

Briefing Paper: The role of the Royal Pharmaceutical Society in relation to Qualified Persons

Summary: A briefing paper for members and other stakeholders on the role of the Royal Pharmaceutical Society (RPS) in relation to Qualified Persons (QPs). It considers the RPS' role in the Qualified Person assessment scheme and the tripartite collaboration between the Joint Professional Bodies (RPS, Royal Society of Chemistry and Society of Biology), the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate. There is an urgent demand for more QPs since there are more QPs retiring than are qualifying. Pharmacist numbers applying to be assessed for QP eligibility are much lower than chemists and biologists and the RPS needs to encourage more pharmacists to apply for QP eligibility. The role of the RPS, the new professional leadership body for pharmacy, in supporting and developing Qualified Persons is described. As the RPS develops its services, such as CPD, accreditation and credentialing, our QP service will link-in with these. Future collaboration with other organisations that represent and support Qualified Persons may enable greater support and a wider pharmacy voice for the Qualified Person.

Introduction: An essential role in pharmaceutical manufacture is the Qualified Person (QP) who has an important quality assurance function and is vital to the safe control of medicines. The QP has a legal responsibility to ensure that every batch of medicines released onto the market complies with its specification and has been made according to good manufacturing practice (human and veterinary medicines). QPs are legally required to certify batches of medicinal products prior to use in a clinical trial (human medicines only).

A pharmacy degree provides a good background for this role. The QP role is also undertaken by scientists from other disciplines including chemistry or biology.

Qualified Person Assessment Scheme: The medicine regulators, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Veterinary Medicines Directorate (VMD), have delegated the Royal Pharmaceutical Society, the Society of Biology and the Royal Society of Chemistry (the "Joint Professional Bodies" (JPB)) to certify the eligibility of their members for nomination as a QP. The Joint Professional Bodies are responsible for certifying QP **eligibility**. The MHRA or VMD are ultimately responsible for determining the suitability of an individual to be named as a QP on a particular manufacturer's authorisation. Each professional body has a panel of QP assessors and a QP Officer. The RPS panel is composed of 8 assessors – Dr Nigel Hodges is the Chair and Ms Gillian Renouf is the Vice-chair.

Members apply for certification via the JPB QP eligibility scheme through their own professional body. The main route of achieving QP certification is the category A route ("permanent provisions") which involves both a written application and an interview. There are also arrangements that enable ad hoc applications via less formal "transitional provisions" (category B, C, D and E). A detailed description of the knowledge and practical experience required for becoming a QP are described in a "Study Guide" produced by the Joint Professional Bodies. The organisations are currently updating the joint documentation for the QP application process.

The interview panel for each assessment involves an assessor from each of the 3 professional bodies. The QP officer attends assessments when a candidate is a member of their professional body. In 2010 there were 17 assessment days and normally there are 3 candidates scheduled for each assessment day. In 2010 the pass rate for all candidates assessments was 65% (total number of assessments = 49).

Each professional body maintains its own separate QP register of eligibility (list of current members who have been certified as eligible for nomination as a QP). The details of this are communicated to the MHRA and VMD. The RPS has 489 members on the current list – of these only 10% approx. (50 members) qualified via the permanent provisions (figure collated Feb 2011). During the last ten years (2001-2010) there have been a total of 446 applications for certification of QP eligibility via the

permanent provisions – of these only 25 candidates applied via the RPS (RPS candidates = 6%, RSC candidates = 59% and SB candidates = 35%). The total number of new additions to the QP eligibility list (via the permanent provisions) for the last ten years is 322 – of these only 21 were new additions to the RPS list (QP eligibility list additions RPS = 7%, RSC = 58% and SB = 35%).

The RPS currently only accepts applications from members who are also registered as a pharmacist. This restriction is being reviewed to reflect the evolving membership criteria of the new organisation. The “Study Guide” describes that the normal 2 year qualifying practical experience is reduced to one year in the case of pharmacists.

There is an annual meeting between the tripartite bodies involved in this scheme (ie. MHRA + VMD + “Joint Professional Bodies”) – the QP “tripartite meeting”. Representatives of the MHRA and VMD are also invited to observe an assessment day. The Joint Professional Bodies are represented by Nigel Hodges on the MHRA GDP-GMP Consultative Committee.

Training courses It is not a formal requirement to attend any additional courses to become a QP and the Joint Professional Bodies do not currently endorse or accredit specific courses for QPs. Some academic institutions and other training providers offer formal courses for QPs. Each QP applicant has a sponsor and the sponsor has a key role in assisting applicants in identifying individual training needs. The sponsor will normally be a member of one of the professional bodies.

The NHS has recently introduced an initiative relating to the training of NHS pharmacist QPs (following concerns about a shortage of QPs in the NHS). The RPS encourages such initiatives and the officer will visit the course to speak to potential candidates about the application process.

The RPS is developing processes for accreditation (of courses) and credentialing (recognising an individual’s qualifications and experience) for the profession and QPs will form part of this work.

The role of the RPS in supporting and developing QPs: There is an urgent demand for more QPs since there are more QPs retiring than are qualifying. A large proportion of the QPs on the RPS register applied under transitional provisions (category B and C) and will be aged 54 years and above. The RPS aims to boost the numbers of QPs by raising awareness of QPs as a career option for pharmacists and “demystifying” the QP application process.

Our career support includes providing advice on the role of a QP and details on how to become a QP. Career information is available from our new website, RPS publications (articles on QPs have recently appeared in the Pharmaceutical Journal and Pharmacy Professional) and we have a dedicated “RPS Support” team to answer member’s enquiries (the QP officer is also based in this team).

Annex 16 of the EU Guide to Good Manufacturing Practice states that QPs have a personal and professional duty to keep their knowledge and experience up-to-date. Our continuing professional development services are integrated across the organisation since many of our activities aim to keep members up to date and support their development. CPD support is also available for members who are no longer registered as pharmacists.

We have created an online “Qualified Persons” network for members on our website. It provides online networking and enables peers to exchange ideas and support their colleagues.

Further opportunity for networking between QPs is available at our events. Events are run to support the development of QPs including the 12th QP joint symposium on April 5 2011. This is a joint event with the RSC and SB and aims to provide an update on legislation identifying key issues for the QP from a regulatory perspective.

For more information on QPs: <http://www.rpharms.com/development/qualified-persons.asp>