JEMO Limited

Ref. A17128

ISO 9000:2000 Series & Pharmaceutical Supplier Auditor/Lead Auditor

How to Carry Out Professional Management System Audits

Course Description

This unique 5-day course is highly recommended for anyone concerned with the quality management systems operated by suppliers of starting materials to the pharmaceutical industry. It has been developed and run over many years in the UK, Europe and the Far East.

The course is based on GMP as it relates to starting materials and specified in the PS 9000 series of standards. PS 9000 applies to contact and secondary packaging and printed components such as labels and patient information leaflets; PS 9100 specifies graded levels of GMP for inactive materials dependent upon their use (e.g. liquids for eye drops would have the same level as the GMP used by the pharmaceutical manufacturer, oils for external ointments would have a lower level of GMP). These standards have been developed over more than 15 years and are published in the UK by the Pharmaceutical Quality Group of the Institute of Quality Assurance (IQA). This is made up of quality executives from most of the major pharmaceutical companies and their suppliers. There is an associated certification scheme for company registration. The UK medicines regulator endorses the PS 9000 series and some of its inspectors have attended the course.

Who Should Attend

The course is designed for **Quality Assurance, Quality Control and Purchasing Professionals** from Pharmaceutical Companies and Suppliers**.** It is also very useful for auditors from **third party certification bodies.** In the UK delegates have attended from BSI, DNV and SGS**.** The course is **highly recommended** to existing and intending **Qualified Persons (QPs)** as part of their Continuous Professional Development (CPD). It is not essential, but recommended that delegates have some prior knowledge of the ISO 9000:2000 series and PS 9000 & PS 9100 before attending the course. We can help with this if required.

The course is registered by the International Register of Certificated Auditors (IRCA) and meets their training requirements for registration as Auditor and Lead Auditor. Successful delegates will obtain invaluable experience and skills in auditing suppliers against the new standards, and the certificate of successful completion is recognised by the auditor registrars of America, Australia, UK and China.

Benefit to Your Business

The company benefits are significant. The MHRA, FDA and other regulators report that the major causes of recalls of pharmaceutical products are due to purchased items. It is therefore imperative that supplier audits are done professionally so that you get a thorough understanding of how quality of critical supplies are managed. IRCA registration also confers

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a professional auditing status on individuals, which is recognised by customers and regulators worldwide.

Course Structure

Instruction and auditing practice are provided in a series of build-up modules illustrated in Figure 1. The tutor(s) are practising third and second party lead auditors and auditors and experienced trainers who use the latest accelerated learning techniques. This involves the delegates in practical learning exercises throughout the course. Experience has shown that compared to the traditional U shaped table and slide presentation approach, this technique improves delegate attention and knowledge retention and significantly improves pass rates on the IRCA set written test.

After the course, we provide practical support to successful delegates for their registration application (including supervised audits of suppliers).

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 Ingleheim, The British Pharmacoepia, 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, Sanophi Synthelabo, Serologicals, Taiwan Healthcare Executive, the MHRA

Comments from Delegates

The following are some of the comments from delegates who have attended the course:

"It opened my eyes to what professional supplier auditing is about"

"Superb explanation of the PS 9000 series of GMP standards and how to audit against them"

"Fulfilled my requirements completely"

"Illustrated throughout with pharmaceutical industry examples"

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Cost

The cost of the public course is £ 2100 + VAT. This includes lunch and refreshments during the course, a comprehensive set of reference materials and complete bound audit checklists against the special requirements of PS 9000 and PS 9100.

Discounts are available for multiple bookings. We can arrange overnight accommodation (at extra cost) to suit your budget.

The course is held in a dedicated conference centre in Bath or can be held in your facilities with considerable savings. A limited amount of tailoring can be done on in-house courses.

FIGURE 1 ~ COURSE STRUCTURE

DAY 1

- **Instruction on ISO 9001: 2008; GMP applied through PS 9000 (packaging); GMP applied through ISO 15378; PS 9100 (excipients); ISO 19011 (auditing)**
- **Preparation for auditing**

DAY 1 & DAY 2

- **Case Study Company document review & report to management**
- **Preparation of audit plan and use of PS 9000 and PS 9100 GMP checklists (bound copies supplied)**
- **Opening Meeting**

DAY 3

- **Audit of Case-study Company. Interactive audit (tutor(s) play auditees) of the processes in a pharmaceutical supplier.**
- **Preparation of the audit report**
- **Closing meeting and presentation of findings**

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DAY 4 & DAY 5

- **Surveillance activities**
- **Mock examination & feedback**
- **The route to IRCA Lead Auditor registration**
- **Revision and examination**

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