

## CQI & IRCA CERTIFIED PHARMACEUTICAL LEAD AUDITOR COURSE

### The ULTIMATE Course For Pharmaceutical Auditors

#### Course Description

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

The course is based on EU GMP and includes ISO 15378, the PS 9000 series of standards and the "Orange Guide". ISO 15378 and PS 9000 apply 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 (excipients) 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 for more than 15 years and are published in the UK by the Pharmaceutical Quality Group (PQG) of the Chartered Quality Institute (CQI). This is made up of quality executives from most of the major pharmaceutical companies and their suppliers. The course leader for this course is a member of the working groups developing ISO 15378 and PS 9000. 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 this course. Other modules (e.g. Good Distribution Practice) can be included dependent upon the sector being trained.

#### 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, LRQA, 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 one of the following standards before attending the course: ISO 9000: 2015 series, EU GMP & PS 9000. We can help with this if required.

The course is certified by the International Register of Certificated Auditors (IRCA) & CQI, and meets their training requirements for registration as Auditor and Lead Auditor. Successful delegates will not only obtain invaluable experience and skills in auditing suppliers against the new standards, they will obtain a certificate which is internationally recognised by Exemplar, the premier personnel registrar in Australia/ USA. This puts them on the same or a higher level of recognition than many customer, certification body and regulatory auditors.

#### Benefits 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 outsourced items and services. It is therefore imperative that supplier audits are done professionally so that you get a thorough understanding of how the quality of critical supplies is managed. IRCA registration

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and PQG endorsement also confers 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 course leader is a practising third and second party lead auditor\* and experienced trainer who uses 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 tests.

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

\* The course leader is Jeff Monk FCQI, CQP who is an IRCA Registered QMS Lead auditor + PS 9000 Lead Auditor and a Registered Corporate Management Systems Auditor. He regularly audits for two major certification bodies and for American pharmaceutical companies.

#### Clients of the course.

The following are some of the companies that 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), Genzyme, LRQA, Medica Packaging, MY Healthcare, Norgine Pharmaceuticals, Norton Healthcare, Patheon, Rhone Poulenc Rorer, Pfizer, Rexham Pharmaceutical Packaging, Roche Products, Roussel, SGS, Sanofi Synthelabo, Serologicals, Taiwan Healthcare Executive, the MHRA, The Macau Health Authority.

#### Comments from Delegates

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

*“The course content and exercises are excellent and meet the needs of my current job responsibilities; I will recommend this course to others both in my company and other parties. The tutor did an excellent job transferring his knowledge and providing clarification professionally”*

*Quality Director of Research-based pharmaceutical company in Asia*

*“I would just like to say how pleased I was with the course. It will prove to be very beneficial. The tuition was of a very high level, with a good mix of team activities to keep things varied. It was good how the both of you managed to integrate the group and as a result it was a good proactive atmosphere. I could honestly say this is one of the best courses I have been part of.”*

*Perry Frances from Biotech Ltd.*

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#### Course Fee

The cost of the public course is £2,100 + VAT for UK resident, zero VAT for non-UK resident. This includes buffet lunch and refreshments during the course, a comprehensive set of reference materials and complete bound audit checklists against the special requirements of PS 9000.

5% discounts are available for multiple bookings and early booking.

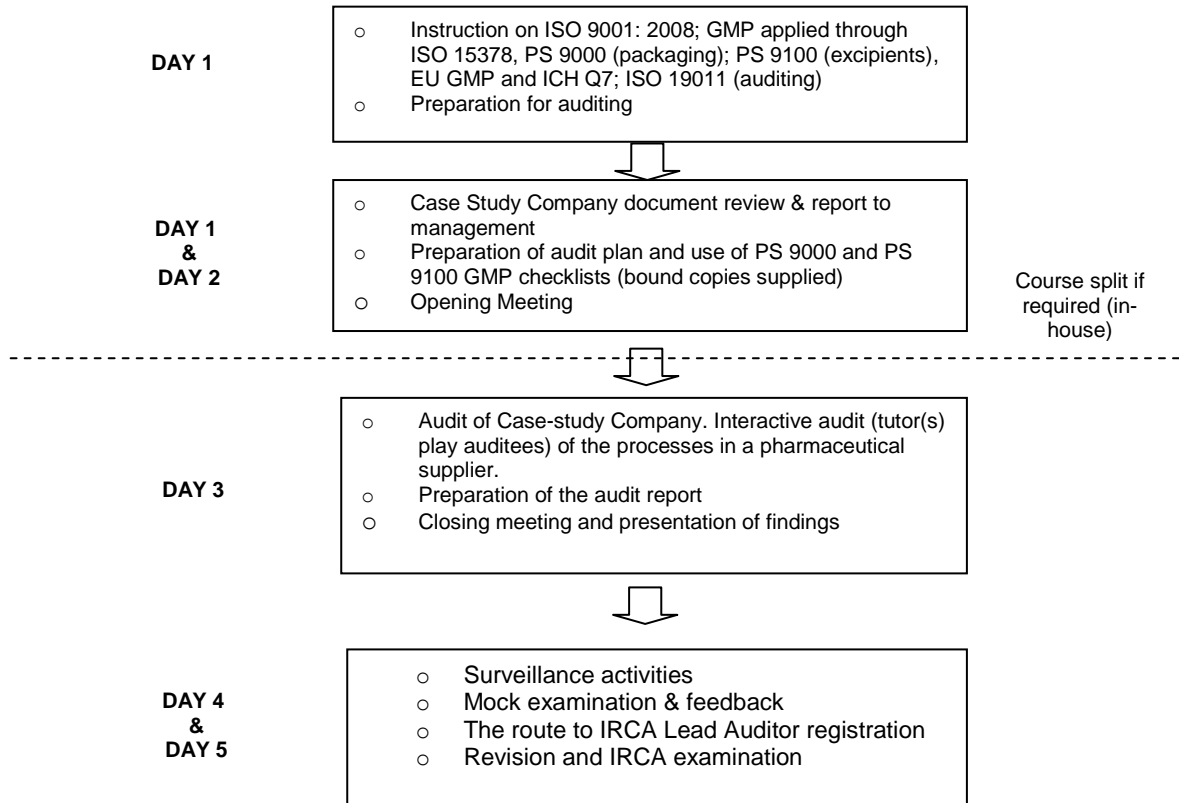
The course is held in Southwest England or can be held in your facilities. A limited amount of tailoring within the IRCA rules (usually at no extra cost) can be done on in-house courses.

#### Book a place

Please fill the [booking form](#) to reserve your place or [contact us](#) for more information.

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**Figure 1 Course Structure**