



## **Qualified Person** Training Courses

Established in 1998, RSSL Pharma Training has an enviable reputation as a provider of high quality industry specific programmes. Industry experts bring current and future thinking to the knowledge content, whilst an emphasis on the latest problem based learning methods ensures that our delegates leave with a pragmatic understanding of the subject, and the confidence to put it into practice in the workplace. All the courses detailed below can be tailored and run for you on site, offering a cost effective way of relating topics to company specific situations.

## What delegates have said about recent QP courses:

"A well put together course, with relevant group exercises that fitted very well with the lectures."

"Fast paced - and very enjoyable - real examples of issues applied to real-life situations."

EU legislation requires medicinal products to be certified as complying with various authorisations, national legislation and GMP. The legislation assigns personal responsibility for these activities to a 'Qualified Person' and requires that every manufacturing site (including those manufacturing investigational medicinal products) employs the services of such a person. Under the permanent provisions of the EU legislation (2001/83/EC), educational and experience criteria need to be fulfilled.



In the UK, this is ensured and administered by three professional bodies who publish a Study Guide against which trainee QPs are ultimately assessed by viva examination. Study is based around 11 subject areas, comprising 3 'Foundation' modules and 8 'Additional Knowledge' modules. The unique and flexible approach that we take in providing training in this area has made it an increasingly popular choice for many companies and individuals alike.

## Key features:

- Modules based on the latest 'QP Study Guide' requirements, with the emphasis on case study and problem-based learning
- Affordable courses lasting only two or three days – save on time away from the workplace
- Courses have a sound practical focus on the key elements and competencies needed to make sensible judgements and rational decisions
- Choose to attend anything from a single module through to the full complement – you choose what is appropriate for your needs
- All 11 training modules are presented over a single calendar year, which means that you can schedule your study at a time convenient to you
- Experienced tutors include a number of current and former QP Assessors
- Courses are equally popular with existing QPs as part of their Continuous Professional Development (CPD)



## Foundation Module: Law and Administration

Qualified Persons must have a comprehensive knowledge of EU Directives and UK Laws and Regulations to perform confidently and to be able to advise their company accurately. This module not only provides that knowledge but explains some of the complex jargon that can prevent a full understanding. The two days of fully interactive tutoring also covers MRAs, Pharmacopoeias and the MHRA and EMEA organisations.

## Foundation Module: Roles and Professional Duties

A Qualified Person (QP) must certify that each batch of medicinal product complies with its Marketing Authorisation or Product Specification File, GMP and certain other requirements. Their conduct overall must comply with the Code of Practice for QPs. This module examines the responsibilities of a QP in depth, including case studies and questions that challenge the attendees' knowledge of the Code and of the Guide to Good Manufacturing Practice.

## Foundation Module: Quality Management Systems

It is a fundamental requirement of GMP that organisations design and implement a Quality Management System (QMS) that is appropriate for their activities, is fully documented and monitored to ensure effectiveness. Without an effective QMS the QP cannot be sure that systems remain in control and cannot be confident that each batch of product has been manufactured according to the requirements. It follows that the QP must be able to judge if the QMS is effective by understanding the feedback that it should provide. This course is designed to cover establishment, implementation, maintenance and effective operation of a QMS and is therefore key to all aspiring QPs, plus others working in both quality and operational roles. It will give practical guidance on all the major elements of a typical QMS.

## Mathematics and Statistics

The study guide emphasises that QPs must have a knowledge of the practical application of basic statistical tools in pharmaceutical production and QA. This knowledge is essential in demonstrating the capability of processes or the acceptability of materials. In particular QPs should be able to demonstrate an understanding of statistical process control, sampling and the statistics employed during method validation. This fully revised course focuses on establishing key learning points regarding the application of techniques rather than the techniques themselves. Presentations are supported by exercises or case studies to reinforce principles and best practices. In addition, the incorporation of ICH Q8, Q9 and Q10 into EU GMP will require QPs to be more able to understand statistical tools and techniques as part of a Quality Management System involving quality by design and risk-based approaches.

## Medicinal Chemistry and Therapeutics

Qualified Persons cannot fulfil their role in a responsible way unless they understand the actions and uses of the medicinal products they are asked to certify. Supported by the top subject matter experts from the University of Reading, School of Pharmacy, this three day module takes major therapeutic categories as examples and together with some basic physiology, discusses the pharmacology of particular drugs used for those categories, before using case studies to explore the implications for the QP.

## Pharmaceutical Formulation and Processing

The Qualified Person should be the company expert in the formulation and processing of medicinal products they are asked to certify. This five day (2 part) module provides basic formulation principles, including preformulation studies, bioavailability considerations and the effect of excipients on physical and chemical stability. Each major product category is considered separately with respect to common formulations and processing techniques and the course includes many exercises of situations for the trainee QP to practise decision making.

## Pharmaceutical Microbiology

The QP needs an understanding of the microbiological control of pharmaceutical products. Delegates will discuss the main types and sources of micro-organisms and the issues associated with them in relation to sterile and non-sterile pharmaceutical production. Specific sessions cover water systems, clean room design and operation, and the concept of sterilisation and sterility assurance.

## Analysis and Testing

The sampling and testing of materials does not by itself assure product quality. It must be part of a comprehensive 'Quality Management System', including QA and GMP, which must be correctly implemented and controlled. This module includes GCLP, interpretation of analytical data and non-conforming results, the principal qualitative and quantitative analytical methods in common use, the principles of method selection and validation, sampling, physical and organoleptic testing, stability testing and the significance of degradation, contamination and adulteration of pharmaceutical materials.



## Pharmaceutical Packaging

The QP needs to fully understand the challenges and risks involved in packaging operations in the Pharmaceutical Industry. A significant percentage of all product related complaints and recalls are related to packaging.

This course closely examines the key stages of pharmaceutical packaging relevant to the QP, from component manufacturers and suppliers to final product release including QP certification. It includes artwork control, labelling, (including braille), anti counterfeiting measures and packaging GMPs. It will give practical guidance on the major challenges and risks associated with packaging operations.

## Active Pharmaceutical Ingredients

This course includes both the technical aspects of manufacturing APIs and the requirements of Good Manufacturing Practice. The Qualified Person is expected to formally certify that each API is manufactured to GMP and the training provided during the two day course will give the QP confidence in coming to a decision on whether to certify or not, or to ask for further information.

## Knowledge Module 8: Investigational Medicinal Products

The QP should be aware of the different requirements between commercial and clinical trial operations. This one day course examines EU legislation and GMP issues, many of which are unique and associated with Investigational Medicinal Products (IMPs). It will provide practical guidance on the major differences between IMPs and commercial operations. Delegates will also have the opportunity to learn about the principles of Good Clinical and Good Laboratory Practice. The course is ideally suited for those wishing to ensure they have sufficient awareness of the specific nature of IMPs and the challenges facing the QP.

## Biotechnology Issues (optional additional workshop)

The QP needs to understand the quality issues associated with the manufacture of biopharmaceuticals. Whilst the other modules cover biotechnology products alongside other product types, based around the study guide, this workshop is designed to pull together the information in a way that provides participants with a good overview of the quality and regulatory issues surrounding the development and production of biopharmaceuticals for global use.

## QP Viva Preparation Sessions

Most QP candidates approach their viva with some trepidation because they do not know what will happen during the one hour or so of questioning. This one day personal tutorial explains to the candidate what will happen, how the viva will be conducted and examines in detail some of the common questions that are asked.

Candidates are shown how simple questions develop into complex scenarios and how they should deal with them. Candidates will benefit most by arranging this programme approximately 4-6 weeks before their viva date.

## Support throughout your Training

Our Pharmaceutical Training Manager and Client Relationship Manager are here to ensure that your experience with us is excellent from your first enquiry to our warmest congratulations when you qualify. We can provide advice and feedback on your individual circumstances and offer advice on the best training approach for you.

Regular 'Buzz Group' Meetings provide you with an opportunity to network in an informal environment; key tutors will briefly introduce controversial and current topics before encouraging you to increase your 'argumentative' muscle in small group discussions!

Once registered for a course with us, you will have access to the most relevant subject matter experts who will be able to answer your questions and challenge your thinking, during and after the courses. This extends to help and advice preparing and submitting your application for certification as a Qualified Person.



For further information or to book a place please contact us by telephone, email or via our website as follows:

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**Terms & Conditions**

There will be no charges providing cancellation is more than 20 working days before the course start date. Cancellation made within 20 working days of the course start date will be charged at the full rate. Delegate substitution is acceptable – but please inform us in advance whenever possible. In the event of unforeseen circumstances, RSSL reserve the right to alter the programme, speaker(s), course date or venue. If a course is cancelled by RSSL, a full refund will be offered, if rescheduling of the course is either not possible or not acceptable to the delegate. However, RSSL Training will not be liable for any other costs incurred by the delegates, associated with the course.