ACTIVE PHARMACEUTICAL INGREDIENTS (API) AUDITING

Delivery: Classroom, Online, In-house **Duration:** 1 day **Cost:** £560 (+ VAT)

Course overview

When auditing Active Pharmaceutical Ingredient (API) manufacturers, there is a responsibility to ensure patient safety. This course provides the assurance required to meet both product safety and regulatory expectations.

This course provides the knowledge and skills to enable effective auditing and reporting of audits on suppliers of active pharmaceutical ingredients (APIs). The course is focused on the requirements of ICH Q7 and EU GMP Part II and the expectations of regulatory bodies both in the USA and Europe.

Who should attend?

The course is suitable for people who have had some auditor training and experience in conducting audits. It is specifically designed for those responsible for assessing the content and findings of API audit reports as part of license applications and variations, as well as those Qualified Persons (QP) responsible for the release of pharmaceutical products.

Course programme

The course covers the following topics:

- Legal and GMP basics
- Audit preparation
- Product specific information
- Materials handling
- Manufacturing methods and equipment
- Cleaning validation
- Introduction to process validation
- Production and packing APIs
- Quality control laboratories (GCLP) including data integrity
- QMS and product release
- Close out, reports and follow up

Learning outcomes

This course will be assessed and certified by RSSL against the standards of ICH Q7. At the end of the course you will:

- Understand the regulatory requirements for conducting API audits
- Be able to provide background information and scope for a supplier audit
- Have the ability to create a structured approach in preparation for an API audit
- Be able to conduct an API audit
- Know how to create a check list of questions to ask
- Be able to identify non-conformities against ICH Q7 and regulatory expectations
- Be able to identify product specific requirements
- Have knowledge on the basic manufacturing techniques and equipment used
- Understand the requirements for Good Control Laboratory Practices (GCLP)
- Know how to produce a report that will satisfy the sponsor organisation as to the ongoing status and compliance of the API supplier
- Be able to produce a report that demonstrates the continuing suitability and certification of the API(s) in question
- Know how to obtain auditee cooperation and acceptance of findings

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