

Bio
Pharma
Chem

Skillnet,

Internal Quality Auditing for Manufacturers of Finished Pharmaceuticals



Delivered by:



bpcskillnet.ie
training@bpcskillnet.ie

Introduction

Internal auditing is fundamental to any quality improvement initiative. In particular, the FDA cGMP's for Pharmaceutical Products require that an organisation conduct internal quality audit to determine the effectiveness of its quality system. EU GMP requirements expect that companies conduct self-inspections. Trained auditors must carry out these audits.

Thousands of internal audits are performed each year providing little internal business benefit. This course focuses on auditing company quality systems for real quality improvement rather than just compliance.

This two day course provides detailed training in developing the skills necessary to be an effective internal auditor.

This course is available exclusively on an In-House basis.

What's covered?

Please Note: A practical audit within the company forms the basis of day 2. Audit areas within the company must be organised prior to the training so that effective preparation can commence on day 1. For this reason the numbers on this course are restricted to max 12 (4 audit groups of 3) to ensure all delegates get the attention needed to ensure they become effective Auditors.

Day 1:

- Introduction to Quality Systems
- Purpose of Internal Quality Audits
- The Audit Process
- Selecting the Audit Team
- Tools available to Auditors
- Audit Preparation
- FDA CFR part 211 cGMP for Pharmaceuticals & additional EU GMP requirements

Day 2:

- Audit Preparation (Follow on from Day 1)
- Audit Performance
- Evaluating & Reporting the Audit

Who Should Attend?

- Any person in the organisation with responsibility for conducting internal audits
- Departmental managers and supervisory staff
- Quality Managers, quality engineers and supervisory staff
- Staff with responsibility for designing and implementing quality systems • Personnel responsible for supplier / external audits

How will you learn?

Participants achieve the following learning outcomes from the programme;

- Understand the requirements of the FDA CFR Part 211 Current Good Manufacturing
- Practice for Finished Pharmaceuticals & EU GMP Part 1 requirements
- Understand the importance of internal auditing within a quality management system
- Understand the responsibilities of Internal Auditors
- Conduct an effective internal audit e.g. plan and organise an internal audit against the organisation's documented procedures
- Collect and analyse evidence objectively
- Evaluate and report the results of an internal audit

In-House Courses

For In-House courses the tutor will contact you in advance to discuss the course programme in more detail in order to tailor it specifically for your organisation.

Course Manual

Delegates will receive a very comprehensive course manual.

This training is delivered on behalf of BioPharmaChem Skillnet by SQT Training.

For further information please contact training@bpcskillnet.ie or phone 087 997 0848

BioPharmaChem Skillnet is co-funded by Skillnet Ireland and member companies. Skillnet Ireland is funded from the National Training Fund through the Department of Education and Skills.



An Roinn Oideachais
agus Scileanna
Department of
Education and Skills



