

## Eligibility for Qualified Persons Application FAQs

### **1. What advice is given to QP applicants with respect to membership of the Royal Society of Biology?**

You should EITHER be a Chartered Biologist (CBiol), OR a Member (MRSB) or Fellow (FRSB) or Associate Member (AMRSB) who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent. In case of difficulty, you should contact the Registration Officer at the Royal Society of Biology for advice.

### **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 QP's training and application for admission to the Register. Our expectation is that the sponsor acts as a mentor and supports you 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'.

Support is required by a sponsor, who must be a member of one of the Joint Professional Bodies (Royal Pharmaceutical Society, Royal Society of Chemistry or Royal Society of Biology). 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 Registration Officer at the Royal Society of Biology 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 should 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.

**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. Will the JPB be able to assess my specific chosen dosage form?**

Yes, the JPB assessment panel have wide experience across many dosage forms.

**11. An applicant holds a PhD from a UK university. Does this count towards the educational requirements of Article 49 of 2001/83/EC?**

No, a UK PhD is not admissible under Article 49 of 2001/83/EC. Article 49 requires "the possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study". As a PhD is a period of research, and not a taught course, it does not qualify towards fulfilment of this statement. If you believe your PhD is a taught course please contact the QP officer at the Royal Society of Biology to discuss.

## **12. 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 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 the RSB website.

## **13. 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 the initial application. Typically the assessment process takes from two to six months. The application is reviewed by the QP officer to verify key information and then by two assessors before making the decision whether to invite the applicant for an assessment interview (check at the bottom of the page, and click on the link to view the form used by the assessors to summarise their decision). The applicant and/or sponsor(s) may be asked to clarify some points or provide additional information to help in this process. On occasion, MHRA may be asked for advice.

## **14. Is it possible to reserve an assessment slot?**

You are 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, the JPB try to accommodate applicants' preferences where possible. Applicants should be ready and prepared to attend the viva at any point after submitting their application.

## **15. Can an applicant change the date of the interview, once agreed?**

You should contact the Registration 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.

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

The JPB do not inform you prior to an assessment which assessors will be present. Typically there will be one assessor from each of the professional bodies plus the QP officer from the candidate's professional body. A trainee assessor, MHRA representative or VMD representative may also be present as observers and they do not contribute to the discussion or decision making process.

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

In 2010, the pass rate under the permanent provisions was 65%.

**18. What is the JPB's policy on releasing and publishing questions asked at QP assessments?**

The JPB do not publish lists of questions asked at QP assessments. The questions asked, but not the answers given, are recorded for internal audit to ensure consistency across all the Interviews, however these are not available outside of the JPB.

**19. What feedback is given to an applicant who passes the JPB QP Panel interview?**

You will be told the result after the assessment. If you are successful you will be sent a letter confirming you have passed and an interim certificate, which the MHRA will accept as evidence of your Eligibility as a Qualified Person if you need to be named on a license immediately. The final certificate has to be signed by the CEOs of the three JPB Societies and takes longer.

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

You will be told the result after the assessment. The Panel of Assessors will give you direct feedback, and you can ask for clarification. They will also give you advice on what to do before making another application. Typically, you will be advised to discuss the matter further with your sponsor and draw up a training plan. You will be advised formally of the result in a letter from the SB. After 28 days following the receipt of the formal notification letter of your result and with your consent your sponsor can contact the RSB to arrange to speak to the chair of your assessment panel, if you and your sponsor think that this will be useful.

If you wish to appeal against the result of your Interview you should contact the Registration Officer of the RSB who will advise you of the Appeals Procedure. You must appeal within the 28 days following receipt of the formal notification letter of your result.

**20. 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. The time recommended by the assessors is for guidance only, and you can reapply when you and your sponsor feel that you have addressed the assessors' concerns. Your second application will be assessed as a new application since 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.

**21. Do the JPB assess members from outside the UK?**

The JPB will assess an application for Qualified Persons, whether the applicant is 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.

**22. 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 and 2001/20/EC. Prospective applicants should contact the VMD for advice.

**23. 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?**

The new QPs required under this directive are eligible to be certificated by the Professional Bodies and to have an entry in the RSB Register of Eligible Qualified Persons. Those eligible for certification will be RSB members. They will have been accepted under the "Grandfathering" clause to act as a QP for investigative medicinal products or traditional herbal medicinal products by the MHRA, and named as a Qualified Person on an appropriate 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 and the specific grandfathering arrangements applicable to your specific area.

**24. What is the RSB's policy for charging retention fees to remain on the Register?**

All members listed in the Register are required to pay an annual retention fee of £25 per year. If you do not pay the retention fee, you will not be listed in the RSB's Register. Further there is an 'opt-in' Register of QP published on the open access pages of the RSB website.

**25. How does the RSB CPD scheme work for QP registrants?**

The RSB has a CPD scheme for members. Details are available in the Professional Development area of the RSB website.

**26. How many QPs are registered with the RSB?**

In March 2011 there were 247 QPs registered. This includes the 32 new registrants who qualified via the permanent provisions in 2010.

