Good Manufacturing Practice Advanced

RSC APPROVED TRAINING

Delivery: Classroom, Online, Inhouse **Duration:** 3 days **Cost:** £2335 (+VAT)

Course overview

This 3-day course systematically builds up the knowledge of delegates over three intensive days. It covers the regulations and guidelines associated with GMPs and the expectations of the MHRA and FDA. Topics examined include incoming materials, including control of suppliers of APIs, excipients, and packaging materials. Other sessions examine manufacturing, packaging, premises, equipment, engineering activities, quality systems, and laboratory practices. The course is highly interactive and also features several real-life case studies.

Classroom courses: Please note, the advertised venue may need to be changed, if the required number of delegates is not met. In this situation, the course will be converted to an Online Virtual course and all delegates notified accordingly. The decision regarding the venue will be made at least 4 weeks before the course is due to run.

Who should attend?

This course is aimed at key personnel working in management, QA, QC, production, engineering, and clinical trials, who wish to have a broader and more extensive appreciation of pharmaceutical good manufacturing practices.

Course programme

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

Day 1	Day 2	Day 3
• Why do we have GMP • UK legislation and licensing • Human and veterinary medicines regulations • Relationship to EC directives • Pharmaceutical quality system • Role of MHRA • How to use the orange guide	• GMP in the USA • Key people and training • Control of incoming materials • Overview and principles of ICH Q9 • Change management • Premises and equipment • Pharmaceutical supply chain • GMP audit points in production and packaging • Deviations and investigations	• GMP, QC, and GQCLP • Calculations, results, and OOS • GMP and documentation • Validation and qualification • Auditing and self-inspections • Contracting out • Complaints and recall

Learning outcomes

Attending this course will ensure that you will:

- Be able to find your way confidently around the rules and guidelines of GMP, UK ‘Orange Guide’, (which incorporates the EU Guide to GMP), FDA Code of Federal Regulations
- Have acquired a broad but comprehensive knowledge of GMP allowing you to speak and act with confidence in your work environment
- Have developed an understanding of the current GMP expectations and how to interpret and apply them in practical situations

TO BOOK
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