Royal Pharmaceutical Society
Royal Society of Chemistry
Society of Biology

Qualified Persons in the Pharmaceutical Industry

Guidance Notes

For Applicants and Sponsors

July 2010
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Reason for issue 12.07.10	- fees removed from Guidance Notes and published separately; - guidance for applicants with part-time experience (section 2.4.6); - guidance for applicants from "virtual" companies (section 2.4.6).
Reason for issue 27.09.10	- change of name from Royal Pharmaceutical Society of Great Britain to Royal Pharmaceutical Society, amended contact details for RPS.

1.0 Introduction

The manufacture within the European Union or importation of medicinal products from countries outside the European Union is subject to the possession of authorisation under the Medicines Act 1968 and the Pharmaceutical Directive 2001/83/EC. The Pharmaceutical Directive requires that, in order to obtain authorisation, the applicant for a Manufacturer's Licence must have available the services of at least one Qualified Person who fulfils certain minimum conditions of qualification and experience. The conditions with regard to qualification relate to possession of a formal qualification in certain specified disciplines including chemistry, biology or pharmacy, together with evidence of adequate knowledge of a number of specified subjects. No existing single first degree or other qualification awarded in the United Kingdom meets the conditions in full.

Similar requirements apply to the manufacture of veterinary medicinal products and are specified in the Veterinary Directive 2001/82/EC.

Directive 2001/20/EC has extended the scope to require a qualified person to release materials for clinical trials. Directive 2004/24/EC amending 2001/83/EC has also extended the scope to require a qualified person to release traditional registered herbal medicinal products.

It has been agreed that in certain circumstances membership of the Society of Biology, the Royal Pharmaceutical Society or the Royal Society of Chemistry, can meet the requirement for formal qualification subject to certification of suitability by the professional body. It has also been agreed that these professional bodies may certify in respect of their members the acquisition of additional required knowledge in specified subjects. The Pharmaceutical Directive was adopted in May 1975. There followed a transitional period of ten years. It was possible for existing practitioners to satisfy the transitional provisions of the Directive either as Qualified Persons in post or by obtaining certification of eligibility for nomination as a Qualified Person.

Each of the three professional bodies has responsibility for certification of its members. Practitioners can also seek to satisfy the permanent provisions of the Directive which call for formal qualifications and knowledge specified in the Directive.

Five categories of practitioner are eligible for certification by the professional bodies under permanent provisions and transitional provisions; they have been designated Category A, Category B, Category C, Category D and Category E. Each has particular conditions relating to eligibility and tenure according to specifications in the Directive and in UK legislation implementing the Directive.

Dates given in this paper are derived from the Directive or the UK legislation and are not open to amendment or re-negotiation on the part of the professional bodies or their individual members.

2.0 Guidance notes for applicants

2.1 Permanent provisions: conditions of eligibility

Category A. Those eligible for certification will hold formal qualifications in chemistry, pharmacy, medicine, veterinary medicine, pharmaceutical chemistry and technology or biology (or Professional Membership of one of the three professional bodies) awarded on completion of a course of study at a recognised institution lasting not less than three years. They must

produce evidence of adequate knowledge of the subjects listed in the Study Guide (Guide to Knowledge and Practical Experience Required by Qualified Persons in the Pharmaceutical Industry), **and** have practical experience for at least two years (one year for Pharmacists), in one or more undertakings authorised according to Article 40 of 2001/83/EC or Article 44 of 2001/82/EC to manufacture medicinal products, or in an undertaking authorised according to Article 13 of 2001/20/EC to manufacture investigational medicinal products for clinical trials. The practical experience must be in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products. The practical experience must be undertaken in the UK or in another EU state.

Application and assessment is according to a formal procedure. Candidates complete a written application (see below) and attend a panel interview.

At the end of the assessment candidates will be informed whether they have satisfied the assessors and have passed or failed. Failing candidates will be informed of those areas where they are deficient and will be required to present themselves again for assessment.

One sponsor is required for each candidate and must be a member of a professional body (the Society of Biology, the Royal Pharmaceutical Society or the Royal Society of Chemistry). The sponsor must be a practising Qualified Person who has known the candidate for the qualifying period of experience required. If this is not possible, a candidate may use a QA line manager provided that the sponsor's report is countersigned by the Qualified Person. The sponsor is expected to:

- certify that the applicant has adequate knowledge of the subjects covered in the Study Guide, or supervise the acquisition of that knowledge to the required state of competency; and
- certify the experience requirement.
- The expectation is that the sponsor acts as a mentor and has regular interaction with the applicant.

2.2 Transitional provisions: conditions of eligibility

Directive 2001/82/EC. Since the change in legislation relating to veterinary products in 2005, applications can no longer be made under the transitional provisions of 2001/82/EC. Intending applicants should contact the VMD.

Category B (Directive 2001/83/EC)**.** Those who, on **22 November 1977,** were engaged in the activities laid down for the Qualified Person (e.g. they were 'named' on an existing Manufacturer's Licence as being responsible for production or quality control) are eligible for certification. They may continue to act in respect of the licence(s) in which they were named and are eligible for nomination in respect of further licence applications irrespective of formal qualification and/or experience. Certification by a professional body is not essential in these circumstances, but such persons are nonetheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which they were named.

Category C (Directive 2001/83/EC)**.** Those eligible for certification will be Members of one of the three professional bodies who commenced the course of study leading to Membership before **22 May 1975** and who, for a period of not less than two years ending **not later than 22 May 1985** had engaged in the activities of production supervision and/or qualitative analysis, quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a 'qualified person' to ensure the quality of medicinal products. Where the

activities referred to were completed **prior to 22 May 1965** a further one year's practical experience is required immediately before appointment as a Qualified Person.

A member whose course of study leading to Membership (post ONC/GCE 'A' level) began after **22 May 1975** has to comply with conditions applicable to Category A.

Category D (Clinical Trials Directive 2001/20/EC). The new QPs required under this directive are eligible to be certificated by the 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 three Professional Bodies. They will have been 'named' as a Qualified Person in an application for a clinical trials manufacturing authorisation made prior to 1 May 2006, and have been accepted to act as a QP for investigational medicinal products by the MHRA and named on the clinical trials manufacturing authorisation. Certification by a professional body is not essential in these circumstances, but such persons are nevertheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which they were named.

Category E (Directive on Traditional Herbal Medicinal Products 2004/24/EC, amending 2001/83/EC). The new QPs required under this Directive are eligible to be certificated by the 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 three Professional Bodies. They will have been 'named' as a Qualified Person in an application for a manufacturing authorisation made prior to 30 April 2013, and have been accepted to act as a QP for traditional herbal medicinal products by the MHRA and named on the manufacturing authorisation. Certification by a professional body is not essential in these circumstances, but such persons are nevertheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which they were named.

A less formalised procedure than is the case for Category A has been required for applications and assessments under Categories B, C, D and E. Applications have been dealt with on an ad hoc basis subject to the submission of the required evidence, certified by a referee acceptable to the Council of their professional body.

2.3 Applications

All applicants must complete and return the full set of forms to their own professional body stating the category under which the application is made. Full details of all relevant information should be given to aid assessment.

2.3.1 Category A applications

The sponsor should refer to the Study Guide and if able to certify that the applicant is entirely suitable for appointment as a Qualified Person allow the statements in Section 10 to stand.

In any event, the sponsor will be asked by the professional body to either:

- confirm his or her endorsement of the applicant's suitability; or
- outline a programme of study/experience that has been agreed with the applicant in order to achieve the required level of knowledge and experience, with an estimated completion date.

In the case of the second option, responsibility will rest with the applicant to make all necessary arrangements to complete the study programme or other required actions and for

all fees or costs that may be incurred.

The sponsor's report shall remain confidential to the Joint Professional Bodies.

2.3.2 Category B, C, D and E certification

Applicants for certification under Category B or C (Transitional provisions of 2001/83/EC) do not need to complete sections 8 and 9 of the application form. They should obtain the signature of a suitable referee in Section 10 of the form. The referee, ideally but not necessarily, should be a member of their professional body and should be demonstrably in a position to offer the necessary certification concerning the applicant's suitability and compliance with the appropriate conditions according to the category. Reference should be made to the Study Guide for details of the subject/topic areas in which adequate knowledge is required by the applicant.

Applications for certification under Category D (Transitional provisions under the Clinical Trials Directive 2001/20/EC) and Category E (Transitional Provisions under the Traditional Herbal Medicinal Products Directive 2004/24/EC) do not need to complete sections 8 and 9 of the application form. These applicants have already been accepted to act as a QP for clinical trials materials or for traditional herbal medicinal products by the MHRA and named on a manufacturer's authorisation. Applicants should send a copy of this authorisation, signed as a true copy by a suitable referee, who should sign section 10. The referee, ideally but not necessarily, should be a member of their professional body.

The referee's report shall remain confidential to the Joint Professional Bodies.

Completed application forms and the relevant application fees should be returned to the applicant's professional body. Their addresses are in section 4.0.

Application and certification fees

Please refer to the websites of the professional bodies for the current fees.

Payment can be made by cheque or credit card. Cheques should be made payable to either 'Society of Biology', 'The Royal Pharmaceutical Society' or 'Royal Society of Chemistry'. Application fees are not refundable and are subject to variation without notice.

An appeals mechanism is in place for this register and details are available on request.

It should be noted that certification by the professional body under these arrangements does not necessarily ensure that nomination as a Qualified Person in respect of any particular Licence Application will be accepted by the Licensing Authority.

Society of Biology

The requirements of the permanent provisions which relate to a biologist are:

(i) Either a Chartered Biologist (CBiol MSB or CBiol FSB), or a Fellow (FSB) or Member (MSB) or Associate with designatory letters AMSB who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent.

(ii) At least two years of practical experience in one or more undertakings, 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 Society of Biology of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Society of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry.

The Royal Pharmaceutical Society

The requirements of the permanent provisions which relate to a pharmacist are:

(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.

The normal two year experience requirement is reduced to one year in the case of pharmacists since the five year period of education and training leading to registration is considered to be equivalent to a five year university course as specified in Article 49 of Directive 2001/83/EC and Article 53 of Directive 2001/82/EC.

(iii) Confirmation from the Royal Pharmaceutical Society of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Society of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry.

Royal Society of Chemistry

The requirements of the permanent provisions which relate to a chemist are:

(i) Either a Chartered Chemist (CChem), or a Fellow (FRSC) or Member (MRSC) or Associate Member (AMRSC) who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent.

(ii) At least two years of experience in one or more undertakings, 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 Royal Society of Chemistry of the acquisition of a body of knowledge which is described in a joint Study Guide prepared by the Society of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry.

2.4 Notes to aid completion of application form

Please download the application form from the website (www.societyofbiology.org; www.rsc.org/qp; www.rpharms.com). Complete electronically, print out and sign. Documentary evidence, e.g. certificates or result letters for postgraduate study relevant to the Qualified Person, may be submitted as photocopies attested by your sponsor or referee. Contact the relevant officer at your professional body in case of difficulty in completing this

form.

1 Category of membership

Please enter your present category of membership of your professional body, and your membership number.

2 Category of application

Please tick the appropriate box to specify which category you are applying.

3 Current status

Please tick the appropriate boxes.

4 Personal details

Please enter your family and given names in normal sequence; enter any title and designatory letters, initials of degrees etc.

5 Address and employment

Please enter the address to which you wish correspondence to be sent.

Please enter your job title, the name and address of your current or most recent employer and a daytime telephone number. If you are taking study leave before your interview, your home telephone number will be useful in case we need to contact you urgently before the interview.

6 Education and training

Please enter in chronological order in the relevant sections, details of all qualifications obtained.

a Certificate or Diploma below Degree level

b Supplementary certificate or equivalent

c First degree or equivalent

d Postgraduate study and higher degree(s)

e Other study relevant to the 'Qualified Person'. If you have completed any QP training courses, list the training provider(s). Please provide copies of any result letter(s) or certificate(s), signed by your sponsor to verify that they are true copies.

f State the employer and the dates worked which satisfy the practical experience requirements. Please also provide the number and date of issue of the Manufacturer's Licence (or Licences) under which these requirements were satisfied. Please ensure that the dates cover the whole period of experience required (2 years for IOB and RSC applicants, one year for RPS applicants). If

your experience was gained part-time, or you were working part-time on appropriate activities under the Manufacturer's Licence and part-time on other activities (non-licensed products or activities not covered by the licence, for example R&D), you should count it pro-rata.

If you work for a "virtual" company which holds a Manufacturer's Licence but contracts out part or all of the manufacturing process, in principle this would meet the legal requirements for QP application. You should explain how you meet the practical requirements of the Study Guide.

g Specify your area(s) of expertise under which you are claiming your qualifying experience. Please refer to the Study Guide.

7 Professional experience

Give a complete statement of your employment since graduation or over the relevant period whichever is the shorter. Please provide (with dates), for each stage of your career, an account of the nature of the work and the responsibility involved in each position you have held.

In column (i), your job title and employer should be indicated.

In columns (ii) and (iii), dates should be clearly indicated.

In column (iv),

(a) please list your key responsibilities for each job and describe the range of products and processes to which these responsibilities are applied.

(b) responsibility levels should be stated as A, B, or C.

A = The person 'named' on the licence as being responsible for the activity;

or

B = working under the direct supervision of the 'named' person;

or

C = working in direct collaboration with the 'named' person.

Wherever possible descriptions of your practical experience should be related to the specific areas as outlined in the Study Guide.

Knowledge requirements

Using the spaces provided please demonstrate the extent to which you feel can satisfy (i) the knowledge, and (ii) the experience to satisfy the requirements of the Study Guide.

8 Foundation knowledge requirements:

Pharmaceutical law and administration;

The role and professional duties of a Qualified Person;

Quality management systems.

9 Additional knowledge requirements:

Mathematics and statistics;

Medicinal chemistry and therapeutics;

Pharmaceutical formulation and processing;

Pharmaceutical microbiology;

Analysis and testing;

Pharmaceutical packaging;

Active pharmaceutical ingredients;

Investigational medicinal products.

10 Sponsors

Category A applicants only

Your sponsor's signature is required on each page of sections 8 and 9, and in section 10. Details of the sponsor's responsibilities will be found in the Guidance Notes for Sponsors. The sponsor must be a member of one of the three professional bodies, and should be a QP. If the sponsor is exceptionally not a QP, the sponsor's form should be countersigned by the QP acting for the activities in which the applicant is engaged. If the applicant's qualifying experience has been gained in more than one establishment, then a sponsor's report from each establishment is required to verify the details of this experience.

Category B, C, D and E applicants only

One referee only is required who can certify the accuracy of the information given by the applicant. The referee should sign in the space provided in section 10.

11 Certification by applicant

To be signed by the applicant.

12 Remittance

Please remember to include your credit card number, or a cheque for the relevant application fee made payable to your professional body, with your application form.

3.0 Guidance Notes for Sponsors (for Category A applicants (permanent provisions))

3.1 Introduction

The role of the sponsor during the Qualified Person's training and subsequent application for admission to the register is an important element of the entire process. Sponsorship should only be undertaken after careful consideration of the role and responsibilities involved. The expectation is that the sponsor acts as a mentor and has regular interaction with the applicant.

The sponsor has responsibilities not only to the candidate but also to the professional bodies who consider applications from aspiring Qualified Persons. These guidance notes are intended to clarify the role and responsibilities of the sponsor. If any doubt exists as to the nature and extent of the role of sponsorship, the appropriate professional body should be contacted for advice.

The submission of an inaccurate or misleading report will be regarded by the professional bodies as professional misconduct.

3.2 The role of the sponsor

The sponsor should act primarily as a **guide** or **mentor** who can assist the aspiring Qualified Person by:

providing guidance and direction on the course(s) of study and experience. This exercise must be carried out well in advance of any oral assessment over a period of about 2 years;

assisting in organising a programme of practical experience;

meeting regularly with the aspiring Qualified Person to monitor and review progress, offer advice and answer questions;

encouraging good record keeping against an agreed programme of training covering both knowledge requirements and practical experience requirements;

arranging introductions to key personnel in the company;

exposing the applicant to external influences such as:

- inspections;
- supplier arrangements;
- contractors;
- distributors;
- customers.

3.3 Requirements for the Sponsor

One sponsor is required for each candidate and must be a member of a professional body (the Society of Biology, the Royal Pharmaceutical Society or the Royal Society of Chemistry). The sponsor must be a practising Qualified Person who has known the candidate for the qualifying period of experience required. If this is not possible, a candidate may use a QA line manager provided that the sponsor's report is countersigned by the Qualified Person. The sponsor has a duty to:

- the applicant;
- the applicant's employer;
- the inspection authority;
- their own professional body;
- the general public.

Before agreeing to act, the sponsor should have formed an impression of the applicant's ability to make difficult ("grey area") decisions and to withstand the pressures that are inevitably associated with the professional duties and responsibilities of a Qualified Person.

The sponsor should emphasise the importance of practical training. The sponsor is encouraged to help draw up a programme of practical work for the applicant.

The sponsor should, wherever possible, help the aspiring Qualified Person to relate the theoretical knowledge to the day to day issues involved in the manufacture and control of medicinal products. Integration of the subject matter is important in providing the Qualified Person with a comprehensive body of knowledge.

Sponsors are urged to ensure that the applicant is fully aware of the basic duties and responsibilities of the Qualified Person and to provide information on the nature and extent of compliance with the Study Guide.

3.4 The sponsor - ideal profile

Wide knowledge and experience of pharmaceutical manufacturing, quality assurance and Good Manufacturing Practice.

Thoroughly conversant and up to date with:

- the legal framework – especially United Kingdom and European Union;
- the relationship of the professional bodies with the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate;
- role and responsibilities of the Qualified Person - including the Code of Practice;
- the Study Guide and practical experience requirements.

Possesses a wide view of the pharmaceutical business from Research and Development through Production to Marketing and Distribution.

Is an excellent communicator and possesses good inter-personal skills.

Has very good contacts within the company.

3.5 The Application Form for Qualified Person eligibility

As it provides the assessors with a "first impression", the quality and clarity of the application form is very important.

The application form represents a summation of evidence regarding eligibility. The basic elements include:

- initial formal qualifications;
- knowledge of Study Guide;
- practical experience requirements;
- professional experience;
- sponsors' supporting reports.

The application form should be reviewed by the sponsor prior to submission to the appropriate professional body. Deficient applications will be returned for further clarification.

3.6 The Sponsor's report

The report is a key part of the sponsor's input and it is not sufficient for the sponsors to simply provide a declaration of belief that an applicant complies with the requirements. It should be a **critical** and **honest evaluation** of the candidate's **technical** and **professional knowledge**. It should also include information on the candidate's **personal attributes**.

A description should be provided of the candidate's ability that covers, but is not limited to, the following criteria:

- Ability to achieve good working relationships with persons in other functions within the company
- Communication skills (oral and written)
- Assertiveness
- Flexibility and open mindedness
- How the applicant operates under pressure
- Planning and organising skills
- Professional ethics and integrity
- Reliability
- Problem solving skills
- Any special achievements

It is important to address each of these points, and reports which do not, may be returned for clarification and, accordingly, may delay the processing of the application.

The sponsor must confirm that the applicant has gained the relevant experience under a full Manufacturer's Authorisation and must provide the qualifying Manufacturer's Licence number and issue date. The confirmation must cover the period for which the applicant is claiming his or her qualifying experience.

3.7 Conclusions

The sponsor's role is important and he/she can provide valuable assistance in helping an aspiring Qualified Person to prepare for the goal of eligibility to act as a Qualified Person.

The application form and supporting information from the sponsor provides documented evidence of the candidate's background as a first step in the assessment process. A well

prepared and presented application provides the assessors with a first impression of both the candidate and the sponsor.

The sponsor's report is a vital document and particular care should be taken in compiling it. The sponsor's report must be submitted with the candidate's application to the appropriate professional body. An application will not be reviewed without the sponsor's report.
It is not expected that the sponsor's report will duplicate that of the candidate. The report should record pertinent additional information only.

The sponsor should remind the applicant that assessment will be on the Study Guide, and should aim to assess the applicant on the Study Guide before assessment.

Should a sponsor require any further advice on fulfilling his or her role, he or she should refer to his or her own professional body:

4.0 Contact details for QP applications and enquiries

Society of Biology
9 Red Lion Court
London EC4A 3EF

www.societyofbiology.org

QP Officer
Royal Pharmaceutical Society
1 Lambeth High Street
London SE1 7JN

www.rpharms.com

Registration Officer
Royal Society of Chemistry
Burlington House
Piccadilly
London W1J 0BA

www.rsc.org/qp