Active Pharmaceutical Ingredients

QP Module – RSC Approved Training

ROYAL SOCIETY OF CHEMISTRY | APPROVED TRAINING

Delivery: Classroom, Online, Inhouse **Duration:** 2 days **Cost:** £1560 (+VAT)

Course overview

The Qualified Person must understand the influence of manufacturing pathways and associated physical and physico chemical attributes of both active pharmaceutical ingredients and major excipients on the quality of the finished dosage form.

QP responsibilities also include formally certifying that each Active Pharmaceutical Ingredient (API) is manufactured to GMP, knowledge of the API supply chain and complying with importation requirements as defined in the Falsified Medicines Directive. This course includes both the technical aspects of manufacturing APIs and the requirements of Good Manufacturing Practice.

Who should attend?

This is an essential course for all those who expect to be taking the QP Viva, it is also a valuable contribution to Continuing Professional Development for QPs who qualified some years ago. This is also suitable for those who require an understanding of the requirements for manufacturing APIs such as purchasing, manufacturing or regulatory affairs staff.

Course programme

The course includes the following topics and is reinforced using group exercises:

Day 1	Day 2
• Methods and equipment including virtual tour of chemical facilities • Methods and equipment for Bio APIs • GMP requirements for API's-Eudralex Vol 4 • GMP requirements FMD and GDP • GMP requirements ICH and impurities	• Registration aspects including QP declaration exercise • Laboratory controls • Process validation overview • Cleaning validation overview • Supply chain and QP responsibilities • The control of API packaging materials • API audit situations

Learning outcomes

At the end of the course you will know:

- The role of the QP relevant to APIs
- The regulatory framework for the manufacture of APIs
- The requirements of the Falsified Medicines Directive and APIs
- How to use the European Guide to GMP for APIs
- The contents of a drug master file
- Methods and equipment used in synthesis
- Requirements for specifications, organic solvents and impurities
- Process and cleaning validation
- The control of packaging materials for an API

TO BOOK
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