The Joint Professional Bodies

Qualified Persons Eligibility Scheme

Newsletter

Published May 2024

The Joint Professional Bodies (JPB) are committed to keeping in touch with the Qualified Person's community and will be releasing a regular newsletter to share relevant updates and information about the QP eligibility scheme.

QP Code of Practice

Last year, it was identified that the QP Code of Practice (COP) needed a review and update. A review panel composed of QP Assessors from each of the three professional bodies was formed to undertake this review. Their aim was to bring the COP up to date to reflect the changes that have occurred over the past few years.

We are now happy to confirm that this updated Code of Practice has been approved by Chairs and Vice Chairs of the JPB Panel of assessors as well as the MHRA and VMD. It has been published on the QP webpages of all three professional bodies.

There have been multiple changes throughout the Code of Practice (COP), but these changes have been made to bring the COP up to date and reflect what QPs are currently doing in their roles. One of the biggest changes is the removal of section 2 which used to list the regulations/ legislation that the QP has to follow. Since these are constantly undergoing review/consultations, this removal negates the need for regular updates. However, please note, that the QP still has a legal responsibility to follow the regulations/ legislation whatever they may be.

Reasons/ Trends for Failure

The JPB have been keeping track of the areas of failure at the interview stage over the past several years. To help current and future candidates prepare for the QP application process, the JPB has decided to share the top five areas where the candidate has not demonstrated the required level of understanding and/or knowledge.

Top five sections of failure in interviews (since 2021) are:

1. C (Pharmaceutical Quality Systems)
2. H (Analysis and testing)
3. B (The role and professional duties of a QP)
4. K (Investigational medicinal products)
5. J (Active Substances and excipients)

Additionally, many candidates who have failed, partly did so due to their inability to extrapolate their knowledge into areas of the Study Guide outside of their chosen dosage form. As part of the interview process, candidates will be assessed on their ability to apply their knowledge and understanding to any area of the Study Guide. This is done because the assessors need to be satisfied that if a candidate passes, after a suitable induction period, they would be able to function as a QP in any licenced undertaking and with any dosage form.

Checking of Qualification Requirements

The process of verifying a candidate's qualifications and their suitability for a QP application was discussed at the most recent annual Tripartite meeting, which is a meeting between the JPB, the MHRA and VMD. As part of this discussion, it was agreed to review this process and investigate whether it needs updating to ensure that qualifications are aligned with the legislation. Further updates will be provided to candidates through the Newsletter.

At this current time, the professional bodies will be maintaining their existing qualification verification processes, which may include confirming the subjects studied in a candidate's degree, diploma, or other formal qualification they have undertaken, against the list of subjects listed in the Human Medicines Regulation 2012 (SI/2012/1916).

Sponsors

The role of the sponsor is a fundamental part of the QP application process and is one of the key reasons why the registration process was enacted. The sponsor has many roles, but their key responsibility is to help prepare a candidate for their future role as a Qualified Person after successfully completing the application process, particularly the interview stage. The JPB expectation is that the sponsor will act as a mentor and have regular interaction with the candidate from the start and throughout their training.

Full details of the sponsor and their requirements can be found in the Guidance notes (section 2.5) but if the prospective sponsor requires any further advice on fulfilling the role, they should refer to their own professional body. Assessors are available to help answer any queries and further information can also be found in the FAQs available on the PBs websites.

Practical Experience vs Professional Experience

Candidates are reminded to use their whole career for appropriate examples when trying to demonstrate that they meet the requirements of the Study Guide. Generally, they are two types of experience:

- First is practical qualifying experience which has legal implications and is specifically about any work related to the manufacture of medicinal products (see section 4 of the Study Guide).
- Second is professional experience which can come from any part of your career and doesn't have to be related to the work connected to a licence to manufacture medicinal products. If a candidate and their sponsor deem an example from any point in a candidate's career to be relevant experience or knowledge against the Study Guide, then please include this in your application form.

QP CPD

QPs have a personal and professional duty to keep their knowledge and experience up to date. We therefore strongly encourage all QPs to keep their CPD up to date and maintain a suitable record of these activities. All three professional bodies have CPD resources which are available to their members, detail of which can be found below:

RPS: Details can be found on the RPS Training Webpage.
RSB: Details can be found on the RSB CPD Webpage.
RSC: Details at the bottom of the RSC QP Webpage and the RSC Profession Development Webpage.

QP Officers
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