



# Auditing – Active Pharmaceutical Ingredients

## Scope

This course provides the basic knowledge base and skills to enable effective auditing and reporting of audits on those 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.

## Suitability

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.

## Learning Outcomes

The course will be assessed and certified by RSSL against the standards of ICH Q7.

By the end of the course you will be able to:

- Understand the regulatory requirements for conducting API audits
- Provide background information and scope for a supplier audit
- Create a structured approach in preparation for an API audit
- Conduct an API audit
- Create a check list of questions to ask
- Identify non conformities against ICH Q7 and regulatory expectations
- Identify product specific requirements
- Have knowledge on the basic manufacturing techniques and equipment used
- Understand the requirements for Good Control Laboratory Practices (GCLP)
- Produce a report that will satisfy the sponsor organisation as to the ongoing status and compliance of the API supplier
- 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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