Frequently Asked Question: 2018

Information on the Joint Professional Bodies’ (JPB) QP Eligibility Scheme appears on each organisation’s website (Royal Pharmaceutical Society, Royal Society of Biology, Royal Society of Chemistry).

1. Where can I find information on membership of the Royal Pharmaceutical Society?

To apply for assessment of QP eligibility you must be a Member or Fellow or Associate or Pharmaceutical Scientist member of the RPS who has qualified on the basis of a formal course of study lasting not less than three years full-time* or equivalent. Further information on applying for RPS membership is available on the membership area of our website.

*Only qualifications that are associated with a taught course of study count towards this statement.

In the UK, a minimum of one year of required practical experience for pharmacists has been approved (see ’Study guide’). Any individual who is not registered as a pharmacist (or has not previously been registered as a pharmacist) in the UK, who wishes to apply via the RPS for assessment of QP eligibility, should contact the RPS QP Officer for advice before applying (contact details are on our website).

2. Who should be the sponsor for my potential QP application?

Advice on sponsors is provided by the three professional bodies in the ’Guidance Notes for Applicants and Sponsors’.

The role of the sponsor is important in the QP’s training and application for admission to the Eligibility Register. Our expectation is that the sponsor acts as a mentor and supports you throughout your training, preparation and application.

Your sponsor must be a member of one of the Joint Professional Bodies (RPS, RSB or RSC).

The sponsor should be a practising Qualified Person who has known the applicant for the qualifying period of experience required. If this is not possible, you may use a QA line manager provided that the sponsor’s report is countersigned by the Qualified Person.

You may need more than one sponsor, for example if your experience has been gained in more than one company.

If your qualifying period was previous to your current employment, you will also need to supply a sponsor form from your current line manager (whether or not a QP).

In case of difficulty, you should contact the QP Officer at the RPS for advice (please contact RPS Professional Support Service (contact details are on our website)).
3. The sponsor form now asks: If this is the applicant's second or subsequent application, please describe how you have helped them to address the concerns of the assessors from their last application. What does this mean?

This question has been added to assist the assessors so that when reviewing your new application and sponsor form, they can see where your sponsor has helped you to develop the areas in which you failed in your previous application(s). It is intended to support applicants on second, or subsequent, applications in encouraging sponsors to take responsibility for aiding applicants needs in addressing the assessors concerns.

4. How much detail should I include on the application form for sections 8 and 9 (Foundation knowledge elements and Additional knowledge elements)?

You are advised to discuss this with your sponsor.

5. Which products and processes are eligible as my area of expertise?

Any, as long as you have appropriate experience under a full manufacturer's authorisation (2001/83/EC, 2001/82/EC or 2001/20/EC).

6. Can I apply for QP eligibility if I only have experience in a bulk manufacture or research and development environment or under a Specials Licence?

Under Article 49 of Directive 2001/83/EC, the relevant practical experience has to be gained in a facility that holds a full manufacturer's authorisation. As most bulk drug (Active Pharmaceutical Ingredients, APIs) and Research & Development (R&D) do not usually require a manufacturer's authorisation, they cannot be used as areas of relevant experience to satisfy the practical experience requirements. Some APIs do require a full manufacturer's authorisation and in these circumstances appropriate experience under the licence can satisfy the practical experience requirements.

7. Can I apply with experience of veterinary products?

You can apply for QP eligibility under the permanent provisions with appropriate experience under a manufacturer's authorisation for veterinary products (2001/82/EC). The VMD also has the capacity to appoint QPs independently.

8. If I have gained a broad practical experience across all areas of the Study Guide, what should I choose as the specialist area of my expertise?

You are advised to discuss this situation with your sponsor.

9. Where can I study the theoretical knowledge requirements for Qualified Persons?

You may wish to undertake personal study to satisfy the theoretical knowledge requirements of the Study Guide. A number of academic institutions and commercial companies offer courses. The Joint Professional Bodies do not recommend or endorse particular courses. For information, there is a list of available courses on our website.

10. How much is application fee for certification of QP eligibility?
The fee for all applications under the Permanent Provisions (category A) is £600. The fee for all applications under the Transitional Provisions (category B,C,D,E) is £200.

You can pay by cheque (RPS members should make their cheque payable to Royal Pharmaceutical Society) or credit card. To arrange credit card payment over the phone please phone RPS Professional Support Service when you send your application (contact details are on our website). We accept all major credit cards except American Express. Your fee will be processed when we receive your application form. The fee is non-refundable. Any change to the fee is announced on our website, we normally give 2 months notice of any change.

11. How long does it take for a QP application to be processed?

The length of time taken to process an application for nomination to the Register of Qualified Persons is dependent on a number of factors, including the quality of your initial application. Typically the assessment process takes about two to six months. The application is reviewed by two assessors before making the decision whether to invite you for an assessment interview.

12. Is it possible to reserve an assessment slot?

You are invited to attend a formal oral assessment once the application has been reviewed by the assessors. It is not possible to reserve an assessment date in advance. Dates are offered on a first-come first-served basis. However, we try to accommodate applicants’ preferences where possible.

13. Can I change the date of the interview, once agreed?

You should contact the QP Officer as soon as possible. If you cancel at short notice, this can result in inconvenience to other applicants and assessors. If you wish to cancel an assessment date with less than 6 weeks notice, there will be a cancellation fee of £250, unless there are extenuating circumstances.

If you need to cancel your assessment due to illness or injury we may waive the fee if you inform us as soon as possible and, if requested, you provide a medical certificate. Such information will be treated in confidence by the Joint Professional Bodies.

14. Where will my assessment be held?

Assessments are normally held in the offices of the RPS or RSB or RSC in London. We will provide you with a map and instructions for finding us. All our buildings are accessible. If you need any help with access or arrangements in the interview room, please ask your QP Officer well in advance of your assessment date.

15. At the QP interview, who will the assessors be?

We do not inform you prior to an assessment which assessors will be present. Assessors are selected for the Panel for their breadth and depth of knowledge and practical experience across the range of products and processes, and can assess applicants from any area of expertise. Most assessors have gained eligibility via the JPB permanent provisions route.

There may be an observer at your assessment. This may be an assessor in training, or occasionally a representative of the MHRA or VMD will observe a day of assessments. The observer is there to see the process, and will take no part in your assessment.
16. What is the current pass rate for Qualified Persons assessments?

In 2017, the pass rate under the permanent provisions was 79% (in 2016 75%).

17. What is the JPB’s policy on releasing and publishing questions asked at QP assessments?

We do not publish lists of questions asked at QP assessments.

18. What feedback is given if I do not pass the JPB QP Panel interview?

The assessors will tell you the outcome after the assessment. They will give you direct feedback, and you will have the opportunity to ask for clarification. You will also be given advice on what to do before reapplying. Typically, you will be advised to discuss the matter further with your sponsor and draw up a training plan. You will be formally advised of the assessment outcome in a letter from the RPS.

19. If I do not pass my oral assessment and it is recommended to re-apply in (for example) twelve months time. Is a second application form and fee required?

Yes, your re-application will be assessed as a new application. As you will have gained additional knowledge and practical experience, you need to complete a new application form to reflect this. The same fee is payable for each application. On re-applying you should also provide details as to how you have addressed the previous concerns of the assessment panel.

20. Do you assess members from outside the UK?

The JPB will assess an application for Qualified Persons, whether you are resident in the UK, Europe or rest of the world. However, you must fulfil the requirements of Directives 2001/83/EC, 2001/82/EC or 2001/20/EC with respect to your qualifications and experience.

If you are not intending to act as a QP in the UK, and intend to seek nomination as a QP on a Manufacturer’s Authorisation issued by another EU Member State, you may wish to contact the competent authority for that state (refer to the European Medicines Agency website).

If you have already been named as a QP on a Manufacturer’s Authorisation in another EU Member State and intend to seek nomination as a QP in the UK, you should not apply to the JPB. The holder of the UK Manufacturer’s Authorisation should apply to the competent authority in the UK (MHRA or VMD) to add you to the authorisation as a QP.

21. How can someone apply under the transitional provisions?

The requirements for eligibility under the transitional provisions of the Directives 2001/83/EC are described in the Guidance Notes.

Since the changes in legislation relating to veterinary products in 2005, applications can no longer be made under the transitional provisions of 2001/82/EC. Prospective applicants should contact the VMD for advice.

22. How can a QP eligible under the transitional provisions of the Clinical Trials Directive 2001/20/EC or the Traditional Herbal Medicinal
**Products Directive (2004/24/EC, amending 2001/83/EC) apply for an entry on the Register?**

If you have been accepted by the MHRA under transitional arrangements to act as a QP for investigational products or for traditional herbal medicinal products, and named as a QP on an appropriate manufacturer’s authorisation, you may be certified to have an entry in the RPS Register of Eligible Qualified Persons. Those eligible for certification will be RPS members (see also question 1).

Certification by a professional body is not essential in these circumstances, but you are nevertheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which you are named. Please refer to the Guidance Notes.

Applicants with appropriate experience under a manufacturer’s authorisation are eligible to apply under Category A. Please refer to the Guidance Notes.

Update Dec 2017: The MHRA has issued information for Transitional IMP QPs (named as a QP in a valid application for a manufacturing authorisation for IMPs made prior to 1st May 2006 under the Medicines for Human Use (Clinical Trials) Regulations 2004). Further information can be found here: [https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice](https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice)

**23. How many QPs are registered with the Royal Pharmaceutical Society?**

In February 2017 there were 344 QPs registered (this includes 62 QPs who qualified via the permanent provisions).