

**ROYAL
PHARMACEUTICAL
SOCIETY**



**Qualified Person involved in the manufacture of
pharmaceuticals**

Guidance Notes

For Applicants and Sponsors

October 2021

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1.0 Introduction

To assure patient safety, the manufacture and distribution of pharmaceutical products is highly regulated within the UK. The Qualified Person (QP) must ensure that all legislative obligations are fully satisfied before any product is certified and released for sale or supply in countries where manufacturing has occurred or where the product will be distributed.

A QP must have a comprehensive knowledge of all current and forthcoming UK and European legislation relating to the manufacture, storage and supply of licensed medicinal products (human and veterinary), Investigational Medicinal Products and the interpretation of the law and guidance. Legislation is subject to regular update and details of major changes can be found in FAQs published on the Royal Pharmaceutical Society, the Royal Society of Biology or the Royal Society of Chemistry websites – hereafter called the Joint Professional Bodies (JPB) or individual Professional body (PB).

The QP fulfils certain minimum conditions of qualification and experience. These conditions are detailed in section 2.1. It should be noted that no existing single first degree or other qualification awarded in the United Kingdom meets the conditions of the Study Guide in full. For any queries regarding your qualifications contact the QP Officer in your PB.

Applications are normally made under the permanent provisions of the UK legislation. These are referred to as category A applications. However, in certain specific cases an application may be made under the transitional arrangements. Applicants who wish to make an application under these arrangements should contact the QP Officer in their professional body in the first instance for further details.

Each of the three PBs has responsibility for maintaining a register of its members eligible to act as QP.

Dates given in these Guidance Notes are derived from the Directives or the UK legislation and are not open to amendment or re-negotiation on the part of the professional bodies or their individual members. The applicant and their sponsor(s) should also refer to the PB FAQ which are updated regularly and used to provide additional clarification and guidance.

Registration by the PB under these arrangements does not necessarily ensure that nomination as a Qualified Person in respect of any particular manufacturer's authorisation will be accepted by the Licensing Authority.

2.0 Applying for assessment for QP eligibility by the permanent provisions (Category A)

2.1 Educational Requirements for application

The following educational requirements for a QP are detailed in UK Statutory Instruments, “The Human Medicines Regulations 2012”, No. 1916, Schedule 7, Part 1 Paragraphs 2, 3 and 4.

A degree, diploma, or other formal qualification in:

- pharmacy;
- medicine;
- veterinary medicine;
- chemistry;
- pharmaceutical chemistry and technology
- biology

A qualification satisfies the requirements of this Part if it is awarded on completion of a university course of study, or a course recognised as equivalent by the Member State in which it is studied, which—

- includes the core requirements listed below; and extends over a period of at least three years of theoretical and practical study of the degree, diploma or formal qualifications listed above.

The core subjects to be covered in the degree, diploma, or other formal qualification must include at least the following core subjects:

- experimental physics;
- general and inorganic chemistry;
- organic chemistry;
- analytical chemistry;
- pharmaceutical chemistry, including analysis of medicinal products;
- general and applied medical biochemistry;
- physiology;
- microbiology;
- pharmacology;
- pharmaceutical technology;
- toxicology; and
- pharmacognosy.

If the original degree, diploma, or other formal qualification does not cover these core subjects then gaps in the original degree, diploma, or other formal qualification may be supplemented by additional educational courses.

Eligibility based on these educational requirements will be assessed as part of a QP application. Applicants who do not meet these education eligibility requirements will not be invited for a viva and may still be charged the full application fee.

Each of the PB has stipulated the educational and experience requirements which are available on the PB website and also available in Appendix 1.

2.2 Practical Qualifying Experience

In addition, the applicant is expected to be able to demonstrate the application of this knowledge through experience. The candidate must be able to demonstrate practical experience for at least two years (one year for Pharmacists), in one or more undertakings authorised according to UK medicines’ legislation or legislation originating in the EU to manufacture medicinal products, or to manufacture investigational medicinal products for clinical trials. The practical experience must be undertaken in the UK or in an EU member state and be in the activities of qualitative analysis of

medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.

The practical experience recorded under the sections of the Study Guide should be reflective of the certifying QP role. While experience gained solely through roles such as auditing, project management and computerised systems is valuable it does not reflect the wider responsibilities of the QP and so should supplement rather than replace core experience. Applicants should also consider that there is a necessary induction and learning curve in a role and therefore consider exceeding the one- or two-year minimum experience requirements if the time spent in roles is short.

Whilst visit to other manufacturing sites may be useful in gaining a wider perspective on how other QPs operate under different quality systems, these site visits do not qualify towards the practical experience required under the study guide. The core experience must be gained by practical hands on experience working in a manufacturing facility or a licensed contract testing laboratory.

2.3 Sponsorship

The applicant must have a sponsor who must be a member of a PB. Ideally the sponsor should be a practising QP, named on a UK MIA and or MIA-IMP, who has known the applicant professionally for the qualifying period of experience required. If this is not possible, the applicant may use a QA line manager provided that the sponsor's report is countersigned by the QP named on the UK MIA / MIA-IMP.

The sponsor is expected to:

- confirm the experience requirement,
- confirm that you have adequate knowledge of the subjects covered in the Study Guide, or supervise the acquisition of that knowledge to the required state of competency

Support from the sponsor is essential to the applicant's success and they must be able to allocate sufficient time to ensure that the applicant is fully prepared for your application. The sponsor should act as a mentor and should support training and advise the candidate when they are ready to apply for assessment. The expectation is that the sponsor must have regular meetings with the QP applicant to prepare them for the viva. The sponsor should refer to the Study Guide and ensure that they are able to verify that the applicant has the necessary skills, knowledge, practical experience and personal attributes to act as a QP.

If the applicant obtained their qualifying experience in more than one establishment a sponsor's report is needed for each period of experience.

2.4 Application documents

The applicant should refer to the Study Guide and QP Code of Practice before downloading the documents from their PB's website (refer to Section 3).

The documents are:

- Guidance Notes for Applicants and Sponsors (this document)
- Registration Form

The application form and sponsor form will be sent to applicants upon receipt and approval of a registration form. The purpose of the registration form is to allow the professional body to check that applicants have the appropriate qualifications, professional body membership level and sponsor(s) to apply for Qualified Person eligibility.

2.5 Guidance Notes for sponsors

2.5.1 The role of the sponsor

The role of the sponsor at the start of and during the QP's training plus subsequent application for admission to the register is an important element of the process. Sponsorship should only be

undertaken after careful consideration of the role and responsibilities involved. The JPB expectation is that the sponsor acts as a mentor and have regular interaction with the applicant.

The application form and the sponsor's form provide documented evidence of the applicant's background as a first step in the assessment process. A well prepared and presented application provides the assessors with a good first impression of both the applicant and the sponsor.

The sponsor has responsibilities not only to the applicant but also to the PB who consider applications from aspiring QPs. If the prospective sponsor requires any further advice on fulfilling the role they should refer to their own PB.

2.5.2 Requirements for the sponsor

The sponsor must be a member of a PB, (the Royal Pharmaceutical Society, the Royal Society of Biology or the Royal Society of Chemistry). The sponsor should be a practising QP who has known the applicant for the qualifying period of experience required. If this is not possible, an applicant may use a QA line manager provided that the sponsor's report is countersigned by the QP acting for the activities in which the applicant is engaged.

The sponsor has a duty to:

- the applicant;
- the applicant's employer;
- the inspection authority;
- their own professional body;
- the general public.

The sponsor should:

- have wide knowledge and experience of pharmaceutical manufacturing, quality assurance and Good Manufacturing Practice.
- be thoroughly conversant and up to date with the legal framework (UK and EU);
- understand the relationship of the professional bodies with the MHRA and the VMD;
- understand the role and responsibilities of the QP, including the Code of Practice;
- understand the Study Guide and the practical experience requirements;
- possess a wide view of the pharmaceutical business from Research and Development through Production to Marketing and Distribution;
- be an excellent communicator and possesses good inter-personal skills; and
- have very good contacts in and outside the company.

Before agreeing to act, the sponsor should have formed an impression of the applicant's ability to make difficult ("grey area") decisions and to withstand the pressures that are inevitably associated with the professional duties and responsibilities of a QP. The role of the sponsor is to act primarily as a **guide** or **mentor** who can assist the aspiring QP by:

- providing guidance and direction on the course of study and acquisition of experience. This should happen well in advance of the applicant submitting the application and follow the journey of training and gaining experience towards application for viva. This may therefore extend over a number of years.
- assisting in organising a programme of practical experience both inside and outside the site on which the applicant is based

- meeting regularly to monitor and review progress, offer advice and answer questions;
- encouraging good record keeping against an agreed programme of training covering both knowledge requirements and practical experience requirements;
- arranging introductions to key personnel in and outside the company; and
- exposing the applicant to external influences such as:
 - o inspections;
 - o supplier arrangements;
 - o contractors;
 - o distributors; and
 - o customers.

The above list is not exhaustive and the sponsor needs to be familiar with the breadth and depth of the study guide to ensure that the applicant is prepared for their interview against the requirements of the Study Guide and that they experience some practice questioning, particularly on scenario-type situations, before assessment.

2.5.3 The sponsor form (sponsor's report)

The completed sponsor form must be submitted to the appropriate PB with the application. An application will not be reviewed without the sponsor's report. The report should record pertinent additional information only and should not duplicate that of the applicant.

The report is a key part of the sponsor's input and it is not sufficient to simply provide a declaration of belief that an applicant complies with the requirements. It should be a **critical** and **honest evaluation** of the applicant's **technical** and **professional knowledge**. It should also include information on the applicant's **personal attributes**, including their strengths and weaknesses or areas for development.

The form requires a description and examples of the applicant's ability that covers, but is not limited to, the following criteria:

- Ability to achieve good working relationships with persons in other functions within the company
- Communication skills (oral and written)
- Assertiveness
- Flexibility and open mindedness
- How the applicant operates under pressure
- Planning and organising skills
- Professional ethics and integrity
- Reliability
- Problem solving skills
- Any special achievements

It is important to address each of these points, and reports which do not, will either be returned for clarification, which may delay the application or lead to the rejection of the application.

The sponsor must also confirm that the applicant has gained the relevant experience under a full Manufacturer's/Importers Authorisation and must provide the qualifying Manufacturer's/Importers

Authorisation number and issue date. The confirmation must cover the period for which the applicant is claiming their qualifying experience. The sponsor can only provide a report for the time for which they have direct experience of the applicant's work. If an applicant's qualifying experience is made up of time in more than one establishment or covers sponsorship by more than one QP, a separate sponsor's report is required for each period. The application documents require further details on the sponsor's relationship to the applicant in respect of employment during their qualifying period of experience.

The sponsor must also sign each part of sections 8 and 9 of the application form where indicated, to confirm that you have reviewed the application and that the contents are accurate. If there are parts of the form where the sponsor cannot confirm experience, for example, if the applicant is describing work done in a different facility, the limitations should be listed on the sponsor's form.

The submission of an inaccurate or misleading report will be regarded by the professional bodies as professional misconduct.

The sponsor's report shall remain confidential to the JPBs.

Should your qualifying experience not be from your current role, you will also be expected to provide a sponsor form from your current employer.

2.6 Completing the application form

All sections of the Application Form need to be completed. As it provides the assessors with a "first impression", the quality and clarity of the application form is very important and all pertinent information should be included. The form and any supplemental information should be reviewed in full by both the applicant and the sponsor prior to submission. Incomplete or deficient forms will be returned, and progression of the application will be delayed. The applicant should be ready for assessment at the time of application. **If the applicant requires any reasonable adjustment or special access arrangements, it is helpful to let the QP officer know at the time of your application.**

Section 1: Name and contact information

Enter the address, telephone number and email address you wish your PB to use for correspondence. Please provide an alternative email and telephone number for the very rare occasion when urgent contact is needed before the interview.

Section 2: Membership

Specify which PB the applicant belongs together with the membership number and designatory letters.

Section 3: Category of application

Confirm the category under which the application is being made and any previous application.

Section 4: Qualifying experience

State the area of expertise (the types of products and processes for which the qualifying experience is being claimed). Please refer to the Study Guide.

State the employer(s) and the dates worked which satisfy the practical experience requirements. Please also provide the number and date of issue of the Manufacturer's/Importers Authorisation (s) under which these requirements were satisfied. Please ensure that the dates cover the whole period of experience required (one or two years for RPS applicants, two years for RSB and RSC applicants).

If your experience was gained part-time, or you were working part-time on appropriate activities under the Manufacturer's/Importers Authorisation and part-time on other activities (non-licensed products or activities not covered by the licence, for example R&D), you should count it pro-rata.

If you work for a “virtual” company which holds a Manufacturer’s/Importers Authorisation but contracts out part or all of the manufacturing process, in principle this would meet the legal requirements for QP application, however, you should explain how the practical requirements of the Study Guide have been met.

Section 5: Employment

Enter the applicant’s job title, the name and address of the current or most recent employer and a daytime telephone number. A brief explanation of the job function is useful as this is not always clear from the job title.

Section 6: Education and training

Provide details of post-A-level or other post-18 educational qualifications and training, and of any other study relevant to the role of the QP. Please provide dates (dd/mm/yy) together with copies of any result letters or certificates, signed by the sponsor to verify that they are true copies. Do not send original certificates as these are not returned.

Section 7: Professional experience

Give a complete statement of employment since graduation or over the relevant period whichever is the shorter. Please provide (with dates – mm/yy), for each stage of the applicant’s career, an account of the nature of the work and the responsibility involved in each position held. List your key responsibilities for each job and describe the range of products and processes to which these responsibilities are applied.

The responsibility levels should be stated as A, B, or C:

A = The person 'named' on the licence as being responsible for the activity,

B = working under the direct supervision of the 'named' person,

C = working in direct collaboration with the 'named' person.

Employment not in licensed activities should be included, as although this does not contribute towards the licensed practical experience requirements, it may have provided valuable additional relevant knowledge and experience.

Sections 8 and 9: Study Guide Knowledge requirements

This section is to demonstrate that the applicant is equipped with the knowledge and understanding needed to act as a QP. The descriptions of practical experience should be related to the specific areas as outlined in the Study Guide. The extent to which the applicant can satisfy (i) the knowledge, and (ii) the experience to satisfy the requirements of the Study Guide. The applicant should discuss the content of these sections with their sponsor. It is important to focus on the applicant’s knowledge and experience and not document their understanding of the underlying principles. These sections of the form should be written against the Study Guide and applicants and sponsors should ensure that experience documented in each section is relevant to the corresponding section of the Study Guide.

Applicants are advised to start on the application form well before you intend to apply as use of both the form and the Study Guide is useful to identify gaps in your knowledge and experience in time to fill them before application.

Section 8: Foundation knowledge elements

- Pharmaceutical law and administration;
- The role and professional duties of a Qualified Person; and
- Pharmaceutical Quality Systems.

Section 9: Additional knowledge requirements

- Mathematics and statistics;
- Medicinal chemistry and therapeutics;
- Pharmaceutical formulation and processing;
- Pharmaceutical microbiology;
- Analysis and testing;
- Pharmaceutical packaging;
- Active pharmaceutical ingredients; and
- Investigational medicinal products.

Education

- Give the course dates (mm/yy to mm/yy or for short courses dd/mm/yy), a brief account of the content of the course and what the applicant gained from it in relation to their knowledge and understanding of the Study Guide.
- If the course was not recent, indicate how you have kept your knowledge up to date.

Experience

- Be specific about involvement in activities which demonstrate experience in each section and the degree to which the applicant was involved, e.g. direct or indirectly, via meetings or visits
- Most applicants have more experience in some areas of the Study Guide than in others. If the applicant has not had much direct experience in an area, explain how they gained the necessary knowledge and understanding, for example by attending courses, visits, time spent at a different company to learn about a different activity. Phrases such as “I am aware of...” or “I have an understanding of...”, need context. For example, “I have achieved an understanding of the ICH guidelines for method validation whilst employed at YYY where I used the guidelines to develop methods of analysis using HPLC for ZZ products”.
- Ensure evidence is relevant. Avoid duplication, although some experience may be relevant to more than one section.

Section 10: Sponsor(s)

The sponsor's signature is required for each part of sections 8 and 9, and in section 10. Electronic signature by an appropriately qualified system is permitted under special circumstances, please contact your PB QP Officer in advance if you wish to use this flexibility.

The sponsor must be a member of one of the three PBs and should be a QP. If the sponsor is exceptionally not a QP, the sponsor's form should be countersigned by the QP acting for the activities in which you are engaged.

If your qualifying experience has been gained in more than one establishment, then a sponsor's report from each establishment is required to verify the details of this experience.

Section 11: Certification by applicant

Please sign and date.

Section 12: Fee

You can pay by cheque, company purchase order (RSC only) or credit card. The current fees are on the PB websites. Application fees are not refundable and are subject to variation without notice, although normally at least two months' notice of any change is given.

Section 13: Completing your application

There is a checklist at the end of the application form. Your sponsor should review your application form, then you should send your completed application to the QP Officer at your own professional body.

2.6 Assessment

Assessment comprises two parts. The applicant submits a written application which is reviewed by the assessors to determine if the applicant has the required qualifying and practical experience described in the Study Guide. Further clarification may be requested by the PB. If this is deemed satisfactory, the applicant will be invited to attend a panel interview.

The interview is normally carried out by a representative from each of the PB and sometimes observers from MHRA, VMD or trainee assessors will be present. At the end of the interview the applicant will be informed whether they have satisfied the assessors and have been recommended for eligibility or not.

2.6.1 Review of application

The QP Officer of the applicant's PB will ensure that the application is complete and that the applicant satisfies the requirements for qualifications and membership (see Appendix 1). The application will then be sent to two assessors from the applicant's PB QP Panel of Assessors

The assessors will review the application against the Study Guide to ensure that all requirements are met. If there is insufficient evidence for the assessors to determine whether the knowledge and experience meet the requirements of the Study Guide, they may ask for more information for one or more sections, which will cause a delay. You should send the additional information within **three months** of the request, so that your application remains an up-to-date account of your experience. The additional information must be approved and signed off by a sponsor(s). After this time a new form and fee may be required.

Only when the assessors are satisfied that the knowledge and experience in the application form satisfies the requirements of the Study Guide will they recommend that the applicant is invited for interview. The QP Officer will contact the applicant to agree an interview date. If the applicant has not already done so, the QP officer must be told of any reasonable adjustment or special access arrangements. The PB will usually give you at least 4 weeks' notice of an interview date, although occasionally dates are available at shorter notice. If the assessors consider that the applicant does not meet the requirements of the study guide, the applicant will not be invited for interview. In such circumstances, the QP Officer will contact the applicant with advice on next steps and advise you how to proceed.

2.6.2 The interview

The interview will normally be face-to-face at the offices of one of the three professional bodies. In some circumstances the interview may be performed remotely. The PB maintain a joint programme of interviews and will offer the first available date. The applicant will be told the location for the interview which may not be your own PB location.

An interview panel is normally made up of three assessors, one from each PB, and chaired by the assessor from the applicant's PB. The applicant's QP Officer (or delegate) will attend and note the questions. There may also be an observer (usually an assessor in training, or a representative of the MHRA and VMD who regularly observe interviews), who will take no part in the interview or the decision-making process for the outcome of the assessment.

The assessment normally lasts 1 to 1½ hours. The applicant is provided with paper and a pen and encouraged to make use of these. The assessors will ask fact-based and scenario questions and inform the applicant of the outcome after the interview. The interview is not recorded.

If the assessors are satisfied that the applicant meets the requirements of eligibility, the applicant can be nominated to the Register of Eligible QPs of the PB. The QP Officer will confirm the outcome in a letter after the interview and a certificate will be sent in due course.

If the assessors are not satisfied, they will outline the reasons and advise on next steps such as particular activities to enhance knowledge and experience and may suggest an approximate time that this might take. This will be confirmed in a letter. The applicant can reapply and with the new application form, sponsors report and fee, evidence should be provided that the assessor's concerns as documented in the letter have been addressed in addition to any other activities.

If you wish to appeal against the process of your assessment, you should contact the QP Officer of your own PB. **An appeal must be made within 28 days of the date on your result letter.** After 28 days on request to the QP Officer the chair of your assessment can have a meeting, typically virtually, with the sponsor to provide further detail and insight into the interview and the next steps.

3.0 Contact details for QP applications and enquiries

For more information or specific queries about the application process, please refer to the websites of each PB or contact a QP Officer:

RPS

QP Officer
Science and Research Team
Royal Pharmaceutical Society
66-68 East Smithfield
London
E1W 1AW

Tel: 020 7572 2737

Email: QPOfficer@rpharms.com

Website: <https://www.rpharms.com/development/education-training/training/qualified-persons-a-guide>

RSB

QP Officer
Royal Society of Biology
1 Naoroji Street
London
WC1X 0GB

Tel: 020 3925 3440

Email: qp@rsb.org.uk

Website: <https://www.rsb.org.uk/careers-and-cpd/registers/qualified-person>

RSC

QP Officer
Royal Society of Chemistry
Thomas Graham House
290-292 Science Park
Milton Road
Cambridge
CB4 0WF

Tel: 01223 432141

Email qp@rsc.org

Website: <https://www.rsc.org/careers/cpd/practising-scientists/qp-pharmaceutical/>

Appendix 1: Permanent Provision requirements for PB

Royal Pharmaceutical Society

The requirements of the permanent provisions which relate to a pharmacist or a pharmaceutical scientist are:

- (i) Member or Fellow or Associate or Pharmaceutical Scientist member of the Royal Pharmaceutical Society who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent. In certain circumstances, Pharmaceutical Scientist membership might not be sufficient and therefore potential applicants should check with the QP Officer that their qualifications meet the eligibility requirements.
- (ii) At least two years' relevant experience in one or more undertakings which are authorised to manufacture medicinal products. The practical experience must be in the activities of qualitative analysis of medicinal products, quantitative analysis of active substances and the testing and checking necessary to ensure the quality of medicinal products.

In the UK the normal two year experience requirement is reduced to one year in the case of pharmacists who have been registered in Great Britain or Northern Ireland since the five year period of education and training leading to registration is considered to be equivalent to a five year university course as specified in UK legislation or legislation originating in the EU. Confirmation from the Royal Pharmaceutical Society of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Royal Pharmaceutical Society, the Royal Society of Biology and the Royal Society of Chemistry.

Royal Society of Biology

The requirements of the permanent provisions which relate to a biological scientist are:

- (i) Either a Chartered Biologist (CBiol MRSB or CBiol FRSB), or a Fellow (FRSB) or Member (MRSB) or Associate with designatory letters AMRSB who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent.
- (ii) At least two years of practical experience in one or more undertakings, authorised to manufacture medicinal products. The practical experience must be in the activities of qualitative analysis of medicinal products, quantitative analysis of active substances and the testing and checking necessary to ensure the quality of medicinal products.
- (iii) Confirmation from the Royal Society of Biology of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Royal Pharmaceutical Society, the Royal Society of Biology, and the Royal Society of Chemistry.

Royal Society of Chemistry

The requirements of the permanent provisions which relate to a chemical scientist are:

- (i) Either a Chartered Chemist (CChem), or a Fellow (FRSC) or Member (MRSC) or Associate Member (AMRSC) who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent.
- (ii) At least two years of experience in one or more undertakings, authorised to manufacture medicinal products. The practical experience must be in the activities of qualitative analysis of medicinal products, quantitative analysis of active substances and the testing and checking necessary to ensure the quality of medicinal products.

- (iii) Confirmation from the Royal Society of Chemistry of the acquisition of a body of knowledge which is described in a joint Study Guide prepared by the Royal Pharmaceutical Society, the Royal Society of Biology, and the Royal Society of Chemistry.