

ROLE OF THE QUALIFIED PERSON

The primary legal responsibility of the Qualified Person (QP) is to certify batches of medicinal products prior to use in a clinical trial (human medicines products only) or prior to release for sale and placing on the market (human and veterinary medicinal products).

The QP is essential to the safe control of medicines and needs to have extensive training and in-depth critical understanding of all the aspects associated with pharmacy manufacturing.

The following quotes describe the varied roles and responsibilities of the QP:

'The role of the QP is very broad as it includes all aspects of the pharmaceutical industry and supply of pharmaceutical products. The role is broader than just sales as it may also include drugs for clinical trials'.

'The role of the QP is like that of a conductor of an orchestra. The QP needs to manage, coordinate, understand what's happening and cajole/encourage where required to get the best possible results'.

'A pharmacist can be a QP responsible for pharmacovigilance within the European Union / European Economic Area'.

'The experience and skills of the QP are recognised globally within my company as a valuable QA resource (not just someone who performs batch release for Europe)'.

'The QP has to use his/her technical knowledge of all aspects of manufacture and control, but also needs to have skills in working with others and making judgements based on the information available'.

'The QP has in effect three "bosses". First and foremost, the patient, who trusts that the products we supply are safe to use. Secondly, the UK Government (and increasingly others) and thirdly the company'.

'Being a QP allows you to work with virtually all departments in the company, other companies if work is contracted out and you must also understand the needs of the patient'.

'The QP is a 'rhinoceros' - thick skinned, broad shouldered and with a definite point'.

JOINT PROFESSIONAL BODIES' QUALIFIED PERSON SCHEME

The Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate require the Royal Pharmaceutical Society of Great Britain, the Institute of Biology and the Royal Society of Chemistry ('Joint Professional Bodies') to assess the eligibility of their members for QP status.

Each professional body has a QP Officer and a Panel of Assessors with a Chairman.

ELIGIBILITY FOR CERTIFICATION

Four categories of practitioner are eligible for certification by the Joint Professional Bodies under permanent and transitional provisions; they have been designated Category A and Categories B, C and D.

Each of the three professional bodies has responsibility for certification of its members. The following information (Category A) applies to RPSGB applicants.

Category A

(i) Registration as a pharmaceutical chemist in Great Britain.

(ii) At least one year's relevant experience in one or more undertakings which are authorised to manufacture medicinal products. The practical experience must be in the activities of qualitative analysis of medicinal products, quantitative analysis of active substances and the testing and checking necessary to ensure the quality of medicinal products.

(iii) Confirmation from the RPSGB of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Joint Professional Bodies. Applications and assessments via the Permanent Provisions (Category A) follow a more formal procedure compared to Categories B, C and D.

Category B

Those who on 22 November 1977 were engaged in the activities laid down for the QP (e.g. they were 'named' on an existing Manufacturer's Licence as being responsible for the production or quality control). Certification by a professional body is not essential.

Category C

Members of one of the three professional bodies who commenced the course of study leading to membership (i.e. post-A level study) before 22 May 1975 and for a period of not less than two years ending not later than 22 May 1985 had engaged in the activities mentioned in category A. Where these activities were completed prior to 22 May 1965 a further one year practical experience is necessary immediately prior to appointment as a QP.

Category D

(Clinical Trials Directive 2001/20/EC)

New QPs required under this Directive are eligible to be certificated by the Joint Professional Bodies and to have an entry in one of the Registers of Eligible Qualified Persons. Those eligible for certification will be members of one of the Professional Bodies.

(NB The MHRA and VMD have the power to grant QP status for specific Manufacturing Licences in special circumstances that may not comply with the Directives).

QP SYMPOSIUM

The 10th Joint QP Symposium 'The Impact of ICH Q8, Q9 and Q10 on the QP' was held in April 2008 at the RPSGB headquarters. Presentations are available on the RPSGB website.

APPLICATION PROCEDURES / GUIDELINES

The following documents are also available on the RPSGB website and collectively aim to provide detailed information on the requirements for certification and the application process:

- Application form
- Guidance notes for applications and sponsors
- Study guide 2008
- Code of Practice for Qualified Persons
- Sponsors' report

Information on QP training courses & frequently asked questions is also provided.

These can be found at www.rpsgb.org/worldofpharmacy/workingwithotherbodies/qualifiedpersonscheme

FURTHER INFORMATION

Pharmacy undergraduates, pre-registration students or pharmacists may refer to:

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Other applicants may refer to:
Institute of Biology: www.iob.org
Royal Society of Chemistry: www.rsc.org



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Pharmaceutical
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*Produced by the Practice Division
Professional Services Directorate
Royal Pharmaceutical Society of Great Britain*

November 2008