Eligibility for Qualified Persons Application FAQs

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.

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.

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.

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.

Which products and processes are eligible as your area of expertise?
Any, as long as they are licensed under a full manufacturer's authorisation.

Can a person apply for QP eligibility if they only have 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.

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.

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.

Will the JPB be able to assess my specific chosen dosage form?
Yes, the JPB assessment panel have wide experience across many dosage forms.

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.

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.

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.

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.

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.

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.

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.

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.

An applicant failed the 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.

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.

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.

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.

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.