Analysis and Testing

QP Module – RSC Approved Training

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

Course overview

It has been recognised for many years that the sampling and testing of materials does not by itself assure product quality. Any testing performed must be part of a comprehensive Pharmaceutical Quality System, including QA and GMP, and it must be correctly implemented and controlled.

This module reviews the principal qualitative and quantitative analytical methods in common use, the principles of method selection and validation. It also includes, sampling plans, physical and organoleptic testing, stability testing and the significance of degradation, contamination and adulteration of pharmaceutical materials. Importantly, it also includes the interpretation of analytical data including non-conforming results and stresses the importance of how these need to be managed. All activities are discussed and explained within the confines of Good Quality Control Laboratory Practice and applicable regulatory guidelines.

Who should attend?

This module forms part of a series designed to satisfy the Study Guide requirements for those wishing to become a QP. It is also suitable for any analysts who 'left the laboratory' a long time ago and other production and QA professionals wishing to top up their knowledge and current understanding of QC laboratory expectations as part of their Continued Professional Development (CPD).

Course programme

This course can be run as a 3-day Classroom course or a 2-day online course and includes the following topics/sessions:

Classroom Course (3 Day)

Day 1	Day 2	Day 3
• Practical laboratory Session that covers chromatography HPLC/IC, microscopy and oral dosage forms (dissolutions, disintegration and friability)	• Basics of analysis and testing • Physicochemical methods • Good Control Laboratory Practice • Chromatography • Incoming goods, sampling, In-process controls • High Performance Liquid Chromatography (HPLC)	• Other Instrumental techniques • Impurities, degradation, contamination, and adulteration • Cleaning validation • Specifications and methods • Analytical method validation • OOS investigations • Stability testing

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Online Course (2 Day)

Day 1	Day 2
• Basics of analysis and testing • Physicochemical methods • Good Control Laboratory Practice • Chromatography • Incoming goods, sampling, in-process controls • High Performance Liquid Chromatography (HPLC)	• Other instrumental techniques • Impurities, degradation, contamination, and adulteration • Cleaning validation • Specifications and methods • Analytical method validation • OOS investigations • Stability testing

Learning outcomes

At the end of this course you will:

- Understand the principal analytical methods in common use in a Pharmaceutical QC laboratory
- Have confidence interpreting analytical data and dealing with non-conforming results
- Understand the principles of method selection and validation
- Be aware of current stability testing requirements and management of stability testing programmes
- Be aware of current EU guidelines relating to analysis and testing

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