

The RSC Register of Eligible Qualified Persons

1 Introduction

The United Kingdom pharmaceutical industry has set high standards of research, development, manufacturing and testing of its products in order to promote the healthcare of patients. The key factor in the success of the pharmaceutical industry is the quality of the people it employs and the training it provides to ensure the maintenance of the established high standards. A Qualified Person, who is responsible for certifying the suitability for release of medicinal products as part of this industry, requires specialised training and experience in order to fulfil the requirements.

In producing this RSC Register of Eligible Qualified Persons, the RSC is complying with its Royal Charter objective “to establish, uphold and advance the standards of qualification, competence and conduct of those who practice chemistry as a profession”.

The Register contains the names and addresses of those members of the Royal Society of Chemistry who have met the conditions of eligibility to be Qualified Persons in the pharmaceutical industry.

2 Requirements

The requirements to be fulfilled by a Qualified Person in the European Union (EU) were initially contained in directives of the Council of the European Communities. It was then necessary to enshrine them in United Kingdom legislation. The relevant legislation is listed in the current edition of the Study Guide for QP applicants.

3 Administrative Procedures

In 1979, on the advice of the Qualified Person Advisory Committee, the MCA (Medicines Control Agency, since 1 April 2003 the MHRA, Medicines and Healthcare products Regulatory Agency) and VMD (Veterinary Medicines Directorate) decided that the three professional bodies for the disciplines concerned (the Institute of Biology, the Royal Pharmaceutical Society of Great Britain and the Royal Society of Chemistry) would advise on the suitability of certain of their members to be Qualified Persons. Joint administrative procedures are in place. Prospective Eligible Qualified Persons should direct their enquiries regarding eligibility to the professional body of which they are members.

4 Categories of Qualified Person on the Register

The following are the five categories of Qualified Person contained in this Register:

- 4.1 Those members of the RSC who have satisfied the transitional provisions of 2001/83/EC (75/319/EEC before 6 November 2001) and are eligible for nomination on manufacturer’s authorisations.
- 4.2 Those members who have satisfied the permanent provisions of 2001/83/EC and 2001/82/EC (75/319/EEC and 81/851/EEC before 6 November 2001) and are thereby eligible for nomination on a manufacturer’s authorisation. The permanent requirements involve both the acquisition of a body of knowledge and also a period of relevant work experience. Those members are identified by an asterisk (*) beside their name.

The previous two categories are eligible to act as the Qualified Persons for both human and veterinary medicinal products.

- 4.3 Those members who are eligible under the transitional provisions of 2001/82/EC (81/851/EEC before 6 November 2001) to be Qualified Persons for veterinary medicinal products only. Those members are identified by (V) beside their name.
- 4.4 Those members who are eligible under the transitional provisions of 2001/20/EC to be Qualified Persons for investigational medicinal products only. Those members are identified by (IMP) beside their name.
- 4.5 Those members who are eligible under the transitional provisions of 2004/24/EC, the amendment to 2001/83/EC to be Qualified Persons for herbal medicinal products only. Those members are identified by (H) beside their name.

5 Professional Conduct

The European Communities Council directives require Member States to ensure that the duties of Qualified Persons are fulfilled “by making such persons subject to a professional code of conduct”. The MHRA and VMD have decided that failure to undertake satisfactorily the duties of a Qualified Person “might be a matter for consideration by the appropriate professional body to which he/she might belong, as a matter of professional misconduct”.

As well as the specific Code of Practice produced jointly by the three professional bodies each professional body also has a disciplinary procedure to deal with cases of alleged professional misconduct. In a serious case a member could be expelled from membership of the professional body (and removed from the statutory professional register in the case of pharmacists), and would thereby be removed from the Register of Qualified Persons. The MHRA and VMD would also be notified in such an event.

The current version of the Joint Professional Bodies Code of Practice can be found on the RSC website at www.rsc.org/qp. A paper copy can be supplied on request.

6 Continuing Professional Development

In common with many other professional groups Qualified Persons work in a changing scientific, commercial and regulatory environment. They adhere to a code of conduct which, among other provisions, requires them to keep abreast of change. In addition, annex 16 of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 requires that “A QP should maintain his knowledge and experience up to date in the light of technical and scientific progress and changes in quality management relevant to the products which he is required to certify”.

The RSC has introduced a Continuing Professional Development (CPD) scheme for the register. CPD has been defined by the RSC as:

“..... the responsibility of individuals for the systematic maintenance, improvement and broadening of knowledge and skills to ensure continuing competence as a professional throughout their career”.

The RSC considered the professional development activities which members undertook against the development objectives they had identified, and the extent to which these demonstrated their commitment to maintaining professional competence.

In 1995 RSC members on the register were issued with a CPD record book as an aid to planning CPD activities. A new CPD framework was implemented in August 2001, in line with the new membership structure, and members are now invited to submit an annual summary of their CPD activity to the RSC.

Where members have participated in the RSC CPD scheme two dates are shown against an individual's entry in this update to the register;

- (i) the year they were admitted to the register; and
- (ii) the year of their last successful CPD review.

In the case of members who choose not to participate in the scheme, there will be no CPD date. Users of the register are reminded that participation in the CPD scheme is voluntary and therefore caution should be exercised in placing any interpretation upon the absence of a CPD date.

7 Annual retention fee

An annual retention fee of £25 is charged for members to remain on the Register. This is requested by the Membership Department at the same time as the RSC membership fee.

8 Professional indemnity insurance

The RSC recommends that all consultants take out professional indemnity insurance. Other QPs may wish to consider whether this is necessary. Further guidance is available from the RSC website at www.rsc.org/members/consultancy.pdf.