



PHARMACEUTICAL AUDITOR TRAINING

AUDIT SUPPORT AND EDUCATION FROM
YOUR TRUSTED NSF EXPERTS



WHY CHOOSE NSF FOR YOUR AUDIT SUPPORT AND EDUCATION?

Whether you're looking to develop yourself or one of your people to become a lead auditor, to train a group of staff on-site, to obtain one-to-one mentoring or contract auditing, NSF International's pharma biotech team has the skills, experience and auditor training programs to meet your needs.

With increasing requirements to monitor and control supply chains, falsified medicines, data integrity and continuous improvement expectations, never before has there been so much pressure on pharmaceutical companies to audit and audit to a high-quality standard.

Today's pharmaceutical auditor needs auditing skills, technical skills and up to date knowledge of the latest regulatory requirements.

Pharmaceutical and biotech companies all over the world trust NSF to provide a comprehensive one-stop shop for all their auditor training and auditing needs.

Here's why you should choose NSF:

- > Highly experienced tutors who are ex-MHRA inspectors and senior managers from the pharmaceutical industry, with years of hands-on experience in carrying out audits to GMP of pharmaceutical quality systems (PQS)
- > Unique style of delivery, highly interactive with comprehensive materials
- > Excellent networking opportunities, virtual alumni for lead auditors
- > Customized solutions as we know one size doesn't fit all
- > Ongoing support from our experts and free access to the NSF resources you need



PHARMACEUTICAL GMP AUDITS AND SELF-INSPECTIONS COURSE

JOIN OVER 1,000 DELEGATES WHO HAVE COMPLETED NSF'S CERTIFIED GMP PQS LEAD AUDITOR COURSE



Course No. 1773

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 www.nsfmedicaldevices.org 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.

INTERNAL AUDITOR WORKSHOP

NSF also offers a two-day interactive foundation workshop covering the essentials of internal audits, focussing on driving continuous improvement for your organization.

FOCUSSED
INTERACTIVE
WORKSHOPS

YOU WILL LEARN:

- > About the organization and management of internal audit programs
- > Why it is still necessary to carry out internal audits
- > Tools and techniques to improve effectiveness and confidence of the internal auditor

This workshop forms an ideal starting point for those new to internal audits or a brilliant refresher for experienced auditors. It provides a great opportunity to share challenges and solutions with industry colleagues and our experts. Join us and learn techniques you can put into practice straight away!

The natural progression from this workshop is our five-day Pharmaceutical GMP Audits and Self-Inspections training course to develop external auditing skills.

CPD FOR AUDITORS

NSF develops CPD courses for professional auditors. CPD is a requirement for the professional auditor and should be carefully planned and chosen to add the most value to your skills portfolio. Choose our blended training courses to benefit from this integrated approach to training.

Range of courses including:

- > Pharmaceutical GMP
- > Pharmaceutical Quality Systems
- > Pharmaceutical Legislation Update
- > Pharmaceutical Microbiology
- > Analysis and Testing
- > Investigational Medicinal Products

Visit www.nsf.org/info/pharma-training for current information on our courses.

We also offer:

- > Free and paid webinars
- > A resource library – white papers, case studies, webinars and more, visit www.nsf.org/info/pblibrary
- > Networking opportunities – virtual auditor training alumni group



Keep up to date with what's going on in the industry and get access to the latest resources through the NSF Pharma app



ONE-TO-ONE MENTORING

YOUR AUDIT, YOUR SUPPLIER, YOUR REPORT, OUR EXPERT ADVICE

We can provide one-to-one auditor mentoring to help you improve your auditing technique, where we offer feedback, suggestions for improvements and best practices.

Mentoring covers all aspects of auditing, including planning the audit at the agenda and logistics stage, carrying out the audit, writing the report and the CAPA follow-up. Our mentors are experienced auditors from the inspectorates, or senior industry professionals, who have carried out hundreds of audits, so you can have confidence in NSF to get the job done right.

CONTRACT AUDITING

If you don't have time or the resource to train your auditors, or are struggling with availability or the right SME for the job, let NSF help through our comprehensive contract auditing!

Contract auditing can range from a single one-day audit to multiple audits of multiple suppliers across multiple countries. We have standard agenda and report templates based on best practice, but we can work to your SOPs and follow your templates! Here's what you can expect:

- > Auditors who cover a wide range of dosage forms
- > Audits performed to the latest GMP regulations and expectations
- > Development, implementation and verification of corrective action plans (CAPAs) that are comprehensive, compliant and sustainable

So whether you're just starting out in auditing, you're a professional auditor looking for CPD, or you want to organize contract auditing or auditor training for a large group of people, you can trust the experts at NSF for all your audit support and educational requirements.



WHAT PEOPLE ARE SAYING

Good balance between lectures and practical exercises.

Sylvain Hallynck-Duflos, Roche.

Thought the trainers were fantastic. It's nice to see some people who are genuinely interested in increasing my capability. Hand on heart I learnt a lot more than I imagined I would over the last few days.

Daniel Sicklen, Procter and Gamble.

It was a highly interactive, well-structured and well-organized training.

Sabine Ilknur Gumuseli-Hircin, Bayer Turk Kimya Sanayi.



CONTACT US

For more information on NSF's auditor training or if you require audit support, call **+44 (0) 1751 432 999**, email **ASlpharma@nsf.org**, or visit **www.nsf.org/info/pharma-training**



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