

**ROYAL  
PHARMACEUTICAL  
SOCIETY**



**Qualified Person involved in the manufacture of  
pharmaceuticals**

# **Guidance Notes**

**For Applicants and Sponsors**

**November 2020**

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## 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, the Human Medicines Regulations 2012 and the Pharmaceutical Directive 2001/83/EC. The Pharmaceutical Directive requires that, in order to obtain authorisation, the applicant for a Manufacturer's Authorisation (may be known as a Licence herein) 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 Royal Pharmaceutical Society, the Royal Society of Biology 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.

Applications can still be made under the transitional provisions of Directive 2001/83/EC.

Alternatively, practitioners can seek to satisfy the permanent provisions of the Directive which call for formal qualifications and knowledge specified in the Directive. 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.

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 Directives and in UK legislation implementing the Directives.

Each of the three professional bodies has responsibility for certification of its members.

Dates given in these Guidance Notes are derived from the Directives or the UK legislation and are not open to amendment or re-negotiation on the part of the professional bodies or their individual members.

**Certification by the professional body under these arrangements does not necessarily ensure that nomination as a Qualified Person in respect of any particular manufacturer's authorisation will be accepted by the Licensing Authority.**

## 2.0 Applying for assessment for QP eligibility by the permanent provisions (Category A)

### 2.1 Requirements for application

Those eligible to apply will hold formal qualifications in chemistry, pharmacy, medicine, veterinary medicine, pharmaceutical chemistry and technology or biology (or in certain circumstances, 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. You must produce evidence of adequate knowledge of the subjects listed in the Study Guide (The knowledge and practical experience required by Qualified Persons involved in the manufacture of pharmaceuticals in the UK), **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. This comprises two parts. You submit a written application which is reviewed by the assessors. If this is deemed satisfactory, you will be invited to attend a panel interview.

At the end of the interview you will be informed whether you have satisfied the assessors and have passed or failed. If you pass, you are eligible for nomination to the Register of Eligible QPs of your professional body. If you do not satisfy the assessors, you will be informed of the reasons, and given guidance on how to prepare for reapplication.

If you wish to appeal against the result of your assessment, you should contact the QP Officer of your own professional body. **An appeal must be made within 28 days of the date on your result letter.**

You require a sponsor, who must be a member of a professional body (the Royal Pharmaceutical Society, the Royal Society of Biology or the Royal Society of Chemistry). The sponsor should be a practising Qualified Person who has known you professionally for the qualifying period of experience required. If this is not possible, you may use a QA line manager provided that the sponsor's report is countersigned by the Qualified Person acting for the activities in which you are engaged. Your sponsor is expected to:

- certify that you have 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.

Support from your sponsor is essential to your success, and he or she should allocate sufficient time to ensure that you are fully prepared for your application. Your sponsor should act as a mentor, and should support your training and advise you when you are ready to apply for assessment. Your sponsor should refer to the Study Guide and ensure that he or she is able to verify that you have the necessary skills, knowledge and personal attributes to act as a Qualified Person.

If you obtained your qualifying experience in more than one establishment, you need a sponsor's report for each period of experience.

## **Royal Pharmaceutical Society**

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

- (i) Member or Fellow or Associate or Pharmaceutical Scientist member of the Royal Pharmaceutical Society who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent. In certain circumstances, Pharmaceutical Scientist membership might not be sufficient and therefore potential applicants should check with the QP Officer that their qualifications meet the eligibility requirements.
- (ii) At least two years' 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.

In the UK the normal two year experience requirement is reduced to one year in the case of pharmacists who have been registered in Great Britain or Northern Ireland 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 Royal Pharmaceutical Society, the Royal Society of Biology and the Royal Society of Chemistry.

## **Royal Society of Biology**

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

- (i) Either a Chartered Biologist (CBiol MRSB or CBiol FRSB), or a Fellow (FRSB) or Member (MRSB) or Associate with designatory letters AMRSB 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 Royal Society of Biology of the acquisition of the body of knowledge which is described in a joint Study Guide prepared by the Royal Pharmaceutical Society, the Royal Society of Biology and the Royal Society of Chemistry.

## **Royal Society of Chemistry**

The requirements of the permanent provisions which relate to a chemical scientist 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 Royal Pharmaceutical Society, the Royal Society of Biology and the Royal Society of Chemistry.

## **2.2 Application documents**

You should download the application documents from your professional body's website (refer to Section 4). You require:

- Study Guide
- Guidance Notes for Applicants and Sponsors
- Application Form
- Sponsor's Form
- QP Code of Practice

## **2.3 Guidance Notes for sponsors**

### **2.3.1 The role of the sponsor**

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 process. Sponsorship should only be undertaken after careful consideration of the role and responsibilities involved. Our expectation is that you act as a mentor and have regular interaction with the applicant.

The application form and the sponsor's form provide documented evidence of the applicant's background as a first step in the assessment process. A well prepared and presented application provides the assessors with a good first impression of both the applicant and the sponsor.

As a sponsor, you have responsibilities not only to the applicant but also to the professional bodies who consider applications from aspiring Qualified Persons. If you require any further advice on fulfilling the role of the sponsor, you should refer to your own professional body.

### **2.3.2 Requirements for the sponsor**

The sponsor must be a member of a professional body (the Royal Pharmaceutical Society, the Royal Society of Biology or the Royal Society of Chemistry). The sponsor should be a practising Qualified Person who has known the applicant for the qualifying period of experience required. If this is not possible, an applicant may use a QA line manager provided that the sponsor's report is countersigned by the Qualified Person acting for the activities in which the applicant is engaged.

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, you 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.

You should emphasise the importance of practical training. You are encouraged to help draw up a programme of practical work for the applicant.

You 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.

You 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.

The sponsor should:

- have wide knowledge and experience of pharmaceutical manufacturing, quality assurance and Good Manufacturing Practice.
- be thoroughly conversant and up to date with the legal framework (UK and EU);
- understand the relationship of the professional bodies with the MHRA and the VMD;
- understand the role and responsibilities of the Qualified Person, including the Code of Practice;
- understand the Study Guide and the practical experience requirements;
- possess a wide view of the pharmaceutical business from Research and Development through Production to Marketing and Distribution;
- be an excellent communicator and possesses good inter-personal skills; and
- have very good contacts in and outside the company.

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

- providing guidance and direction on the course of study and acquisition of experience. This should happen well in advance of the applicant submitting the application, perhaps over a period of about two 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 and outside the company; and
- exposing the applicant to external influences such as:
  - inspections;
  - supplier arrangements;
  - contractors;
  - distributors; and
  - customers.

You should remind the applicant that assessment will be on the Study Guide, and should ensure that he or she experiences some practice questioning, particularly on scenario-type situations, before assessment.

### 2.3.3 The sponsor form (sponsor's report)

Your completed sponsor form must be submitted to the appropriate professional body with the application. An application will not be reviewed without the sponsor's report. Your report should record pertinent additional information only, and should not duplicate that of the applicant.

The report is a key part of the sponsor's input and it is not sufficient for you to simply provide a declaration of belief that an applicant complies with the requirements. It should be a **critical** and **honest evaluation** of the applicant's **technical** and **professional knowledge**. It should also include information on the applicant's **personal attributes**, including his or her strengths and weaknesses or areas for development.

You should provide a description, and examples, of the applicant'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 application.

You must also confirm that the applicant has gained the relevant experience under a full Manufacturer's Authorisation and must provide the qualifying Manufacturer's Authorisation number and issue date. The confirmation must cover the period for which the applicant is claiming his or her qualifying experience. You can only provide a report for the time for which you have direct experience of the applicant's work. If an applicant's qualifying experience is made up of time in more than one establishment, a sponsor's report is required for each period. The application documents require further details on the sponsor's relationship to the applicant in respect of employment during his/her qualifying period of experience.

You must also sign each part of sections 8 and 9 of the application form where indicated, to confirm that you have reviewed the application.

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

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



Should your qualifying experience not be from your current role, you will also be expected to provide a sponsor form from your current employer.

## **2.4 Completing the application form**

You should complete all sections of the Application Form. As it provides the assessors with a “first impression”, the quality and clarity of the application form is very important. You and your sponsor should review the form prior to submission. Include all pertinent information on the form. Incomplete or deficient forms will be returned.

### **Section 1: Name and contact information**

Enter the address, telephone number and email address you wish us to use for correspondence. Please provide an alternative email and telephone number for the very rare occasion when we need to contact you urgently before the interview.

### **Section 2: Membership**

Specify which professional body you belong to, and add your membership number and designatory letters.

### **Section 3: Category of application**

Specify the category under which you are applying, and state whether you have applied before.

### **Section 4: Qualifying experience**

State your area of expertise (the types of products and processes for which you are claiming your qualifying experience). Please refer to the Study Guide.

State the employer(s) and the dates worked which satisfy the practical experience requirements. Please also provide the number and date of issue of the Manufacturer’s Authorisation(s) under which these requirements were satisfied. Please ensure that the dates cover the whole period of experience required (one or two years for RPS applicants, two years for RSB and RSC applicants).

If your experience was gained part-time, or you were working part-time on appropriate activities under the Manufacturer’s Authorisation and part-time on other activities (nonlicensed 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 Authorisation 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.

### **Section 5: Employment**

Enter your job title, the name and address of your current or most recent employer and a daytime telephone number. You should briefly explain your job function as this is not always clear from your job title.

## **Section 6: Education and training**

Provide details of your post-A-level or other post-18 educational qualifications and training, and of any other study relevant to the role of the QP. Please provide dates (dd/mm/yy). You should provide photocopies of any result letters or certificates, signed by your sponsor to verify that they are true copies. Do not send original certificates as these are not returned.

## **Section 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 – mm/yy), for each stage of your career, an account of the nature of the work and the responsibility involved in each position you have held. You should list your key responsibilities for each job and describe the range of products and processes to which these responsibilities are applied.

The responsibility levels should be stated as A, B, or C:

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

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

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

You should include employment not in licensed activities, as although this does not contribute towards the licensed practical experience requirements, you may have gained valuable additional relevant knowledge and experience.

## **Sections 8 and 9: Study Guide Knowledge requirements**

This is your opportunity to demonstrate that you are equipped with the knowledge and understanding you need to act as a QP. The descriptions of your practical experience should be related to the specific areas as outlined in the Study Guide. You should demonstrate the extent to which you can satisfy (i) the knowledge, and (ii) the experience to satisfy the requirements of the Study Guide. You should discuss the content of these sections with your sponsor.

You are advised to start on the application form well before you intend to apply. You and your sponsor can then use the form and the Study Guide to identify gaps in your knowledge and experience, and ensure they are filled before you apply.

### **Section 8: Foundation knowledge elements**

- Pharmaceutical law and administration;
- The role and professional duties of a Qualified Person; and
- Pharmaceutical Quality Systems.

### **Section 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; and
- Investigational medicinal products.

### **Education**

- Give the course dates (mm/yy to mm/yy or for short courses dd/mm/yy), a brief account of the content of the course and what you gained from it in relation to your knowledge and understanding of the Study Guide.
- If the course was not recent, indicate how you have kept your knowledge up to date.

### **Experience**

- Be specific about your involvement in activities which demonstrate your experience in each section. Were you directly involved, or indirectly via meetings or visits?
- Most applicants have more experience in some areas of the Study Guide than in others. If you have not had much direct experience in an area, explain how you gained the necessary knowledge and understanding, for example by attending courses, visits, time spent at a different company to learn about a different activity. If you write “I am aware of...” or “I have an understanding of...”, please add some context. For example, “I have achieved an understanding of the ICH guidelines for method validation whilst employed at YYY where I used the guidelines to develop methods of analysis using HPLC for ZZ products”.
- Ensure your evidence is relevant. Avoid duplication, although some experience may be relevant to more than one section.

### **Section 10: Sponsor(s)**

Your sponsor’s signature is required for each part of sections 8 and 9, and in section 10.

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 you are engaged.

If your 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.

### **Section 11: Certification by applicant**

Please sign and date.

### **Section 12: Fee**

You can pay by cheque or credit card. The current fees are on the websites. Application fees are not refundable and are subject to variation without notice, although normally we will give at least two months’ notice of any change.

## Section 13: Completing your application

There is a checklist at the end of the application form. Your sponsor should review your application form, then you should send your completed application to the QP Officer at your own professional body.

### 2.5 The assessment process Review of application

Your QP Officer will ensure that your application is complete and that you satisfy the requirements for qualifications and membership. Your application will then be sent to two assessors from the QP Panel of Assessors for your own professional body.

The assessors will review your application against the Study Guide to ensure that you meet all the requirements. If there is insufficient evidence for the assessors to determine whether your knowledge and experience meet the requirements of the Study Guide, they may ask for more information for one or more sections, which will cause a delay. You should send the additional information within **three months** of the request, so that your application remains an up-to-date account of your experience. Your additional information must be approved and signed off by your sponsor.

Only when the assessors are satisfied that your account of your knowledge and experience satisfies the requirements of the Study Guide will they recommend that you be invited for interview. When the assessors are satisfied, your QP Officer will contact you to agree an interview date.

You should be ready for assessment when you apply. We will usually give you at least 4 weeks' notice of an interview date, although occasionally dates are available at shorter notice.

If the assessors consider that you should not be invited for interview, your QP Officer will contact you and advise you how to proceed.

### The interview

Your interview will be in London at the offices of one of the three professional bodies. We have a joint programme of interviews and will offer you the first available date regardless of location. You will be sent an invitation with details on the address for your interview (this may differ from our contact details). If you require any reasonable adjustment or special access arrangements, please contact your QP Officer at the earliest possible opportunity.

An interview panel is normally three assessors, one from each professional body, and the interview will be chaired by the assessor from your own professional body. Your QP Officer will attend and will note the questions. There may also be an observer (usually an assessor in training, or a representative of the MHRA and VMD who regularly observe interviews), who will take no part in the interview.

The assessment normally lasts 1 to 1¼ hours. The assessors will ask fact-based and scenario questions. They will inform you of the result after the interview.

If you have satisfied the assessors, you are eligible for nomination to the Register of Eligible QPs of your professional body. Your QP Officer will write to you to confirm the result and you will receive your certificate.

If you have not satisfied the assessors, they will tell you why and will advise you on how to proceed. They may recommend particular activities that they consider would help you enhance your knowledge and experience, and may suggest an approximate time that this might take. This will be confirmed in a letter. You can reapply, and when you do, you should ensure that you and your sponsor have read the letter from your previous application, and provide evidence that you have addressed the assessors' concerns. You should submit a new application form and fee.

### 3.0 Applying for certification by the transitional provisions (Category B, C, D and E) 3.1

#### Requirements for applying for certification

A less formal procedure than is the case for Category A is required for application and certification under Categories B, C, D and E. Applications are considered individually subject to the submission of the required evidence, certified by a referee acceptable to their professional body.

**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 Authorisation 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 Manufacturer's 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 Manufacturer's 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 Manufacturer's 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 Manufacturer's 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.

### **3.2 Application documents**

You should download the application documents from your professional body's website (Refer to Section 4). You require:

- Study Guide
- Guidance Notes for Applicants and Sponsors
- Application form
- QP Code of Practice

### **3.3 Completing the application form**

You should complete sections 1 to 7 and 10 to 13 of the application form.

For Category B or C certification (Transitional provisions of 2001/83/EC), you do not need to complete sections 8 and 9 of the application form. You should obtain the signature of a suitable referee in Section 10 of the form. Your referee should be a member of one of the professional bodies and should be demonstrably in a position to offer the necessary certification concerning your eligibility and compliance with the appropriate conditions according to the category, that is they have direct personal knowledge of the activities. You should refer to the Study Guide for details of the subject/topic areas in which adequate knowledge is required. The referee's report shall remain confidential to the Joint Professional Bodies.

For 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) certification, you do not need to complete sections 8 and 9 of the application form.

You 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. You should send a copy of this authorisation, signed as a true copy by a suitable referee, who should sign section 10. Your referee should be a member of one of the professional bodies.

### **3.4 Certification**

If your evidence is satisfactory, you are eligible for nomination to the Register of Eligible QPs of your professional body. Your QP Officer will write to you to confirm the result and you will receive a certificate. If your evidence is insufficient to establish your eligibility, we will request you to provide additional evidence to fill any gaps.

#### **4.0 Contact details for QP applications and enquiries**

If you need more information or have questions about your application, please refer to the websites of each professional body, or you can contact your QP Officer:

##### **RPS**

QP Officer  
Science and Research Team  
Royal Pharmaceutical Society  
66-68 East Smithfield  
London  
E1W 1AW

Tel: 020 7572 2737

Email: [QPOfficer@rpharms.com](mailto:QPOfficer@rpharms.com)

Website: [www.rpharms.com](http://www.rpharms.com)

##### **RSB**

QP Officer  
Royal Society of Biology  
1 Naoroji Street  
London  
WC1X 0GB

Tel: 020 7685 2550

Email: [qp@rsb.org.uk](mailto:qp@rsb.org.uk)

Website: [www.rsb.org.uk](http://www.rsb.org.uk)

##### **RSC**

QP Officer  
Royal Society of Chemistry  
Thomas Graham House  
Science Park, Milton Road  
Cambridge  
CB4 0WF

Tel: 01223 432141

Email [qp@rsc.org](mailto:qp@rsc.org)

Website: <http://rsc.li/qp>