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.

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

Sections

Updated 24th January 2022

Section 1: Brexit and Covid-19

The Medicines Legislation relating to the QP changed because of the UK leaving the EU. Can you advise what the QP applicant is expected to know?

The candidate is expected to know the legislation surrounding the UK withdrawal from the EU (Brexit) as it impacts the Qualified Person. Specifically:

- The licensing structure in the UK and the requirements for national licences;
- The application of EU directives in Northern Ireland and the role of the NI protocol;
- Mutual Recognition agreements between the UK and other countries, and between EU and other countries ;
- Current and proposed arrangements for importation or export of medicinal products;
- The scope and application of the Human Medicines Regulations 2012 (Statutory Instrument 2012 No.1916 (as amended)).
- New guidance and information for industry provided by the MHRA to be followed from 1 January 2021.
- The scope and application of the Veterinary Medicines Regulations 2013 (Statutory Instrument 2013 No.2033 (as amended)).
- The VMD Information Hub provides information for all the Veterinary Medicines Directorate's communications on current and future regulatory changes.

Do IMPs manufactured in Great Britain need to be tested upon importation into EU as required by commercial products (with Great Britain now being classed as a Third Country)?

Article 11.2 of 2003/94/EC states “For Investigational Medicinal Products… When the products are imported from third countries, analytical control shall not be mandatory” so long as GMP, equivalent to that in the EU, is confirmed. Since GMP legislation and guidance in Great Britain has not changed, the Qualified Person should continue to determine if release testing needs to be repeated upon importation into EU (although QP certification is required).

My experience was gained in the EU rather than in the UK. Does this count as qualifying experience now that I want to be a QP in the UK?

Yes, if it is relevant, it can be signed off appropriately and it meets the requirements of the MHRA and the UK study guide therefore EU qualifying experience is admissible.

Is there any further guidance on what counts as qualifying experience?

The Human Medicines Regulation 2012, SCHEDULE 7, Qualified Persons, Part 1, section 8 advises that Qualified Persons must have practical experience in an undertaking authorised to manufacture medicinal products of—

(a) qualitative analysis of medicinal products;

(b) quantitative analysis of active substances; and

(c)the testing and checking necessary to ensure the quality of medicinal products.

The QP study guide advises that applicant must have had at least one/two[1] years relevant practical experience in one or more Quality Assurance activities in premises Authorised for the Manufacture of medicinal products. It is important for applicants to demonstrate direct qualifying practical experience of Quality Assurance within an Authorised Manufacturing facility. It should be noted that site visits do not qualify for practical experience in the candidates preferred dosage form stated on the application form.

It is recommended that applicants critically review their experience to ensure this meets the requirements described in the HMR 2012 and VMR 2013.

Applicants should also review the qualification of their experience with their sponsor prior to making their application.

Qualifying experience gained only in specific Quality Assurance roles (e.g. auditing or project management) is unlikely to provide sufficient practical experience to prepare the applicant fully for their interview scenario questions, and therefore the qualifying time in these roles may need to be extended and/or additional wider QA experience may be required.

Where roles have responsibilities split between licenced and unlicenced facilities, the qualifying experience can only count as contributing where it is related to completing Quality Assurance activities in the licenced facility.

For example, if an applicant had spent 2 years in a development quality support role (where the job description required 50% Quality Assurance activity, and the remaining time is spent in project activities), then this would only be equal to 1 year of experience. A further full year spent in a central QA role would be required to meet the requirement of two-year qualifying experience.

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. As stated previously, direct practical experience is required for the dosage form stated on the application form. Site visits can only be used to provide the additional knowledge for dosage forms other than the dosage form stated on the application form.

[1] In the UK, the MHRA and VMD have approved one year of practical experience for pharmacists)

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 and regulatory flexibilities.

I am unable to travel to London for medical reasons related to Covid 19. Can I have a virtual interview even if face to face interviews have restarted?

You need to consult your QP officer regarding the current interview 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 interview?

Your QP officer will contact you to discuss potential dates. You will be given a minimum of 4 weeks' notice before your interview date. As a guide, it should take between 2 – 3 months from your submission date to your interview, however, this is dependent on assessor availability, conflicts of interest and whether the assessors request any updates to your written application.

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 interview.

Section 2: Registration Form and Transition Period

Why have you started a registration process?

In the past, we have encountered numerous candidates who have applied with an unsuitable sponsor, the wrong membership level, or without the appropriate formal qualifications. This has led to lengthy delays for these candidates before their applications were accepted by the JPB's, as well as rejection of the application. The purpose of this additional step is to help us identify any eligibility issues in advance, and to encourage candidates to identify a suitable sponsor as early in the process as possible. Any issues will be communicated directly to the candidate.

I plan on submitting before the 2nd May 2022 deadline, what should do I do?

We would encourage you to submit a registration form to ensure that your sponsor, membership level and formal qualifications are suitable, although you can continue to use the previous version of the application form and Study Guide and proceed as normal.

I plan on submitting after the 2nd May 2022 transition period deadline, what should I do?

You should complete a registration form. Once you are, successfully registered, you will receive a copy of the new application form. You should prepare your application form against the updated version of the Study Guide.

If I am submitting before the 2nd May 2022 transition period deadline, should I submit a registration form?

You do not need to submit a registration form, however, we would strongly encourage you to do so, so that we can check that your sponsor, membership level and formal qualifications are suitable before you apply.

I have submitted a registration form, is there a deadline for me to then submit my application form?

No. There is no submission deadline for your application form once you have, successfully registered. We do request an intended submission date on the form, but this only serves as a guide for the QP Officer and you will not be expected to submit by this date. You should only submit your full application when you and your sponsor agree you are ready to do so.

I don't have a sponsor yet; can I still submit a registration form?

No. The sponsor is a vital component of the application process. They are there to guide you through the training and ensure you are ready to submit your application. You should identify a sponsor before you start preparing your application form. There is also a section in the registration form to be completed by your sponsor.

What happens if I don't have an appropriate Sponsor?

The QP Officer will explain to you why your sponsor is not appropriate and will provide guidance on who would be appropriate to act as your sponsor. You will then need to identify a suitable sponsor and submit a new registration form with your sponsor's details. Please note, we cannot select a sponsor for you, we can only provide guidance on the requirements of a sponsor.

What happens if I don't have the correct qualification?

It depends on your situation as you may be able to gain the necessary qualifications during your QP training. If this is the case your QP Officer will inform you on how you can meet the required qualification requirements and will provide you with a copy of the application form and sponsor forms.

If I submit my application form before the 2nd May 2022 transition period deadline but then get asked to make additions or corrections, do I need to update the whole form to reflect the new Study Guide?

No. If you have submitted your application form before this deadline and then receive a request for further information or clarification, you won't have to change forms or Study Guide's. You can just make the requested changes to your current form and re-submit that, even if this takes you past the May deadline.

I failed my interview before the 2nd May 2022 transition period deadline and plan on re-submitting my application after this deadline. Can I submit my application against the old version of the Study Guide?

No. Even if this is your 2nd application, you will be treated as a new applicant and therefore you will use the new application forms and make sure your next application reflects the new Study Guide.

Section 3: 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.

Should your qualifying experience not be from your current role, you will also be expected to provide a sponsor form from your current employer.

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 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 any 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). This is reduced to one year if the applicant is a qualified pharmacist.

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 does not 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. The whole process generally takes between two to six months. The application is reviewed by two assessors who make the decision whether to invite you for an assessment interview. The assessors may request more information from you. This will be done through the QP Officer and you should aim to re-submit your updated application within three months of this request. If more time is required, please contact your QP Officer.

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 conducted either remotely through video conferencing software or face to face. Your QP officer will discuss the options available to you when they invite you to the formal assessment. If it is face to face, it will normally be held in the offices of the Royal Society of Chemistry, 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.

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 to practice answering questions verbally with their sponsors, 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 2020, the pass rate under the permanent provisions was 70%.

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 your professional body.

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 application fee, current at the time, will be payable for each application.

Do you assess members from outside the UK?

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 on the MHRA website here: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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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:

RPS

QP Officer
Science and Research Team
Royal Pharmaceutical Society
66-68 East Smithfield
London
E1W 1AW

Tel: 020 7572 2737
Email: QPOfficer@rpharms.com
Website: https://www.rpharms.com/development/education-training/training/qualified-persons-a-guide

RSB

QP Officer
Royal Society of Biology
1 Naoroji Street
London
WC1X OGB

Tel: 020 3925 3440
Email: qp@rsb.org.uk
Website: https://www.rsb.org.uk/careers-and-cpd/registers/qualified-person

RSC

QP Officer
Royal Society of Chemistry
Thomas Graham House
290-292 Science Park
Milton Road
Cambridge
CB4 0WF

Tel: 01223 432141
Email qp@rsc.org
Website: https://www.rsc.org/careers/cpd/practising-scientists/qp-pharmaceutical/