

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 manner in which 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 EU Directives 2001/20/EC, 2001/82/EC and 2001/83/EC. These Directives apply to the manufacturers of investigational, veterinary and human medicinal products respectively.³ The EU Directives have 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 or prior to release for sale and placing on the market. It is a legal requirement for a manufacturer of finished medicinal products to have at their disposal the services of at least one QP.

5 EDUCATIONAL REQUIREMENTS

There are three 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 institute in Ireland. If the pharmacy course has been completed outside of Ireland then it should be a course that is recognised by the Pharmaceutical Society of Ireland.

Route 2

A candidate has attained an academic qualification at least equivalent to a level 8 primary course in a scientific discipline that may allow entry into a recognised post-graduate course which, together with the primary qualification, satisfies the educational requirements as defined in EU Directives 2001/82/EC and 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'. It should be noted that these provisions only applied for a limited period around the time of transposition of the Directives into the relevant national legislation.

6 QUESTIONS AND ANSWERS

6.1 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 1⁴. The HPRA has evaluated each course and is satisfied that their curricula cover the required subjects in line with the Directive's requirements.

6.2 Can I call myself a QP when I satisfactorily 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 manufacturer's/importer's authorisation (MIA) application or MIA variation application. As part of the assessment for 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.

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

Your employer should submit a variation to their MIA to request that you be added as a QP.

6.4 Do I require a specific amount of work experience before my employer can submit a variation to include me as a QP on the MIA?

All candidates should have acquired practical experience, in one or more undertakings which are authorised to manufacture medicinal products, in the activities 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 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. Other experience gained in a pharmaceutical facility may be considered acceptable.

6.5 What type of training do I have to undertake at my company before the variation application is submitted to include me as a QP on the MIA?

Each 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 disposition.

6.6 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.

6.7 I have satisfactorily completed studies in another country within the European Economic Area (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 eligible to become a 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 Directives 2001/82/EC and 2001/83/EC.

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

Directive 2001/82/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to Veterinary Medicines

Directive 2001/83/EC of the European Parliament and of the Council of 6th 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 institutes offering courses which satisfy the educational requirements for QPs:

Institute: Trinity College Dublin

Course title: Pharmaceutical Manufacturing Technology (MSc/P.Grad.Dip)

Institute: Sligo Institute of Technology

Course title: MSc in Industrial Pharmaceutical Science

Institute: University College Cork

Course title: MSc in Pharmaceutical Technology and Quality Systems