

RPSGB Frequently Asked Questions - 2009

1. What advice is given to QP applicants with respect to membership of the Royal Pharmaceutical Society of Great Britain?

To apply for QP eligibility via the RPSGB you must be a registered member of the RPSGB.

2. Who should act as a sponsor for a potential QP applicant?

The advice given by the three professional bodies is published in the 'Guidance Notes for Applicants and Sponsors'. The role of the sponsor is important in the QPs training and application for admission to the Eligibility Register. The expectation is that the sponsor acts as a mentor and supports the applicant throughout the process.

3. Does an applicant's sponsor have to be a Qualified Person?

The advice of the professional bodies is stated in the 'Guidance Notes for Applicants and Sponsors'.

You need the support of a sponsor, who must be a member of one of the Joint Professional Bodies (the Society of Biology, Royal Pharmaceutical Society of Great Britain or Royal Society of Chemistry). The sponsor must 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. More than one sponsor may be required, for example if your experience has been gained in more than one company.

In case of difficulty, you should contact the QP Officer at the RPSGB for advice.

4. How much detail should an applicant 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 your area of expertise?

Any, as long as they are licensed under a full manufacturer's authorisation (2001/83/EC, 2001/82/EC or 2001/20/EC).

6. Can a person apply for QP eligibility if he/she only has experience in a bulk manufacture or research and development environment?

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 licence. As most API (bulk drug) and R & D do not currently (and typically) require a manufacturer's licence, they cannot be used as areas of relevant experience to satisfy the practical experience requirements.

7. Can a person apply with experience of veterinary products?

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

8. **If an applicant has gained broad practical experience across all areas of the Study Guide, what should he/she choose as the specialist area of expertise?**

You are advised to discuss this situation with your sponsor.

9. **Is the JPB Assessment Panel biased towards an applicant's chosen area of expertise (specific dosage form)?**

Assessors are nominated for membership of the Panel on the basis of their breadth and depth of knowledge and practical experience across the range of products and processes. Most assessors have gained eligibility via the JPB permanent provisions route.

10. **Where can an applicant 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 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 the RPSGB website

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 Eligible Qualified Persons is dependent on a number of factors, including the quality of the 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 will be invited to attend a formal 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 an applicant change the date of the interview, once agreed?**

You should contact the QP Officer as soon as possible. If an assessment is cancelled 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.

14. **At the QP interview, who will an applicant's assessors be?**

We do not inform applicants prior to an assessment which assessors will be present.

15. **What is the current pass rate for Qualified Persons assessments?**

In 2007, the pass rate under the permanent provisions was 78%.

16. **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.

17. **What feedback is given to an applicant who does not pass the JPB QP Panel interview?**

You will be told the outcome of the assessment at the time of assessment. The Panel of Assessors will give you direct feedback, and you will have the opportunity to ask for clarification. You will also be given advice on how to progress to gain certification as an eligible Qualified Person at your next application. 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 RPSGB.

18. An applicant failed his/her oral assessment and is recommended to re-apply in (for example) twelve months time. Is a second application form and fee required?

Yes, as the second 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.

19. Do the JPB 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.

20. How can an applicant 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.

21. How can a QP eligible under the transitional provisions of the Clinical Trials Directive 2001/20/EC apply for an entry on the Register?

The new QPs required under this directive are eligible to be certificated by the Professional Bodies and to have an entry in the RPSGB Register of Eligible Qualified Persons. Those eligible for certification will be RPSGB members. They will have been named as a Qualified Person in an application for a clinical trials manufacturing authorisation made prior to 1 May 2006, and have been accepted to act as a QP for investigational medicinal products by the MHRA and named on the clinical trials manufacturing authorisation. Certification by a professional body is not essential in these circumstances, but such persons are nevertheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which they were named. Please refer to the Guidance Notes.

Pharmacist applicants with at least 1 years experience under a manufacturers licence issued under Directive 2001/20/EC are eligible to apply under Category A. Please refer to the Guidance Notes.

22. How many eligible QPs are registered with the RPSGB?

In October 2009 there were 522 pharmacists registered as being eligible QPs.

23. What is the assessment fee?

Applications under Category A = £550

Applications under categories B, C, D = £200

Please refer to guidance notes for applicants for further information.