

Have you heard of the Qualified Person and wondered exactly what they are qualified to do? Read on to find out why the QP role is essential in pharmaceutical manufacturing and how you can become eligible

Qualified Persons: what they do and how you can become one



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By **Rachel Norton**, MRPharmS

Qualified Persons have a wide impact on patient care by assuring the quality of all medicines manufactured for the European market. A QP is legally responsible for certifying that each

batch of a medicinal product is suitable for release for sale or for use in a clinical trial, and will be named on the manufacturer's authorisation.

QPs are essential in the quality assurance of medicines and are responsible for ensuring that good manufacturing practice is in place. If there are any changes in manufacturing or quality control the QP will assess whether these impact on product quality.

To be named as a QP on a manufacturer's authorisation, you first need to be deemed eligible. QP

eligibility is assessed through an application to the Joint Professional Bodies (described in more detail on p240).

Although QP roles are most common in pharmaceutical

Write about CAREER DEVELOPMENT

This *Clinical Pharmacist* series looks at all aspects of career advancement and development of pharmacy roles. Any pharmacist with ideas for future pieces or who would like to write for *Clinical Pharmacist* is invited to contact the editor.

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companies, there are other settings where this expertise is required — for instance, some NHS pharmacy departments hold a manufacturer's authorisation (eg, to manufacture investigational medicinal products) and so are required to appoint a QP.

Other types of qualified person, for example, the Qualified Person for Pharmacovigilance (QPPV), are not described in this article.

Skills and attributes

In the UK, pharmacists and other scientists, including chemists and biologists, can become QPs.

Specific knowledge and practical experience are needed to work as a QP and these are set out in a QP study guide (see Box 1) — available along with application documents from the Royal Pharmaceutical Society website.

A pharmacy degree can provide the initial knowledge needed to become a QP and certain skills, such as professional decision-making, are transferable. Although there is no formal requirement to undertake additional training courses to become QP-eligible, relevant courses are available.

QPs need to have a good understanding of all aspects of the medicines manufacturing and supply chain. Strong leadership and oversight are necessary — before certifying a batch of medicine for release, the QP must be satisfied that all relevant checks and tests have been performed and documented.

QPs also need to be confident in the judgements they make, especially when “grey areas” arise, and be prepared to act decisively when things go wrong. If routine quality control testing should identify an impurity in a medicinal product, panicking is not an option; the QP needs to cope well under pressure, be flexible and be able to take appropriate steps based on the information available.

Eligibility

To be eligible, pharmacists need to fulfil the study guide requirements, including at least one year of practical experience working under a manufacturer's authorisation

Box 1: Knowledge and practical experience

The Joint Professional Bodies study guide describes the knowledge and practical experience required by Qualified Persons in the UK.

The three foundation elements, requiring thorough understanding, are:

- Pharmaceutical law and administration
- Role and professional duties of a QP
- Quality management systems

Additional knowledge requirements are:

- Mathematics and statistics
- Medicinal chemistry and therapeutics
- Pharmaceutical formulation and processing
- Pharmaceutical microbiology
- Analysis and testing
- Pharmaceutical packaging
- Active pharmaceutical ingredients
- Investigational medicinal products

(chemists, biologists and other pharmaceutical scientists need at least two years' experience).

Interested individuals first need to apply to their respective professional body — the Royal Pharmaceutical Society, the Royal Society of Chemistry or the Society of Biology (collectively the Joint Professional Bodies) — to be assessed for eligibility. The professional bodies follow a joint process for assessing their members

for eligibility and each has a QP officer and a panel of QP assessors.

Most applicants follow the “category A” route to achieve QP eligibility. The steps in this joint assessment process culminate with a written application and a viva, as described in Box 2. Successful applicants are added to the QP eligibility list for their professional body.

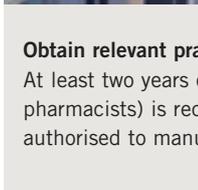
Certain types of application can go through less formal, transitional

Box 2: Steps to achieving QP eligibility status



Find a sponsor

Your sponsor will support your qualifying period of experience and training, help you prepare for assessment, provide a report on your ability to act as a QP and verify information on your application form.



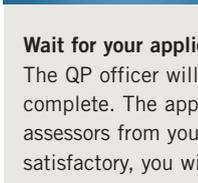
Obtain relevant practical experience

At least two years of experience (one year for pharmacists) is required in one or more facilities authorised to manufacture medicinal products.



Apply via your professional body

Apply when both you and your sponsor believe you are ready — submitting the application form, £600 fee, sponsor's report and countersigned copies of certificates.



Wait for your application to be assessed

The QP officer will confirm whether your application is complete. The application is initially assessed by assessors from your professional body and, if it is satisfactory, you will be invited to attend an interview.



Attend an interview (viva)

Interviews take place in London. Candidates who pass will receive a certificate and be added to the professional body's QP eligibility list.



TAKE A LOOK AT THE APPLICATION PROCESS AND BEGIN TO COMPLETE THE FORMS EARLY ON — THIS WILL HELP YOU IDENTIFY GAPS IN YOUR KNOWLEDGE AND ANY FURTHER TRAINING OR EXPERIENCE YOU NEED



Box 3: Case studies

Eric Che

After graduating from the University of Nottingham, I spent my preregistration year at Epsom and St Helier University Hospital NHS Trust.

For the past eight years since registering, I have been working in the NHS. In my current role as quality assurance manager at St George's Healthcare NHS Trust, I oversee Good Manufacturing Practice activities on-site and provide a QA consultancy service to 18 external units.

I passed my QP viva and my name has been added to the RPS QP eligibility list. I have subsequently been named as the QP on the trust's manufacturing authorisation for investigational medicinal products (IMPs). Since then I have been carrying out batch certification of manufactured IMPs.

Most recently, I have undertaken work to facilitate importation and certification of IMPs manufactured outside the EU.

Attia Hasnain

I completed my preregistration training at the Royal London Hospital and thereafter moved to St Thomas' Hospital as a basic grade pharmacist for a year before going on to do my PhD in pharmaceuticals at the School of Pharmacy, University of London.

Immediately after completing my PhD I went to work in R&D at Aventis Pharma, where I became increasingly interested in the quality of the medicines produced. I wanted to know who in the company was personally responsible for ensuring medicines' safety, quality and control before they could be sent out for use by patients. In other words, I wanted to know who was working on behalf of the patient.

Once I had discovered the role and responsibilities of the QP, I decided that I wanted to become one. Certainly, as a pharmacist, I felt my degree and background would help enormously in achieving this goal. It was during the latter part of my time

at Aventis Pharma that I started the Brighton University MSc QP course. Unfortunately, I was unable to complete my training because the R&D site closed in 2000.

After a brief stint in community pharmacy I returned to my roots at the Royal London Hospital, which by then had merged with St Bartholomew's Hospital. I spent the first three years there as principal pharmacist for training and development before taking up the role of quality assurance manager for Barts Health NHS Trust. When I was given the opportunity of pursuing my ambition to become a QP, I jumped at it. I recently passed my QP viva and my name is now on the RPS QP eligibility list.

I have since moved to the role of QA and development manager at Great Ormond Street Hospital.

Further details on these and other pharmacists' experiences of applying for QP eligibility are available to RPS members at www.rpharms.com

provisions, known as grandparenting arrangements (referred to in the QP guidance notes as categories B, C, D and E).

Taking action

If you want to become QP-eligible, an initial step is to discuss this with your employer and colleagues. Contact the QP named on the manufacturer's authorisation that you are working under and ask him or her to sponsor your application. Your

sponsor will also act as your mentor during your training.

Take a look at the application process and begin to complete the forms early on — this will help you identify gaps in your knowledge and any further training or experience you need to apply.

When your QP eligibility has been confirmed, your employer can apply to the Medicines and Healthcare products Regulatory Agency or the Veterinary Medicines Directorate to have your name

added to its manufacturer's authorisation — only when this is approved can you begin to undertake your QP role and legal responsibilities.

The RPS offers online networks and a mentoring service for members, through which you can learn more from colleagues about becoming a QP.

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