

Pharmaceutical GMP Auditor/Lead Auditor Training

LEARN TO AUDIT WITH THE BEST
Europe's leading and most successful IRCA registered
Pharmaceutical GMP Auditor/Lead Auditor Course

Do you want to perform audits for your organisation? If so, you are an ambassador for your company, and so it is essential that you perform these audits professionally. This 5-day Pharmaceutical GMP Auditor/Lead Auditor training course covers how to effectively plan, perform, report and follow-up pharmaceutical audits against a range of pharmaceutical standards, including GMP, API GMP, Excipient GMP, Packaging Supplier Standards and GDP. Plus, the course is registered with IRCA, the International Register of Certificated Auditors, so you can become an internationally registered pharmaceutical auditor.

Who will the course benefit?

This course is aimed at internal and supplier auditors along with key personnel involved in Quality Assurance and Quality Management Systems. The course will also benefit those involved in the purchasing of incoming materials and individuals who look after the whole supply chain. Additionally, the course is ideal for trainee Qualified Persons (QPs) as well as existing auditors who have had no formal auditor training.



Course overview:

This is a unique training course for pharmaceutical auditors who will audit against pharmaceutical Good Manufacturing Practice (GMP) and/ or audit suppliers to pharmaceutical manufacturing sites. The course trains auditors how to professionally plan, perform, report and follow-up internal and supplier audits and is presented in a pharmaceutical context throughout the whole course.

The course covers the requirements of European Union GMP (EU GMP), including the requirements of ICH Q9 and 10 and how these are used as the main reference base when auditing pharmaceutical manufacturing sites. Also included in the course is an overview of key standards for suppliers to the pharmaceutical industry, including ISO 9001, Active Pharmaceutical Ingredient GMP (API GMP), Excipient GMP, Packaging Supplier Standards as well as Good Distribution Practice (GDP) and how these should be used when auditing suppliers.



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Course accreditation:

This course is approved by IRCA (the International Register for Certificated Auditors) and meets their current Pharmaceutical GMP Auditor/ Lead Auditor training course requirements. On successful completion of this course delegates may begin registration with IRCA as an internationally recognised auditor of Pharmaceutical Quality Management Systems (PQMS). IRCA course reference number – A17632. Delegates are assessed by continuous assessment throughout the course and a final examination on the final day. Due to the interactive nature of this course we aim to limit the numbers to a maximum of 12 delegates per course.

Course contents:

Quality Management Systems

- The latest FDA and EU GMP thoughts on Quality Management Systems.
- The structure and legal status of EU and USA GMP
- GMP and the importance of product quality and the patient
- Auditing the Warehouse, Production, Packaging and Laboratories
- Auditing systems – Training, Internal Audits, Management Review, Deviations, Complaints, CAPAs

Auditing suppliers

- Supplier standards - API GMP, Excipient GMP, Packaging Suppliers Standards and Good Distribution Practice (GDP)
- The evolving role of Quality Assurance
- The enhanced role for Senior Management
- ISO 9001, ICH Q8, 9 and 10 and their role
- Using audits to promote continual improvement
- Thinking beyond GMP and product quality
- Organisational efficiency, effectiveness and continual improvement



Auditing

- Reasons for first, second & third party audits and using them effectively
- How to plan, execute, report and close-out internal and external audits
- Opening and closing meetings
- Auditing Senior Management and their commitment to the system
- How to perform audits professionally
- Audit role-play exercise with pharmaceutical facility video and over 300 documents and records to review
- Good auditing techniques
- Checklist construction
- Auditing for compliance to GMP
- Adding value as an auditor
- How to conduct audits that promote increased process performance
- ISO 19011 guidelines for quality and management systems auditing



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Pre-course knowledge:

It is recommended that attending delegates have an appreciation of the standards covered during the course, but this is not essential. This includes knowledge of the requirements of ICH Q10 (plus ICH Q8 and ICH Q9) and a basic knowledge of Eudralex Volume 4 (European Union GMP).

Course feedback:

This highly raised and prestigious course has been used to train over 1 000 pharmaceutical auditors in the past 10 years. It has been presented all over the world, including Europe, America, Japan and South Africa and is presented as both a public course or for in-house presentations. Delegate feedback is outstanding, with a selection of feedback shown below:

The best trainers I have ever come across

QA Team Leader, GLAXOSMITHKLINE

The best training in Quality I have ever had

Supplier Quality Auditor, GSK BIOLOGICALS

I cannot speak highly enough of this course

Quality Specialist, ASPEN

I had heard many great things about this course and it met my expectations

QA Officer, PHARMASERVE

Fantastic – this was one of the best (perhaps the best) training courses I have ever been on

QA Manager, CLINICAL BIOMANUFACTURING FACILITY



We have also received outstanding feedback from the independent feedback organisation Reviews.io – please visit their website for further information.

Arminda P

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Very interesting course that gave me the possibility to improve my knowledge and skills about "how to perform an audit". All training contents were provided in a such enthusiastic, passionate and helpful way that kept me really motivated along the entire course.

Darren W

* * * * *

Excellent training course, the materials are very comprehensive and the instructors were enthusiastic and knowledgeable. It is a full week of learning and work but well worth the effort. I left with a full understanding of the requirements of the standard and the skills needed to audit.

Tutors:

Peter Lavis



Arguably the finest Quality Management Systems tutor in the business, Peter's enthusiasm for quality system thinking and his outstanding training abilities have gained him international praise and appeal. Peter is a leading quality management systems auditor and encourages auditors to think outside the "GMP box".

Dominic Parry



Dominic has worked in the pharmaceutical industry since 1992, and is a leading pharmaceutical quality management specialist. He is generally recognised as one of the leading GMP trainers in the UK and brings an enormous amount of interest, enthusiasm and fun into the training he presents.

Andy Martin



Andy started working in the Pharmaceutical industry in 1985 for Smith & Nephew. Following this he had a number of roles culminating when he took over as QA Microbiology Manager for Catalent Pharma Solutions. In 2012 he became a consultant specialising in Pharmaceutical Microbiology and Quality Systems.

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Course dates, venues and times:

Please [visit our website](#) for full details of the course venues. If required, you should book accommodation yourself directly with the hotel. It is recommended that delegates stay at or close to the course venue. Please note that the cost of accommodation is not included in the course cost.

Monday 21st January to Friday 25th January 2019

Reading, Berkshire UK

Monday 4th March to Saturday 9th March 2019

Osaka, Japan (course with translators - 6 days duration)

Monday 18th March to Friday 22nd March 2019

Reading, Berkshire UK

Monday 13th May to Friday 17th May 2019

Central London, UK

Monday 24th June to Friday 28th June 2019

Dublin, Ireland

Monday 23rd September to Friday 27th September 2019

Reading, Berkshire UK

Monday 4th November to Friday 8th November 2019

Manchester, UK

Sunday November 17th – Thursday 21st November

Dubai, UAE

Monday 2nd December to Friday 6th December 2019

Reading, Berkshire UK



This is an intensive course with assessments throughout. The timings are as follows:

Day 1: 09.00 – 18.45

Days 2, 3 & 4: 08.30 – 18.30

Day 5: 08.30 – 16.30 (includes final examination)

There is also approximately 1 hour of evening work each evening.

Costs:

The cost of attending is £3295 per delegate for the 5-day course (UK & Eire). [For group booking discounts of up to 50% for more than one delegate please visit our website for further information.](#) Please visit our website for further details of what is included in the course costs.

The course will be charged in GB pounds. VAT (tax) will not be charged for courses held outside the UK. VAT will be charged for the courses held in the UK, however delegates from outside the UK but within the European Union (EU) will not be charged VAT if they supply their own company's national VAT number when booking. VAT will not be charged for any delegates coming from outside the EU.

Payment and cancellations:

Full payment must be made before the course start date in order to secure a place. Payments will only be refunded in full if cancelled in writing 4 weeks before the start of the course. Delegate substitution is acceptable but please inform us.

Contact us:

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