Guidance Notes

For Applicants and Sponsors

Contents

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1.0 Introduction

To assure patient safety, the manufacture and distribution of pharmaceutical products is highly regulated within the UK. The Qualified Person (QP) must ensure that all legislative obligations are fully satisfied before any product is certified and released for sale or supply in countries where manufacturing has occurred or where the product will be distributed.

A QP must have a comprehensive knowledge of all current and forthcoming UK and European legislation relating to the manufacture, storage and supply of licensed medicinal products (human and veterinary), Investigational Medicinal Products and the interpretation of the law and guidance. Legislation is subject to regular update and details of major changes can be found in FAQs published on the Royal Pharmaceutical Society, the Royal Society of Biology or the Royal Society of Chemistry websites – hereafter called the Joint Professional Bodies (JPB) or individual Professional body (PB).

The QP fulfils certain minimum conditions of qualification and experience. These conditions are detailed in section 2.1. It should be noted that no existing single first degree or other qualification awarded in the United Kingdom meets the conditions of the Study Guide in full. For any queries regarding your qualifications, contact the QP Training Officer.

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

2.1 Educational Requirements for application

The following educational requirements for a QP are detailed in UK Statutory Instruments, “The Human Medicines Regulations 2012”, No. 1916, Schedule 7, Part 1 Paragraphs 2, 3 and 4.

A degree, diploma, or other formal qualification in:

- pharmacy;
- medicine;
- veterinary medicine;
- chemistry;
- pharmaceutical chemistry and technology
- biology

A qualification satisfies the requirements of this Part if it is awarded on completion of a university course of study, or a course recognised as equivalent by the Member State in which it is studied, which—

- includes the core requirements listed below; and extends over a period of at least three years of theoretical and practical study of the degree, diploma or formal qualifications liM

medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure iityof(m)-6 (edi)2.7 (c)-2 (i)2.6 (nal)2.6 ((pr)-5.9 (od)10.5 u(c)-2 (t)-6.6 (s)-2 .f)4.3 ( )]TJ0 Tc

- meeting regularly 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.

The above list is not exhaustive and the sponsor needs to be familiar with the breadth and depth of the study guide to ensure that the applicant is prepared for their interview against the requirements of the Study Guide and that they experience some practice questioning, particularly on scenario-type situations, before assessment.

The sponsor must not be a member of the applicant's family. This includes spouses and unmarried partners.

2.5.3 The sponsor form (sponsor's report)

The completed sponsor form must be submitted to the appropriate PB with the application. An application will not be reviewed without the sponsor's report. The 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 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 their strengths and weaknesses or areas for development.

The form requires 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)
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The sponsor must also confirm that the applicant has gained the relevant experience under a full Manufacturer's/Importers Authorisation and must provide the qualifying Manufacturer's/Importers Authorisation number and issue date. The confirmation must cover the period for which the applicant is claiming their qualifying experience. The sponsor can only provide a report for the time for which they have direct experience of the applicant's work. If an applicant's qualifying experience is made up of time in more than one establishment or covers sponsorship by more than one QP, a separate 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 their qualifying period of experience.
The sponsor must also sign each part of sections 8 and 9 of the application form where indicated, to confirm that you have reviewed the application and that the contents are accurate. If there are parts of the form where the sponsor cannot confirm experience, for example, if the applicant is describing work done in a different facility, the limitations should be listed on the sponsor's form.

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 JPBs.

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

2.6 Completing the application form

All sections of the Application Form need to be completed. As it provides the assessors with a "first impression", the quality and clarity of the application form is very important and all pertinent information should be included. The form and any supplemental information should be reviewed in full by both the applicant and the sponsor prior to submission. Incomplete or deficient forms will be returned, and progression of the application will be delayed. The applicant should be ready for assessment at the time of application. **If the applicant requires any reasonable adjustment or special access arrangements, it is helpful to let the QP officer know at the time of your application.**

Section 1: Name and contact information

Enter the address, telephone number and email address you wish your PB to use for correspondence. Please provide an alternative email and telephone number for the very rare occasion when urgent contact is needed before the interview.

Section 2: Membership

Specify which PB the applicant belongs together with the membership number and designatory letters.

Section 3: Category of application

Confirm the category under which the application is being made and any previous application.

Section 4: Qualifying experience

State the area of expertise (the types of products and processes for which the qualifying experience is being claimed). 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/Importers 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/Importers Authorisation and part-time on other activities

    - Pharmaceutical Quality Systems.
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3.0 Contact details for QP applications and enquiries

For more information or specific queries about the application process, please refer to the websites of each PB or contact a 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
Website: https://www.rpharms.com/development/education-training/training/qualified-persons-a-guide

RSB

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

Tel: 020 3925 3440
Email: qp@rsb.org.uk
Website: https://www.rsb.org.uk/careers-and-cpd/registers/qualified-person

Appendix 1: Permanent Provision requirements for PB

Royal Pharmaceutical Society

(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.