

The RSC Register of Eligible Qualified Persons

1.Introduction

The Qualified Person is responsible for certifying the release of every batch of a pharmaceutical product. In the UK, the Royal Society of Chemistry, the Royal Pharmaceutical Society and the Society of Biology assess the eligibility of their members for QP status on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA) of the Department of Health, and the Veterinary Medicines Directorate (VMD) of the Department of the Environment, Food and Rural Affairs (DEFRA).

This Register includes the names of Royal Society of Chemistry members who have met the conditions of eligibility to be Qualified Persons.

2. Eligibility of Qualified Persons

No designation

Transitional provisions of 2001/83/EC (75/319/EEC before 6 November 2001).

- * Permanent provisions of the Human Medicines Regulations 2012 (2001/83/EC and 2001/82/EC before 2021 and 75/319/EEC and 81/851/EEC before 6 November 2001).
- (V) Transitional provisions of 2001/82/EC (81/851/EEC before 6 November 2001), Qualified Persons for veterinary medicinal products only.
- (IMP) Transitional provisions of 2001/20/EC, Qualified Persons for investigational medicinal products only
- (H) Transitional provisions of 2004/24/EC amending 2001/83/EC, Qualified Persons for herbal medicinal products only.

3. Professional Conduct

QPs are subject to a professional code of conduct. As well as the Code of Practice produced jointly by the three professional bodies (www.rsc.org/qp), the Royal Society of Chemistry has a disciplinary procedure to deal with cases of alleged professional misconduct. In a serious case a member could be expelled from membership and would also be removed from the QP Register.

4. Continuing Professional Development

Annex 16 of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The "Orange Guide") 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". There is a CPD scheme for the register. CPD is 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".

Members are invited to submit an annual summary of their CPD activity. Participation is voluntary, but for members who have participated in the scheme, two dates are shown against the entry in the Register:

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

5. Annual retention fee

An annual retention fee of £55 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.

6. 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 information can be found in the RSC members portal.