HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Attainment of Qualified Person Status in Ireland: Educational Requirements, Training and Licensing

1 INTRODUCTION

This document is intended to provide guidance to individuals considering pursuing a career in the pharmaceutical industry as a Qualified Person (QP). It identifies the educational requirements to become a QP and the way the Health Products Regulatory Authority (HPRA) approves QP candidates. It also provides candidates with suggestions for additional reading material which should be considered before embarking on further education.

2 DEFINITION

A Qualified Person or 'QP', is defined within Irish law applicable to human medicinal products as 'a person with the qualifications and experience specified in Schedule 5 and named in the manufacturer's authorisation as being responsible at the manufacturer's premises for the functions set out in Regulation 13(3)'.[1] A similar definition is provided for in Irish law relevant to veterinary medicinal products.[2] The qualifications, experience and licensing requirements pertaining to QPs in Ireland are described below.

3 LEGAL BASIS

The legal bases for QPs are described in the EU Regulations 536/2014 and 2019/6, and the EU Directive 2001/83/EC. These regulations and the directive apply to the manufacturers of investigational, veterinary and human medicinal products respectively.[3] The Directive has been transposed into Irish national law.[1]

4 LEGAL RESPONSIBILITY

The primary legal responsibility of the QP is to certify batches of medicinal products prior to use in a clinical trial, export or prior to release for sale and placing on the market. It is a legal requirement for a manufacturer of medicinal products to have at least one QP available.

5 EDUCATIONAL REQUIREMENTS

There are four routes by which a person can qualify to become a QP in Ireland:

Route 1

A candidate has completed a recognised pharmacy degree course at a third level institution in Ireland. If the pharmacy course has been completed outside of Ireland, then applicants should provide one of the following documents:

- Evidence of Pharmaceutical Society of Ireland (PSI) registration.
- A letter from the EU competent authority where the pharmacy degree was pursued which states that the candidate's degree meets the educational requirements of Article 49 of EU Directive 2001/83/EC and Article 97 of the EU Regulation 2019/6.

Route 2

A candidate has attained an academic qualification at least equivalent to a level 8 primary course in a scientific discipline and has successfully completed a recognised post-graduate course[4] in Ireland that satisfies the educational requirements as defined in the EU Regulation 2019/6 and the EU Directive 2001/83/EC.

Route 3

At the time of application of the relevant EU Directives in Ireland or in another Member State, the candidate was undertaking the activities of a QP. These were referred to as the 'transitional arrangements' or 'Grandfather Clauses'.

Applicants should provide evidence that the proposed person had acted as a QP, under a relevant MIA in Ireland authorised for the type of medicinal product which is the subject of the application (i.e. human, veterinary, IMP and/or traditional herbal medicinal products).

Refer to Article 50 of Directive 2001/83/EC for more details.

Route 4

A candidate that has completed a postgraduate QP eligibility course in another EU Member State, that satisfies the educational requirements.

6 EXPERIENCE REQUIREMENTS

A candidate should have acquired practical experience, in one or more undertakings which are authorised to manufacture medicinal products, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and of testing and checking to ensure the quality of medicinal products. The duration of practical experience is usually at least two years, but it may be reduced by one year if the primary course of study lasts for at least five years and by a year and a half where the course lasts for at least six years. Relevant work experience that counts towards the two years criteria must have been obtained at sites which hold a MIA within the European Economic Area (EEA).

Notes:

- Experience gained at a site that holds an active substance registration (ASR) but does not hold an MIA does not count towards relevant work experience.

- Only experience gained at a site that holds an MIA in the United Kingdom (UK) up until 31 January 2020 (day the UK left the EU) counts as relevant work experience; with the exception of Northern Ireland, where experience gained post 31 January 2020 still counts.

- Experience gained at a site prior to the issue of the site's MIA does not count towards relevant work experience.

- The reduction in the requirement for practical experience due to a university course being five or six years in duration only applies when a single course was completed to meet the educational requirements as defined in the EU Regulation 2019/6 and the EU Directive 2001/83/EC. Where more than one course is completed to meet the educational requirements, combining the duration of multiple courses cannot be utilised to reduce the number of years of practical experience required to less than 24 months.

7 TRAINING REQUIREMENTS

A candidate should have completed training in all key elements of the company's quality management system to enable them to effectively carry out the routine duties of a QP. This should include a documented justification that the QP candidate has gained the necessary knowledge and experience in relation to the types of products which they will be expected to perform disposition.

8 QUESTIONS AND ANSWERS

8.1 My primary qualification fulfils the educational requirements outlined in section 5 (Route 2) above. What additional course do I need to study and complete before I can become a QP candidate?

There are several educational institutes in Ireland that offer a course that will fulfil the educational requirements as outlined above. These institutes and course are listed in Appendix 1[4]. The HPRA has evaluated each course and is satisfied that their curricula cover the required subjects in line with the Directive's requirements.

8.2 Where can I obtain further information on courses?

If you do not hold a pharmacy degree but have a scientific qualification which may be acceptable to gain entry to one of the courses referenced in Appendix 1, contact a third level institute of your choice to discuss your interest in studying the appropriate course. It is important that candidates interested in pursuing courses leading to eligibility to act as a QP verify in advance of registration that the course they are applying for meets the legal educational requirements, as there are a number of courses with similar titles and not all are accepted for this purpose.

8.3 What type of level 8 degree is considered suitable as a primary degree?

Any medical, health or relevant science based level 8 degree. If the science-based degree has been completed outside of Ireland, evidence that the course is recognised as meeting a level 8 degree should be provided.

8.4 Can I call myself a QP when I successfully complete my exams?

If you can demonstrate that you meet the requirements outlined in section 5 above, you are eligible to become a QP candidate on a HPRA MIA. As part of the assessment of the application

your experience and training are reviewed to determine if you can act in the capacity of a QP. If approved, your name and qualifications are included on the MIA.

8.5 How do I become named as a QP on the MIA held by a finished product manufacturer in Ireland?

Your employer should submit an application for variation to its MIA to request that you be added as a QP.

8.6 I have satisfactorily completed studies in another country within the EEA and the local competent authority for the regulation of medicinal products in that country recognises the course as fulfilling the education requirements, as described above, to enable me to become an eligible QP candidate. Do I have to complete another university course in Ireland?

No. As the course you studied satisfies the EU Directive requirements for the EEA, the course is recognised in Ireland as being equivalent to courses which are offered in Ireland. You may be asked to provide documentary evidence from the competent authority in the Member State where the studies were undertaken, indicating that it recognises the course as fulfilling the educational requirements as defined in EU Directive 2001/83/EC and Regulation 2019/6.

8.7 What level of training is required at the MIA holder site before my employer can submit a variation to include me as a QP on the MIA?

Prior to undertaking any QP batch certification activity you should be appropriately trained on the pharmaceutical quality system, have knowledge of the type of products to be certified and be familiar with the manufacturing operations performed at the MIA site where you are being nominated as a QP. Previous experience at an MIA holder site for similar dosage forms may be considered.

The following records should be submitted to support the application:

- A summary of training, relevant to the role of QP, performed at the manufacturing site concerned. This should be in the form of a training programme for the role of QP at the site rather than simply a printout of training in various standard operating procedures (SOPs), for example as might be obtained from a learning management system. This should be signed by the proposed QP and, if applicable, their relevant superior.
- Details of product specific training should also be included in cases when the proposed QP does not have previous experience of the product types to be certified.
- Where all relevant training has not been completed at the time of application, then a statement should be included in the training summary or in the application submission stating that the required minimum training will be completed prior to commencement of batch certification activity by the proposed QP.

Further information is available on the HPRA website www.hpra.ie.

HPRA
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APPENDIX 1 REFERENCES

1 Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007), as amended

2 European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007), as amended

3 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use

4 Irish educational institutions offering courses for which the taught modules satisfy the educational requirements for QPs:

Institute	Course title
Trinity College Dublin	Pharmaceutical Manufacturing Technology (MSc/P.Grad.Dip)
Sligo Institute of Technology	MSc in Industrial Pharmaceutical Science
University College Cork	MSc in Pharmaceutical Technology and Quality Systems