

HOW DOES ONE BECOME A QUALIFIED PERSON?

Seen or heard the term “QP” or “qualified person” and wondered what it meant? Interested in the career opportunities provided by the pharmaceutical industry? Malcolm E. Brown outlines what QPs do and how to become one, and Sadia Khan follows with a more detailed look at the QP registration process

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A typical salary for a new qualified person (QP) is £40,000 a year. Senior positions including QP status pay up to £80,000. These often exceed salaries of pharmacists in other spheres. Moreover, a demographic time bomb is ticking as more QPs are retiring than are qualifying.

The QP is the quality assurance professional for medicines defined by British law, based upon European Union directives. The QP ensures that every batch released to the market complies with its specification and has been made according to good manufacturing practice. Medicines from outside the EU also often have to be analysed and assessed as suitable for use by EAU patients.

“Judgement day” for any batch is when the QP decides whether or not to certify approval for release on the batch’s “birth certificate”. Before such approval, the QP will need to be comfortable with aspects such as safe working systems, internal audit, training and analytical results. A QP who delays, let alone stops, the release of a batch worth £1m may be unpopular with top management so certain personal qualities are required. The dispensing pharmacist erring during checking a prescription may place one patient’s life at risk; the QP certifying, in error, an industrial batch may put thousands of lives at risk.

Variety of QP role

Are you a student who likes to smell the different forms of medicines you prepare or dispense? Did you love your chemistry set, the fizzing and crackling? Would you like to fabricate medicines by the ton? Does overseas travel appeal? If so, the variety of a QP role

might interest you. For example, you might find yourself reviewing medicines for humans, chickens, sheep, rabbits or salmon. Human investigational medicinal products (phases 1, 2 and 3) also require QP certification.

Registering as a QP requires satisfying oral examiners representing the Institute of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry. You must complete an application form, including work experience and sponsorship details and probably a course lasting two to four years; generally, employers pay the expensive course fees. Each professional body maintains a register of persons eligible for nomination as QPs.

A company needing a QP selects an individual from a register and submits the name to the regulatory authority (Medicines and Healthcare products Regulatory Authority or the Veterinary Medicines Directorate). The regulatory authority decides whether that individual is suitable for that application. Only after that individual has been approved is QP status granted.

Registering as a QP

There are four ways to register as an eligible QP with a professional body. These routes are designated Category A (permanent provisions) and Categories B, C and D (transitional provisions). The following steps cover the application process for pharmacists applying for eligibility via the Category A route. This route follows a more formal procedure compared with applications via the transitional routes. Detailed information on applications via the different routes

and useful documentation is available on the Royal Pharmaceutical Society’s website (www.rpsgb.org).

Each professional body has a QP officer and panel of assessors with a chairman and vice-chairman. The members of the Society’s panel of assessors are all experienced, practising-pharmacist QPs.

Before applying, candidates should refer to the documents mentioned below and ensure that the requirements for qualifications, knowledge and practical experience set out in the study guide are met:


- Study guide 2006
- Guidance notes for applicants and sponsors
- Application form
- Sponsor form
- QP Code of Practice

The joint professional bodies do not recommend or endorse particular QP training courses. However, details of different course providers are available on the Society’s website.

Pharmacist applicants should have at least one year’s relevant practical experience in one or more undertakings, with an authorised full manufacturing licence for medicinal products or investigational medicinal products for clinical trials.

Applicants need to provide evidence of knowledge and relevant practical experience. A completed application form, sponsor’s report and application fee should be sent to the Society’s QP officer.

The sponsor’s report is used to verify details provided by the applicant. The



The "Study guide — guide to the knowledge and practical experience required by Qualified Persons in the pharmaceutical industry" aims to help applicants applying for certification as a Qualified Person by setting out the body of knowledge and practical experience required when certifying medicinal products suitable for release within the pharmaceutical industry.

The study guide is available on the Society's website (www.rpsgb.org). If you would like to find out more about the guide contact Sadia Khan (e-mail: sadia.khan@rpsgb.org or telephone 020 7572 2537).

sponsor should preferably be a practising qualified person who has known the candidate for the qualifying period of experience and must be a member of one of the three professional bodies. The "Guidance notes for applicants and sponsors" set out the requirements for completion of the application form and sponsor's report.

The office undertakes a preliminary assessment of documentation to ensure that the application is complete and that requirements for qualifications, Society membership and manufacturers' licences are met.

Copies of the documents are sent to two members of the Society's QP panel of assessors to ensure that the experience cited meets requirements and all areas of the study guide have been covered. The candidate is invited for interview provided that the assessors are satisfied that the candidate meets the required standard from their paper assessment.

Occasionally the office may need to contact the candidate for further details or clarification on the application.

The candidate is invited for interview at the headquarters of one of the joint professional bodies, which have a joint programme of interviews and will offer the first available date regardless of location.

The QP interview panel usually comprises one assessor from each professional body and is chaired by an assessor from the candidate's own professional body. The Society's QP officer attends to minute questions from Society candidates. An observer may also occasionally attend.

The assessment includes a mixture of factual and scenario-type questions. The assessors ask questions in turn and aim to determine the candidate's application of knowledge and experience across all dosage forms. At the end of the interview the panel makes a pass or fail decision.

The outcome of the interview panel's decision is relayed to the candidate at the end of the viva, and via a letter indicating a pass or fail.

If the candidate passes he or she is added to Society's register of eligible QPs and receives a certificate. If candidates fail they are advised how to proceed (may require further study, possible reapplication, etc).

Each professional body maintains its own separate QP register of eligibility, details of which are communicated to the MHRA.

Further information can be found on the Society's website. If you want to find out more about any aspects of the oral assessment process can contact the Society's assessors for an informal discussion via Sadia Khan, the Society's QP officer (e-mail sadia.khan@rpsgb.org tel; 020 7572 2537). — Sadia Khan, Royal Pharmaceutical Society. ■