ROYAL PHARMACEUTICAL SOCIETY

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Frequently Asked Question: 2020

Information for RPS members

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

This updated version of the FAQ now provides answers to questions frequently asked by QP candidates and sponsors in relation to BREXIT, COVID-19 restrictions and content of the study guide. Future changes will be made to the study guide, but this is a lengthy process and in the meantime these FAQ are intended to provide useful guidance. Please see Section 2 for this information.

Candidates are encouraged to contact their QP officer in case of any questions or specific concerns not covered here (QPOfficer@rpharms.com).

Section 1

1. **What are the requirements for applying for assessment of QP eligibility through 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 fulltime*, 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 – (the contact details are available 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 your sponsor will act as a mentor and support 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 you (the applicant) for the qualifying period of experience required. If this is not possible,

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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 prior to your current employment, you will also need to supply a sponsor form from your current line manager (whether, or not, they are a QP).

If you have any queries, you should contact the QP Officer at the RPS for more advice (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 our QP assessors, in easily identifying where, and how, 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 by encouraging sponsors to take responsibility for supporting applicants' needs in addressing the assessors' concerns.

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

   You are advised to discuss this with your sponsor.

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

   Any, providing 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 must 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.

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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 any particular courses. For information, there is a list of available courses on our website.

10. **How much is the application fee for certification of QP eligibility?**

    The fee for all applications under the Permanent Provisions (category A) is £700. 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 the Royal Pharmaceutical Society) or credit card. To arrange credit card payment over the phone please phone RPS Professional Support Service when you submit 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 and we normally provide two 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 between two to six months. Your application is reviewed by two assessors who will provide a written assessment which will determine whether you are invited for an oral assessment.

12. **Is it possible to reserve an assessment slot?**

    You are invited to attend a formal oral assessment once your 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 do 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.

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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. *Note: currently face-to-face assessments are on hold due to COVID-19. Please see section 2 for detail on virtual assessments.*

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 2018, the pass rate under the permanent provisions was 69% (in 2017 80%).

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 that I reapply 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 will 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 assessment panel's previous concerns.

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20. What are the most common areas that applicants fail in at oral assessment stage?

Over the last few years, the JPB have been tracking the most common reasons for failure at oral assessment stage. The following elements, of the Study Guide, are where most applicants fail:

- The role and professional duties of the Qualified Person
- Pharmaceutical Quality Systems
- Pharmaceutical formulation and processing
- Pharmaceutical microbiology

In addition, unsuccessful applicants tend not to structure their answers and fail to demonstrate a logical approach to scenario solving. We would advise applicants to get plenty of practice in answering oral questions, and to make sure they have a method for ensuring that all elements of scenario-based questions are responded to.

21. Do you assess members from outside the UK?

The JPB will assess an application for Qualified Persons, regardless of 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 should 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.

22. 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.

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?

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 are named as a QP on an appropriate manufacturer's authorisation, you

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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-andgooddistribution-practice

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

In June 2019 there were 304 QPs registered (this includes 68 QPs who qualified via the permanent provisions).

Section 2:

1. What aspects of pharmaceutical law does a QP candidate need to know?

The basis of the QP was established by the European Union (EU) and is embedded in legislation followed by all EU member states. It is anticipated that at the end of 2020 when the UK Transition from EU is complete, updates to UK GMP legislation will be made to ensure the requirements for the QP in the EU and UK remain closely aligned. The active role taken by MHRA within PIC/S will also support continued close alignment of GMP requirements between EU and UK.

You are expected to know about the detail of UK law and how this aligns with EU law and where UK national legislation is different to EU law. We therefore recommend that candidates continue to follow the current study guide for the advice on directives and ensure that they stay up to date with any new EU or UK legislation as the Brexit transition progresses.

2. How is the QP study guide going to change due to Brexit and why hasn't it changed yet?

Updating the study guide is a lengthy process since the current version makes significant reference to the current EU Legal framework. The future legal framework under which the UK will operate is still being negotiated and is yet to be described. We encourage candidates to stay up to date with the status of the negotiations on the MHRA website. An update to the study guide is anticipated to be completed in 2021, once the precise UK framework has been finalised.

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3. **The requirements around export of products from the UK to the EU and whether we will have an MRA aren't clear yet, so how should any supply chain question in my viva be answered?**

   Any response to a question on the supply of products needs to be based on the legislation in place at the time. You will not be asked to speculate or predict what the legal framework will be. As always, you are encouraged to ask questions to clarify any scenario question you are asked during the viva.

4. **The restrictions around travel due to COVID-19 have stopped me visiting other pharmaceutical companies, can I still submit my application form?**

   Candidates should have some experience in dosage forms in addition to those declared as qualifying experience in their application. To acquire knowledge of these processes, potential failure modes and control strategies etc, it is usual to perform visits or audit other suppliers. Due to the restriction of travel with Covid 19 it is recommended that similar attempts to acquire knowledge of these processes are made virtually, for example sharing process maps, pictures, video, and virtual discussions with a QP at that site. Therefore, your application can be submitted, but should include a description of the activities you have completed to gain experience and knowledge of other dosage forms.

5. **Changes to EU and UK GMP Guidance were made during the COVID-19 restrictions, such as remote auditing and remote signing of documents. Do I need to know about this even if I have not used them myself?**

   The requirement in the study guide is that you have an in depth understanding of law. This includes the COVID-19 guidance.

6. **Are the Joint Professional Bodies (JPB) considering virtual assessments for assessing QP Candidates?**

   The JPB and MHRA have agreed that a process for virtual assessments will go live in November 2020. Your QP officer will contact you to arrange your assessment, once your application form has been accepted, as per the standard process before COVID-19. We expect the situation to continue to evolve as government guidance develops and your QP officer can advise.

   There is currently a backlog of candidates awaiting assessment due to the COVID-19 restrictions. Your QP officer will contact you to discuss potential dates. You will be given a minimum of 4 weeks' notice before your viva date. At the current time it is impossible to give any indication of timelines.

7. **I am unable to travel to London for medical reasons related to COVID-19. Can I have a virtual viva even if face to face assessments have restarted?**

   You need to consult your QP officer regarding the current assessment process. We want to support candidates during their QP assessment process regardless of circumstances and will consider this on a case by case basis to ensure that the process is fair for all candidates

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8. **I have submitted my form but now left that company. Do I need to resubmit my application form?**

   Please let your QP officer know your current circumstances, who will in turn update the assessors. There may be no requirement to resubmit sections of your application form, but this will be discussed on a case by case basis. Our expectation is that you will continue to work with your sponsor as you prepare for your viva.