Understand the component parts of a quality management system process and how the processes inter-relate
- Establish audit checklists in the same sequence of the process
- Establish an audit programme which ensures an efficient audit
- Use the most appropriate approach for obtaining information from the auditees
- Report the audit findings in a constructive manner and categorise any nonconformities and improvement opportunities found
- Put the audit findings and possible corrective actions into a business impact matrix (cost versus benefit)

#### Course Deliverables

The course will provide a number of trained auditors who can be utilised immediately (preferably initially under the supervision of experienced auditors) to fulfil the audit programme.

It will also provide a number of completed audits arising from the practical auditing sessions



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The trainer will also provide on request a verbal statement of his opinion of the state of the quality management system

### What The Delegates Are Provided With

Each delegate is given a set of course notes which include all the PowerPoint presentations used by the tutor (a data projector is used and provided by us).

They are also provided with copies of relevant standards (for copyright reasons these must be returned at the end of the course) and other useful reference documents.

### The Course Tutor

The course is run by Jeff Monk FCQI, CQP who is an IRCA registered Corporate Auditor, QMS 2000 Lead Auditor and PQG listed PS 9000 Pharmaceutical Lead Auditor (Cert No A001154). He has many years experience of training auditors at all levels up to and including IRCA Lead Auditors in many parts of the world. He is a practicing audit team leader working for SQA Services based in the USA, AJA Registrars and various international pharmaceutical companies.

### Clients of the course

The following are some of the companies who have sent delegates on this course:

*Abbott Laboratories, AstraZeneca, Aventis, Avecia (previously ICI), Boehringer Ingelheim, The British Pharmacopoeia, The British Standards Institute (BSI), Ciba Geigy, Courtaulds Betts, Novartis, Cox Pharmaceuticals, Det Norske Veritas, Eli Lilly, Field Boxmore Healthcare Packaging, Fauldings, Ferring Pharmaceuticals, GlaxoSmithkline (GSK), Medica Packaging, MY Healthcare, Norgine Pharmaceuticals, Norton Healthcare, Patheon, Rhone Poulenc Rorer, Rexham Pharmaceutical Packaging, Roche Products, Roussel, Sanofi Synthelabo, Serologicals, Taiwan Healthcare Executive, the MHRA*



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### Maximum Number Of Delegates

To obtain the maximum benefit from the course it is preferable to limit the maximum number of delegates to 6, but this limit can be exceeded.

### Sample Programme

An outline course programme is shown on the next two pages. Because of the modular structure this can be readily modified to suit individual client needs.

### The Teaching Methods

We employ accelerated learning techniques which blend instructive presentations with hands-on "explore and discover". Using carefully facilitated practical exercises our experience obtained in many countries is that this helps maintain the delegates' interest and greatly enhances their knowledge retention. The practical auditing is carried out "real time" and the audit results are constructively reported to the responsible management if practicable.

### Cost

The cost of the course is £ 975 + VAT and tutor expenses per day\*. For this we can train up to 6 people. For more people (up to 10 maximum), an additional charge of £150.00 is made per delegate.

\*Expenses are limited for UK courses to miles driven from our Chippenham base at 55p per mile plus accommodation and subsistence at cost.