IRCA QMS Lead Auditor for the Pharmaceutical Supply Chain (PS9000/ISO9001) – PR330

Course Overview

(PQG) PS9000 Pharmaceutical Supplier Standards. This 5 day fully residential course provides the most comprehensive certification for Lead Auditors to the supply chain in the Pharmaceutical industry. Fully accredited by IRCA and PQG, this is a highly customised Lead Auditor Training course that has been specifically developed for Lead Auditors who audit Pharmaceutical Suppliers to standards such as ISO9001/PS9000.

Successful completion of this course provides the delegate with a qualification in auditing that is recognised by the International Register of Certified Auditors (IRCA) to ISO9001 Quality Management Systems and The Pharmaceutical Quality Group

This course is founded on the audit principles defined in ISO19011:2018, and supporting ISO standards, and provides an excellent structure on which to introduce, develop or monitor both internal and external audit processes.

PR330 incorporates the principles of performing 1st, 2nd and 3rd party audits as a Lead Auditor to the supply chain of pharmaceutical manufacture. This course is intended for individuals to acquire the knowledge and skills to lead audits of suppliers utilising ISO9001, PS9000, ISO9001, EXCiPACT, ISO15378, and IPEC. The regulatory background for medicinal products and an overview of the standard content is discussed. Exercises are also included for ICHQ7 for active pharmaceutical ingredients however this does not form part of the examination process detailed below.

The course includes review of risks in establishing an audit programme of the numerous components of a medicinal product and how the supply chain audit programme objectives may be met. Understanding the end use of the product or service provided by the supplier and how this may impact the patient are applied through case studies.

This course incorporates two exams:

- PQG Certification exam (PS9000)– 1 hour
- IRCA Lead Auditor exam (ISO9001 QMS) Certification exam (PR330) – 2 hours

About PS9000

PS9000 is a pharmaceutical supplier standard introduced by The PQG for manufactures and suppliers of pharmaceutical packaging materials, who are not regulated to GMP standards.

Suppliers that gain PS9000 certification have demonstrated to the pharmaceutical industry that they conform to the same GMP standards expected for other suppliers to the industry. Only auditors that have met the requirements of the PQG approved PS 9000 training course, can verify that suppliers are complying with the standards required to become a PQG Certified Supplier.

Who should attend

This course is suitable for auditors who have experience of auditing – perhaps internal auditing and/or supported external audits – and have now been asked to take the lead in external supplier audits.

Knowledge of ISO9001, ISO15378, PS9000, IPEC and EXCiPACT standards is desirable prior to the course, however, just in case you are new to them, we have designed pre-course work to help you. During the course, our tutors will take you through each stage of the audit process, and provide you with experience of applying different standards in an audit situation, with a final full audit process using ISO9001.

It is also desirable you have some knowledge in the following areas: Quality Management Systems and the core elements of a management system and the interrelationship between top management responsibility, policy, objectives, planning, implementation, measurement, review and continuous improvement, The quality management principles (see ISO 9000) are also desirable and the relationship between quality management and customer satisfaction and also ISO9001.

Venue & location information

This is a fully residential course run at the prestigious CIM Moor Hall Conference Centre, Cookham, Maidenhead, Berkshire, SL6 9QH. The course fee includes 4 nights accommodation and includes; breakfast, lunch and an evening meal.