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 that confidence that the training provided is of the highest standard and is relevant to the aspiring QP. Our outstanding success rate >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.

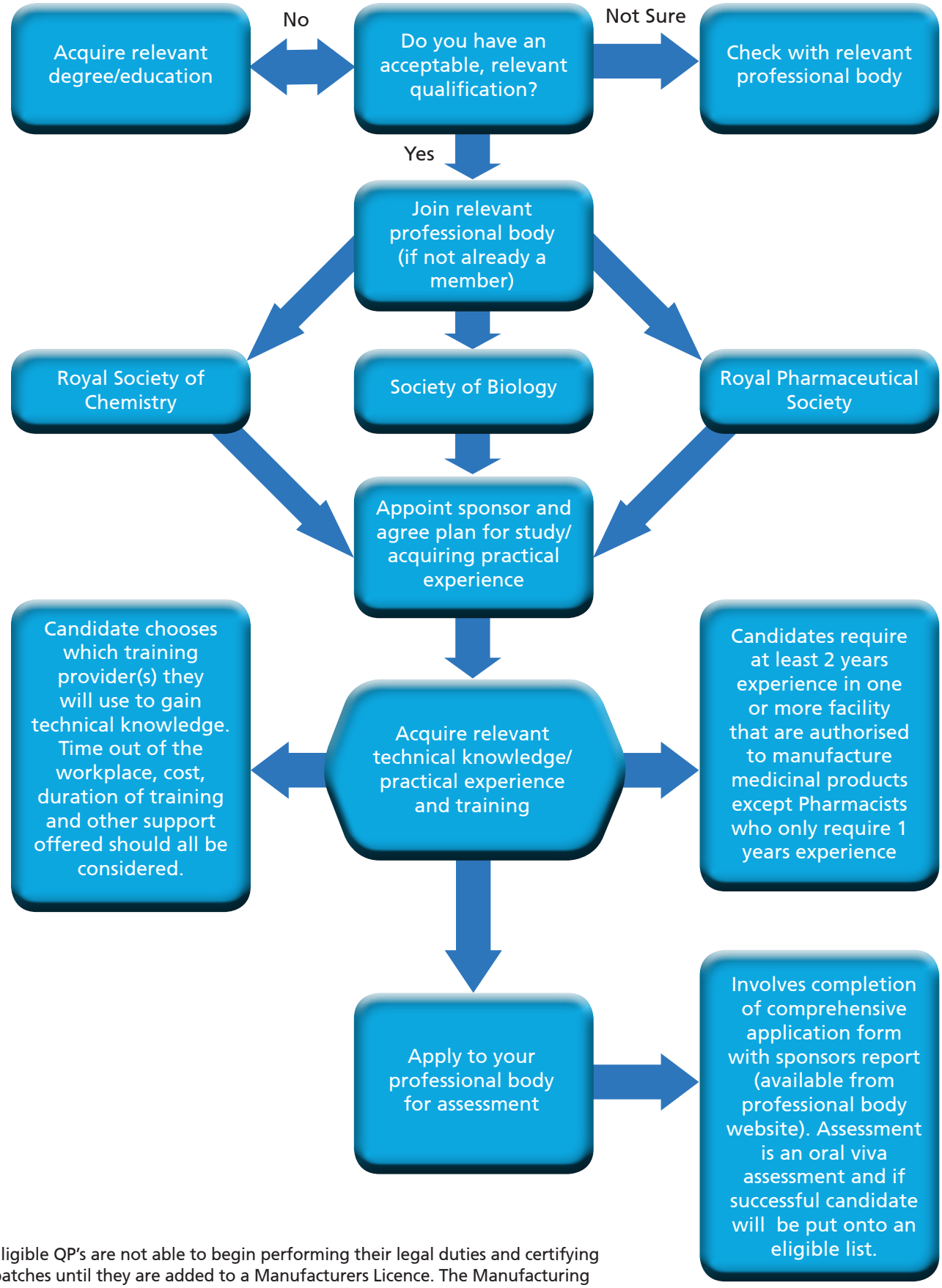
How our training will benefit you

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 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 and former 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 skills gap analysis to identify your specific needs
- Our one to one tutor support includes help with preparing and submitting your application for eligibility as a QP




The stages involved in becoming a QP



Eligible QP's 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.

What you will learn

Law and Administration

Foundation

To assure patient safety, the manufacture and distribution of pharmaceutical products is highly regulated with 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. QPs also need to demonstrate a thorough knowledge of GMP requirements. This module also covers the requirements for site and product authorisations, regulatory inspections, the role of the Pharmacopoeias and international harmonisation.

Roles and Professional Duties

Foundation

A QP must certify that each batch of medicinal products complies with its Marketing Authorisation or Product Specification File, GMP plus 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. This module examines the responsibilities of a QP in depth, including legal and professional duties, how to be an effective QP, certification processes according to Annex 16 and post certification duties. It includes case studies and questions that challenge understanding of the overall role of a QP.

Quality Management Systems

Foundation

The manufacture of pharmaceutical products requires the establishment and implementation of an effective Quality Management System (QMS). The QMS must be appropriate for the activities performed, be fully documented and monitored to ensure effectiveness. Without an effective QMS, 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 QMS as well as giving practical guidance on all major elements of a typical QMS. 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 QMS involving quality by design and risk-based approaches.

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. This module takes major therapeutic categories as examples including pain, cardiovascular, infections, renal disease, skin disease, cancer and with basic physiology discusses the pharmacology of particular drugs used.

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 major dosage forms in detail and covers basic formulation principles including preformulation studies, bioavailability considerations and the effect of excipients on physical and chemical stability. It also includes sessions on the Orange Guide Annexes, process validation, scale-up, facility design, utilities and sterilisation processes.




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.

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 QP must have a thorough understanding of how the manufacture and control of drug substance affects the fitness for purpose of the finished product. 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 GMP Guide.

Investigational Medicinal Products

Additional Knowledge

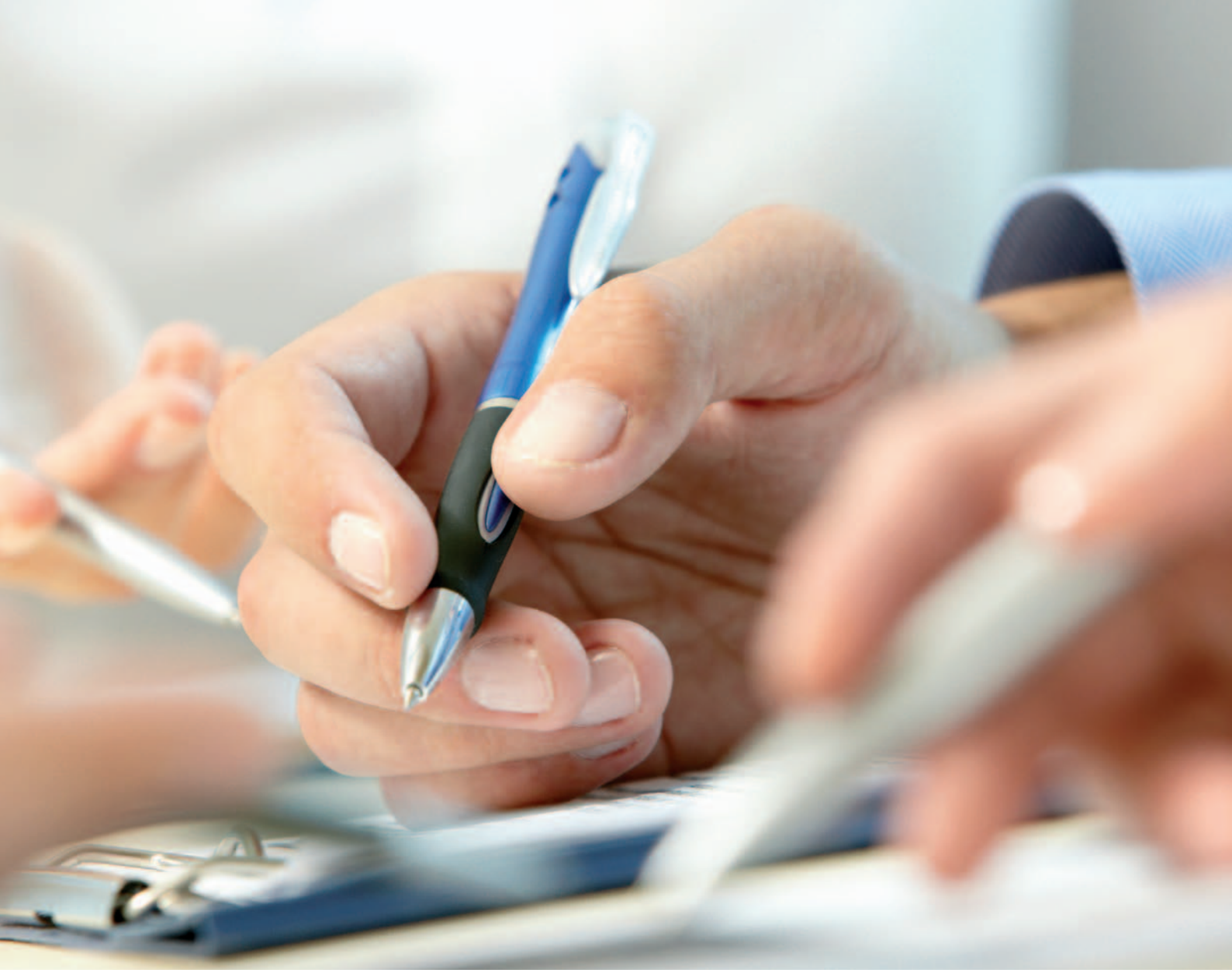
The QP needs to have an understanding of the different requirements between commercial and clinical trial operations. This module examines the EU legislation relevant to Investigational Medicinal Products (IMPs), their manufacture, control and supply. Practical guidance on the major differences in GMP expectations between IMPs and commercial products will be given.

Biotechnology

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 area www.rssl.com or better still, get in touch with Nikki Cooke on 0118 918 4168 or nicola.cooke@rssl.com



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 'Knowledge and Skills Forums' 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. Once registered for a course with us, you will have online access to discussion groups and assessments to help you consolidate your learning, and revise effectively. 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 area www.rssl.com or better still, get in touch with Nikki Cooke on 0118 918 4168 or nicola.cooke@rssl.com

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