

GMP PQS LEAD AUDITOR TRAINING COURSE

JOIN OVER 1,500 DELEGATES WHO HAVE COMPLETED NSF'S CERTIFIED GMP PQS LEAD AUDITOR COURSE



NSF's five-day CQI and IRCA certified GMP PQS lead auditor training course is designed and developed by ex-MHRA inspectors and industry experts. One of the most popular certified courses, we have trained over 1,000 auditors with pass rates of 95 percent, so you can trust our experts for your certified lead auditor training.

The course provides extensive practical support and training for the pharmaceutical auditor, including a practiced toolkit of skills. Successful completion, along with the relevant experience, can lead to you becoming a certified CQI and IRCA GMP PQS lead auditor.

COURSE OVERVIEW

This highly interactive course is designed to give you the skills and tools that have taken many experienced auditors decades to develop. It follows the auditing guidance of ISO 19011 and is a virtual audit of a manufacturing facility which makes a range of dosage forms, with its own PQS and observations for you to find and classify, along with the opportunity to practice an opening and close-out meeting.

Plan and prepare audits of the supplier and your own supplier audit system. The course is built around personal practice with exercises and teamworks in planning, preparation and performance, addressing who, why and how we audit.

Although this is an intense and challenging course, delegates describe it as "fantastic" and "worth it". You will be supported by a personally assigned tutor to answer any questions you may have.

This course is designed for auditors assessing:

- > Manufacturing operations
- > Contract manufacturing organizations
- > API suppliers
- > Excipient suppliers
- > Packing component suppliers
- > Service providers

And aimed at individuals from a range of pharmaceutical backgrounds; including QPs, quality assurance, self-inspectors from QA and operations teams, virtual companies and quality unit staff.

Many companies require their auditors to be trained through the NSF certified lead auditor course.



WHAT PEOPLE ARE SAYING

Fantastic course, good pace and mix of presentation and group sessions.

Clare Hargreaves, Seqirus.

Thoroughly enjoyable – although very intensive. Covered all my expectations and more.

Susan Callan, PTC Therapeutics International.

THE COURSE DAY BY DAY



WHAT EXPERIENCE DO YOU NEED TO ATTEND?

You should have a working pharmaceutical GMP knowledge gained from ideally three to five years of experience or from NSF's GMP course.

The course team will support you before you attend the course to confirm your prior knowledge.

ASSESSMENT

You will be continually assessed for the duration of the training during teamworks and individual exercises, supported by a personally assigned tutor.

The final exam is designed to be challenging, but pass rates have been **95 percent**. Should an auditor fail the exam, he/she will be offered a free-of-charge opportunity to retake the exam at an agreed date and venue.



MEDICAL DEVICES

Did you know we also have a CQI and ICRA certified medical devices lead auditor course?

This course provides extensive practical training to prepare medical device auditors to perform audits that identify critical nonconformities and meet international regulatory requirements.

During the course, you will plan and prepare audits based on case studies which simulate supplier and third-party audits, utilizing both ISO 13485:2016 and the Medical Device Single Audit Program (MDSAP) audit requirements.

Visit <https://www.nsf.org/training/series/cqi-irca-certified-qms-lead-auditor-iso-134852016-mdsap-requirements> for more information.

WHAT PEOPLE ARE SAYING

Truly excellent course. I was already a lead auditor for internal and external audits, but the course has provided me with massive opportunities for improvements in my tools and techniques, and especially writing audit observations, which I will take back and improve the audit process. Thank you.

Jennifer Hynes, Benchmark Vaccines.

An intense course which will provide the learning to provide high quality audit reports, consistently. An amazing mix of experience, really learned from colleagues as well. A great course, recommend for any auditor or quality professional who may undertake an audit.

Anthony Pinney, Creo Pharma.

This course has exceeded all expectations. It is the first time a training course has struck the right balance between learning the modules and having good and productive interactions between classmates. Well done to all of you for designing such a useful course.

Brandy Koslop, Ecolab.

Intense and challenging but brilliant. Very interactive and good atmosphere (great people). Set at a level for all levels of experience. Has given me the knowledge and confidence to start auditing. Increased my interest in auditing. Presented extremely well with very knowledgeable tutors.

Kate Waterhouse, Napp Pharmaceuticals.

Great training course. Tutors were great, approachable and shared a lot of knowledge. I feel inspired to become an auditor.

Tishwant Kanwarjit, Guy's & St Thomas' NHS Foundation Trust.