Becoming A Qualified Person

Industry leading

Unique and flexible approach

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The aspiring Qualified Person – your first step

Why become a Qualified Person (QP)? The role of the QP is essential to the safe control of medicines; you will have the personal responsibility to ensure that medicinal products are certified as complying with required authorisations, national legislation and good manufacturing practice (GMP). You will need to have comprehensive training and an in-depth understanding of all aspects of pharmaceutical manufacturing.

Becoming a QP will open up new career opportunities for you, however it involves a level of investment and commitment. You need to ensure that you get the best and most cost-effective training available, and that it suits your needs – this is where we can help.

Our outstanding reputation as one of the most trusted pharmaceutical training providers, gives you confidence that the training provided is of the highest standard and is relevant to the aspiring QP. Our outstanding first time success rate of >90% and the unique, flexible and innovative approach we take to training makes us the preferred training partner of choice for many companies and individuals alike.

How our training will benefit you

Our industry experts provide face to face, in-depth tuition with an emphasis on the latest case study and problem based learning methods.

- Our 11 modules are designed to meet the requirements in EC Directives 2001/82/EC and 2001/83/EC and the latest UK Qualified Person Study Guide
- All of our modules are presented twice in a single calendar year, which means you can schedule your study at a time and pace to suit you
- Our industry experienced tutors include current QP assessors
- Our modules are practical in nature, focusing on the key elements and competencies delegates need to make sensible judgements and rational decisions
- We limit delegate numbers to maximise delegate/tutor interaction
- We can carry out a gap analysis of your skills and experience to identify your specific needs
- Our 1:1 tutor support includes help with preparing and submitting your application for eligibility as a QP
- Our highly interactive WebTorials build on and reinforce recent QP modules studied




What you will learn

Law and Administration

Foundation

To assure patient safety, the manufacture and distribution of pharmaceutical products is highly regulated within the EU. QPs must have a comprehensive knowledge of EU Directives and National legislation relating to the manufacture, storage and sale or supply of medicinal products for human and veterinary use. This module also covers the requirements for site and product authorisations, regulatory inspections, the role of the Pharmacopoeias and international harmonisation.

Medicinal Chemistry and Therapeutics

Additional Knowledge

To fulfil the role of a QP, it is essential that you understand the actions and uses of medicinal products. This knowledge is important, for example, when evaluating the significance of cross contamination hazards or product quality complaints, and to ensure products are fit for their intended use. This module takes major therapeutic categories as examples (including pain, cardiovascular, infections, renal disease, skin disease, cancer) and discusses the pharmacology of particular drugs used in the context of the basic physiology. The module also looks at examples of interfaces with Pharmacovigilance and the interdependencies with GMP. This module is supported by a number of professors and senior lecturers from the University of Reading School of Pharmacy.

Pharmaceutical Quality Systems

Foundation

The manufacture and supply of pharmaceutical products requires the establishment and implementation of an effective Pharmaceutical Quality System (PQS). The PQS must be appropriate for the activities performed, and be fully documented and monitored to ensure effectiveness. Without an effective PQS, the QP cannot be sure that the required, inter-related systems remain in control, and that each batch of product has been manufactured according to both the relevant licence requirements and GMP. This module is designed to cover establishment, implementation and effective operation of a PQS, as well as giving practical guidance on all major elements of a typical PQS. It will focus on the challenges associated with each major element and how these can be effectively addressed.

Mathematics and Statistics

Additional Knowledge

The practical application of basic statistical tools in production and QA is an essential skill for QPs. Focusing on the techniques and their application, this module will ensure that you can demonstrate an understanding of statistical process control, sampling, method validation and statistical tools/techniques as an integral part of a PQS, involving quality by design and risk-based approaches.

Roles and Professional Duties

Foundation

A QP must certify that each batch of medicinal products (for human or veterinary use) complies with its Marketing Authorisation or Clinical Trial Application, GMP and certain other requirements depending where manufacture was carried out. The QP must also ensure that they discharge their duties in accordance with the Code of Practice for QPs. This module examines the responsibilities of a QP in depth, including legal and professional duties and how to be an effective QP.

Pharmaceutical Formulation and Processing

Additional Knowledge

The formulation and processing conditions employed in the manufacture of medicinal products can have a significant effect upon their safety, quality and efficacy. Even small changes to the input materials and/or processing conditions can affect attributes such as bioavailability and stability, which would not typically be detected during routine QC testing. It is very important that as a QP, you understand the principles of formulation and pharmaceutical processing. This module considers the formulation and processing of the major dosage forms in detail, and covers other key principles including preformulation, bioavailability and the effect of excipients on product performance, quality and stability. It also includes sessions on process validation and scale-up, facility design, utilities, water systems and sterilisation processes. This module includes a practical day in The University of Reading School of Pharmacy manufacturing tablets and creams.




Pharmaceutical Microbiology

Additional Knowledge

Microbiological contamination of products and processes is a key concern of the industry and its regulators. Completing this module will give you an understanding of the significance of bacteria, yeasts, moulds, viruses and toxins in raw materials, intermediates, products and the environment. It will also cover microbiological control, clean room design, water systems, the concept of sterilisation and sterility assurance.

Analysis and Testing

Additional Knowledge

Sampling and testing are part of the overall quality management system which is designed to ensure materials and products are of satisfactory quality. This module reviews the principal qualitative and quantitative analytical methods, the principles of method selection and validation. It also provides information on sampling plans, physical testing, stability testing, the significance of degradation, contamination and adulteration. Interpretation of analytical data including non conforming results is also covered. This module includes a practical foundation day in our state of the art analytical facilities in Reading.

Pharmaceutical Packaging

Additional Knowledge

The QP needs to fully understand the challenges and risks associated with packing operations to minimise the possibility of mix ups, cross contamination or substitutions. The key stages of pharmaceutical packaging, from component manufacture and supply, to final product release including QP certification, are covered in this module.

Active Pharmaceutical Ingredients

Additional Knowledge

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.

This module covers the technical aspects of manufacturing APIs and the requirements of good manufacturing practice, with particular emphasis on Part II of the EU Guide to GMP.

Investigational Medicinal Products

Additional Knowledge

All QPs need to understand the different Good Manufacturing Practice (GMP) requirements for commercial and Investigational Medicinal Products (IMPs), and the unique additional GMP requirements for IMPs. This module examines the EU legislation relevant to the manufacture, control and supply of IMPs. It provides practical guidance on the major differences in the GMP requirements between IMPs and commercial products, and the unique areas that QPs need to consider when releasing IMPs.

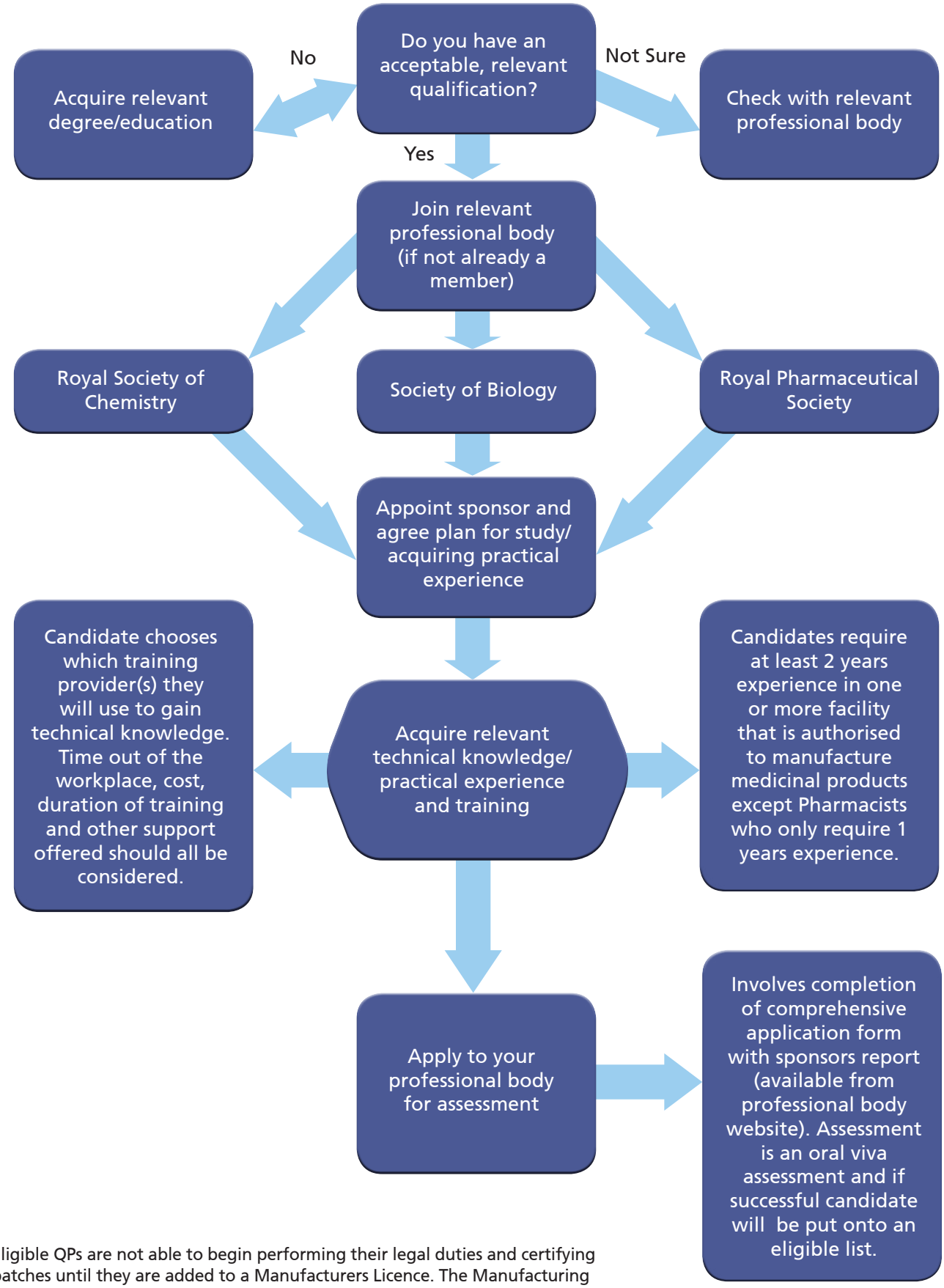
Biotechnology Issues

Optional

The QP needs to understand the quality issues associated with the manufacture of biopharmaceuticals. This module is designed to pull together information on biotechnology products in a way that provides a good overview of the quality and regulatory issues surrounding the development and production of biopharmaceuticals for global use.

For more information visit our website www.rssl.com or better still, get in touch with Customer Services on +44 (0)118 918 4076 or enquiries@rssl.com

The stages involved in becoming a QP



Eligible QPs are not able to begin performing their legal duties and certifying batches until they are added to a Manufacturers Licence. The Manufacturing Authorisation holder applies to the MHRA to have an eligible person act as their QP and the MHRA then check the application and make a decision.

Supporting you throughout your training

Our dedicated team are here to ensure that your experience with us is first rate - from your initial enquiry to our warmest congratulations when you qualify. We will help by reviewing your experience and individual circumstances and advise on the best training approach for you.

Regular 'Continuing Professional Development Seminars' and online WebTorials provide you with an opportunity to network in an informal environment, keeping you up to date with industry 'hot topics' and delve in to some of those invaluable 'soft skills'.

All your training will take place in our purpose built facilities in Reading, close to good motorway, rail and air transport links. Café style working groups ensure high levels of engagement and effective learning. The most relevant subject matter experts will be able to answer your questions and challenge your thinking, including help and advice preparing and submitting your application for the viva examination.

We constantly seek constructive feedback from our delegates and do our best to action all the good ideas that you put forward, in order to continuously improve your training experience.

For more information visit our website www.rssl.com or better still, get in touch with Customer Services on +44 (0)118 918 4076 or enquiries@rssl.com

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