Frequently Asked Questions

Purpose

The JPB QP assessor panel have created a set of Frequently Asked Questions (FAQ) covering current topics relating to the preparation, application and assessment processes for Qualified Persons (QP) in the UK. This will be updated on a periodic basis.

This FAQ 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.

Candidates are encouraged to contact their QP officer in case of any questions or specific concerns not covered here.

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Updated 21st October 2020
Section 1: Brexit and Covid-19

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.

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.

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.

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.
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.

Are the Joint Professional Bodies (JPB) considering virtual vivas for assessing QP Candidates?

The JPB and MHRA have agreed that a process for virtual vivas will go live in November 2020. Your QP officer will contact you to arrange your viva, 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.

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 vivas have restarted?

You need to consult your QP officer regarding the current viva 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.

After I have submitted my application form, how quickly would I be invited to attend my viva?

There is currently a backlog of candidates due to Covid 19 restrictions. The JPB is discussing the introduction of additional vivas once the restrictions are lifted. 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.

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.
Section 2: QP Application

Who should be my sponsor for my QP application?

Please refer to 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 (Royal Pharmaceutical Society, Royal Society of Biology or Royal Society of Chemistry). Your sponsor should be a practising Qualified Person who has known you professionally 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 acting for the activities in which you are engaged. You may need more than one sponsor, for example if your experience has been gained in more than one company.

Your sponsor is vitally important in your training and application for admission to the Register. Our expectation is that your sponsor acts as a mentor and supports you throughout your training, preparation and application.

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).

Whether you have changed jobs, your sponsor has moved on from your company or not a member of one of the professional bodies, please get in contact with your QP Officer at the earliest opportunity (details at the end of the document) for advice specific to your circumstances.

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.

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. Taking a course is not compulsory, and the Joint Professional Bodies do not recommend or endorse particular courses. For information, there is a list of some course providers on the RSC website.

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

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

Can I apply for QP eligibility if I only have experience in API manufacture or research and development, 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 API (bulk drug) and 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 manufacturer's authorisation, and appropriate experience is acceptable. Experience in an establishment which has only a Specials Licence cannot contribute to the experience requirement.

**Can I apply with experience of veterinary products?**
You can apply for QP eligibility with appropriate experience under a manufacturer's authorisation for veterinary products (2001/82/EC). The VMD can also appoint QPs independently.

**If I have gained broad practical experience across all areas of the Study Guide, what should I put as my specialist area of expertise on the application form?**
You should discuss this with your sponsor.

**How much detail should I include on the application form for sections 8 and 9 (Foundation knowledge elements and Additional knowledge elements)?**
You should discuss this with your sponsor.

**How long will it take for my QP application to be processed?**
This depends 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 who make the decision whether to invite you for an assessment interview.

**Can I reserve an assessment slot?**
You will be invited to attend a formal assessment once the application has been reviewed and approved by the assessors. You cannot 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.

**Where will my assessment be held?**
Assessments are normally held in the offices of the RSC, Royal Pharmaceutical Society or Royal Society of Biology in London. We will provide you with a map and instructions for finding us. All our buildings are accessible. If you need any special considerations relating to access or conditions in the interview room, please discuss them with your QP Officer well in advance of your assessment date. *(The situation has changed due to the COVID-19 pandemic, please refer to section 1)*

**Can I change the date of the interview, once agreed?**
You should contact your 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 six weeks’ notice, there will be a cancellation fee of £250, unless there are extenuating circumstances.
At the QP interview, who will my 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.

What are the most common causes of failure?
The JPB have been tracking the most common reasons for failure for several years. The following areas are where most people 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 advise applicants practice answering questions verbally, and to make sure they have a method for ensuring they cover all parts of answering scenario based questions thoroughly.

After the interview, can I have a copy of the questions I was asked?
We do not release lists of questions asked at QP assessments.

What is the current pass rate for Qualified Persons assessments?
In 2019, the pass rate under the permanent provisions was 72%.

What feedback will I get if I fail?
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 RSC.

I failed my assessment and the assessors recommended that I re-apply in (for example) twelve months’ time. Do I need to send a second application form and fee?
Any suggested time period is a recommendation, and you should discuss with your sponsor how to find opportunities to address the concerns of the assessors. Your re-application will be assessed as a new application. You should complete a new application form to reflect your additional knowledge and practical experience. You should ensure that you explain what you and your sponsor have done to address the concerns of the assessors for your previous application, and your sponsor should provide a new sponsor’s report. The same fee is payable for each application.
Do you assess members from outside the UK?

We will assess an application for eligibility to act as a QP, 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 first to contact the competent authority for that state (refer to the European Medicines Agency).

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

How can I 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, you can no longer apply under the transitional provisions of 2001/82/EC. You should contact the VMD for advice.

I am eligible to act as a QP 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). Can I apply for an entry on the Register?

If you have been accepted by the MHRA under transitional arrangements to act as a QP for traditional herbal medicinal products, and have been named as a QP on an appropriate manufacturer’s authorisation, you can apply for a certificate and an entry in the Register (Category E applications). 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.

If you have the relevant practical experience under these manufacturer’s authorisations, you 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
Section 3: RSC Specific

Where can I find out how to join the RSC?
To apply for QP eligibility, you must be 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. You can find out how to apply for membership in the Members section of the RSC website (http://rsc.li/join).

How many QPs are registered with the RSC?
In April 2020 there were 556 QPs registered. This includes 400 registrants who qualified via the permanent provisions.
All members listed in the Register pay an annual retention fee of £55 per year. This payment is requested at the same time as your membership subscription. If you do not pay the retention fee, you will not be listed in the Register.

How does the RSC CPD scheme work for QPs on the Register?
The RSC has a CPD structure for members from when you join and throughout your career. Please see rsc.li/qp for further details.

Does the RSC publish information on QP salaries and statistics?
The RSC produces a remuneration survey that includes information about QP salaries. You can find it in the members’ section of the RSC website.

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Contact details for QP applications and enquiries
If you need more information or have questions about your application, please refer to the websites of each professional body, or you can contact your QP Officer:

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