Pharmaceutical Auditor Training

Pharmaceutical GMP Audits and Self-Inspections

PQMS Auditor/Lead Auditor Training Course
Why Choose

Pharmaceutical and biotech companies all over the world trust NSF Health Sciences Pharma Biotech to perform comprehensive audits to the latest GMP regulations and expectations, and to work with them in the development, implementation and verification of corrective action plans (CAPAs) that are comprehensive, compliant and sustainable. We apply this same level of rigorous knowledge to the development and execution of our professional Auditing Training Programme offered globally.

Pharmaceutical GMP Audits and Self-Inspections:
Introducing the first International Pharmaceutical QMS Auditor/Lead Auditor Certification (A17638)

At NSF Pharma Biotech, in-house experts designed and developed the first internationally recognised and certified course for pharmaceuticals based on Good Manufacturing Practice (GMP) and auditing the quality management system. This course is certified by IRCA (the International Register of Certificated Auditors) and provides extensive practical support and training for the pharmaceutical auditor, including a practiced toolkit of skills. This course has grown over the past few years with hundreds now trained and many companies requiring the training and certification of those joining their audit teams.

Course Overview
The course is designed to give you the skills 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 that makes a range of dosage forms. This allows you to plan and prepare audits of the supplier and your own supplier audit system. Throughout the course, there is personal practice with exercises and teamworks in planning, preparation and performance that address who, why and how we audit.

“Extensive course notes and excellent lectures given by knowledgeable and professional tutors who were very easy to approach with any problems during the course.”
Amjeid Saddique, Herd Mundy Richardson

Reserve your place w www.nsf.org/info/pharma-training t +44 (0) 1751 432999 e ASIpharma@nsf.org
The Course Day by Day

**Day One**
- Standards
- Introduction
- Audit System
- Different Types of Audit
- Terminology

**Day Two**
- ICH Q8, 9, 10 + Risk Management
- Audit Process
- Virtual Facility Audit
- Auditing the QMS
- Auditor Skills and Competencies
- Communication
- Cultural Differences
- Useful Techniques
- Planning Information Team Logistics
- Detailed Planning of the Audit
- ICH Q10
- System Auditing

**Day Three**
- Exam
- Create an Audit Plan
- Introductory Meeting
- Audit Materials Management
- Audit Plans and Aide-Mémoires
- Key Messages
- Writing Observations
- New Developments
- Audit Follow-up
- Report Writing

**Day Four**
- Q & A Time
- Preparation for Exam
- Close Out Meeting
- Principles of Auditing
- Auditor Skills and Competencies
- Communication
- Cultural Differences

**Day Five**
- Exam
- Individual Tutor Meeting
- Q & A Time
- Preparation for Exam
- Close Out Meeting
- Principles of Auditing
- Auditor Skills and Competencies
- Communication
- Cultural Differences

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Pharmaceutical GMP Audits and Self-Inspections

This course is designed for auditors assessing:
> Manufacturing Operations
> Contract Manufacturing Organisations
> API Suppliers
> Excipient Suppliers
> Packing Component Suppliers
> Service Providers

These auditors could come from a number of pharmaceutical backgrounds including Qualified Persons, Quality Assurance, self-inspectors from QA and operations teams, virtual companies and Quality Unit staff.

The course has been designed to simulate the roles auditors face when auditing. Activities include group work, solo work and feedback to a group of up to 20 trainee auditors.

Attendees should have a working knowledge gained from ideally 3-5 years of experience or from the NSF Pharma Biotech four-day GMP course. They should be familiar with:
> EudraLex Volume 4 Chapters 1-9 or CFR 210/211
> ICH Q8, Q9, Q10
> ISO 19011 (working copies are provided on the course)

Assessment
The course is busy and intense. The days are long and there is homework as well as pre-read material. There is continuous assessment and support from your personally assigned tutor. The final exam is designed to be challenging. Based on past performance, pass rates have been 95%. 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.

Other Auditor Training
NSF Pharma Biotech develops continuing professional development courses for professional auditors.

Pharmaceutical Quality and GMP MSc programme including:
> Formulation and Processing
> Active Pharmaceutical Ingredients
> Investigational Medicinal Products
> Analysis and Testing
> Pharmaceutical Microbiology
> Mathematics and Statistics
> Quality Management Systems
> …plus many more

Tailored auditor workshops such as the ‘How to Audit’ series covering:
How to Audit…
> Sterile Products Manufacture
> Bulk Biotech Operations
> Chemical API
> Key Excipients

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

How to Reserve a Place
To provisionally reserve a place on any auditor course, please contact ASIpharma@nsf.org

Online Reservation
Provisional and firm bookings can be made via our website www.nsf.org/info/pharma-training

“Got exactly the essential information and training I needed – can’t wait to use it!”
Alan Sarup, Orifarm Generics A/S

“Excellent course, materials and tutors. Surpassed my expectations. Thanks!”
Barry Cook, Sanofi-Aventis Pharma

“Very good tutors with extremely highly level of knowledge. Thank you for that fantastic training.”
Kathrin Haberstroh, Roche

“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

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Choose NSF Health Sciences for Professional Auditing, Training and Consulting

The right people. The right solution. The first time.™

We believe in planning for the future and we offer:

> Excellent connections with industry and regulatory bodies (EU, FDA, WHO)
> Expert knowledge of pharmaceutical regulations to help you interpret, set and implement standards based on good science and pragmatism
> A thorough understanding of best industry practices and future trends, with thousands of clients worldwide
> Crisis management and crisis prevention expertise

We also believe in challenging the status quo, thinking differently and we:

> Listen (diagnose before we prescribe)
> Question (using the 5 whys)
> Challenge from all angles and innovate
> Share best practice
> Mentor and guide to deliver best-fit solutions
> Customise solutions as we know one size doesn’t fit all

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