GMP LEAD AUDITOR (PQS) CQI AND IRCA ACCREDITED (PR325)

CQI IRCA CERTIFIED COURSE

Delivery: Classroom, Online, Inhouse **Duration:** 5 days **Cost:** £3475 (+VAT)

Course overview

Do you audit your GMP environment, either self-inspections or outsourced providers? Are you armed with the tools required to carry out audits to the latest guidelines? This course provides the essential skills to plan and conduct audits with improved ability and confidence, ensuring you know how to correctly assess conformance to the correct GMP and ICH Quality guidelines.

Fully accredited by IRCA, our GMP PQS Lead Auditor (PR325) course covers the whole audit cycle, from setting the annual audit programme, through to planning, conducting, reporting, and follow-up of audits to cGMPs, ICHQ10, API, and excipient standards and guidelines. Delegates will be assessed through practical tasks, using real-world case studies and mock audits covering internal audits and self-inspections, external outsourced GMP supplier audits, and a range of dosage forms.

We are proud to have trained hundreds of auditors from across the world. With a pass rate over 90% (the IRCA average is 76%), our tutors are world-class auditors in their field, who are passionate about transferring their skills to the next generation of auditors.

Our Lead Auditor courses are IRCA accredited, flexible, and tailored to industry needs. We offer a wide range of delivery options, including face-to-face (residential), online via instructor-led blended learning, or in-house through tailored programmes for the whole team. To maintain the quality and attention one would expect of our training, course attendee numbers are limited to 12.

What's included in the course cost?

- Course and supporting materials (available in digital or hardcopy)
- Course attendance certificate
- Accommodation and all catering (this is unique to RSSL)
- Full access to our expert tutor's support during course times
- Examination fees
- Free 1-2-1 feedback session (on day 5)

To hear what recent delegates said about this course, please scan this QR code

Who should attend?

This course is for those intending to acquire the knowledge and skills to audit a cGMP Pharmaceutical Quality System, including ICHQ10. It will enable you to conduct effective self-inspection internal audit and external audit programmes that will significantly contribute to your GMP-assurance obligations. Delegates should have a good working knowledge of GMP with ideally 3-5 years of experience working in a GMP environment before attending the course.

RSSL prides itself on providing a safe and nurturing learning environment for all delegates; we are also specially trained to provide an effective learning environment for neurodivergent people.

Course pre-requisites

To comply with the IRCA certification rules, a tutor will conduct a short interview, prior to course attendance. This will help you understand the level of participation expected during the course, pre-reading, and pre-course preparation, plus discuss your personal learning objectives so we can meet your needs.

Course assessment

Delegates are assessed throughout the course, concluding with a an examination set by IRCA. Successful course participation and passing the IRCA examination will allow you to apply for IRCA Lead Auditor registration, giving your CV and profile a step-up within the industry. In the unlikely event you do not pass, RSSL will continue to support you and you will be able to re-sit the examination at the next available date.

Course programme

The course covers the following topics for either face-to-face or virtual instructor-led training (VILT) methods. All sessions include practical exercises, real-world case studies, and audits with highly participative proven learning techniques.

Day 1	Day 2
• Accreditation structure and auditor competence • Types of audits • The principles of auditing • Establishing an audit programme • Risk analysis • Conducting an audit	• Conducting internal audits and self-inspections • Construction of non-conformities • Writing effective non-conformances • Pharmaceutical Quality Systems and GMPs • Good Manufacturing Practice in the EU & UK Orange Guide • Good Manufacturing Practice in the USA & Rest of the World • ICH Quality Standards (ICHQ8, Q9, Q10) • Audit role play

Day 3	Day 4	Day 5
• Roles and responsibilities • Conducting opening meetings • Personal attributes and active listening • Questioning techniques • Communication during meetings • Conducting closing meeting • Audit role play	• Audit role play including, opening meeting, conducting the audit, preparation for the closing meeting and closing meeting, communicating non-conformances • Effective Communication • Categorising audit findings and completing audit reports • Maintaining and reviewing an audit programme	• Definitions revision • Non-conformity reporting further exercises • Review of ISO 19011 and GMP standards • Individual tutor feedback to help with development planning • IRCA Lead Auditor Exam

Learning outcomes

By the end of the course you will:

- Understand the ISO 19011 'Principles of Auditing' and how it applies to both internal and outsourced auditing environments
- Understand how to apply the appropriate GMP standards for auditing to internal self-inspections or pharmaceutical suppliers
- Plan, conduct, report, and follow up an audit according to the audit cycle of ISO 19011
- Create a structured audit programme
- Conduct an opening and closing meeting
- Create a checklist of questions to ask
- Write clear, concise non-conformity reports
- Appreciate the importance of reporting and follow up
- Know how to behave to avoid conflict and gain auditee acceptance

To book onto this course, please scan this QR code