

19.B.3 Qualification and experience

The initial Directive 75/319/EEC explained in detail the required qualifications and experience to become a Qualified Person. These requirements, then called “*minimum conditions of qualification*”, have been adopted into the codified Directive 2001/83/EC unchanged. When Directive 2001/83/EC was amended by Directive 2004/27/EC the terminology was changed from “minimum conditions of qualification” to “conditions of qualification”.

The basic requirement to become a Qualified Person (QP) in a Member State of the European Union is a completed four years theoretical and practical study – or a shorter study e.g. of three years recognized as equivalent by the Member State concerned – in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology. However, if this study is not pharmacy, all basic subjects from the curriculum of pharmaceutical studies that have not been studied have to be acquired by additional training courses. The adequacy of this training has to be confirmed by the relevant National Authority.

Additionally, acquired practical experience is required over a period of at least two years, in one or more companies authorized to manufacture medicinal products in the EU, covering qualitative analysis of medicinal products, quantitative analysis of active substances and testing and checking the quality of medicinal products.

The relevant paragraphs of the Directive 2001/83/EC describing the required qualification and experience are cited in figure 19.B-3.

The preference for pharmacists as QPs, anchored in Directive 75/319/EEC after a European consultation and legislation procedure – obviously unnoticed and missed by the professional societies representing natural sciences like biology or chemistry – is disputed until today. As a consequence, it represents the requirement within the QP regulations that is interpreted very differently by Member States during adoption into national legislation.

Member States like the UK have a long tradition of natural scientists acting as Heads of Quality Control, Assurance and Operations, with only limited resources of industrial pharmacists. In the UK the professional scientific bodies – Institute of Biology, the Royal Pharmaceutical Society and the Royal Society of Chemistry – perform the initial and the ongoing continuous training of natural scientists to qualify as Qualified Person, based on a Study Guide, which has been jointly developed and adapted. Furthermore, these societies are required by the authorities to assess the eligibility of their members for Qualified Person status and to run an indicative register of Qualified Persons. A totally different approach is taken by France, strictly requiring that the *Pharmacien responsable* is a pharmacist.

Figure 19.B-4 lists the different approaches of the various Member States as known today.

Directive 75/319/EEC and the following revisions and amendments require national Regulatory Authorities to keep an indicative register or equivalent documentation ensuring that a Qualified Person named in the Marketing Authorization or in the Manufacturing Authorization is appropriately qualified according to the

Minimum conditions of qualification according to Directive 2001/83/EC as amended by Directive 2004/27/EC**Article 49; 2.**

A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines:

- pharmacy,
- medicine,
- veterinary medicine,
- chemistry,
- pharmaceutical chemistry and technology,
- biology.

[...](Paragraphs describing equivalency of shorter studies, not cited here)

The course shall include theoretical and practical study, bearing upon at least the following basic subjects:

- Experimental physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Physiology
- Microbiology
- Pharmacology
- Pharmaceutical technology
- Toxicology

Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).

Studies in these subjects should be so balanced as to enable the person concerned to fulfill the obligations specified in Article 51.

In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfill the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.

Article 49; 3.

The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products, 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 duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

Figure 19.B-3 Required Qualification and Experiences

Differences between national qualification requirements	
Member States strictly requiring a study of pharmacy as qualification.	France, Estonia, Portugal, Slovenia
Member States requiring an additional university study of selected elements and modules of a full study of pharmacy as qualification	Germany (rigidity depending on local authority)
Member States requiring additional training of elements and modules of a study of pharmacy as qualification, provided by an university, by professional bodies or commercial suppliers (in connection with a university certification process)	Austria, Czech Republic, Denmark, Ireland, Italy, Lithuania, Netherlands, Belgium, Luxembourg, Spain, Sweden, UK, Finland (however, if the Qualified Person is not a Pharmacist, the company has to engage a pharmacist responsible for the Pharmacovigilance system)

Figure 19.B-4 Requirements for natural or medicinal scientists to qualify as Qualified Persons

terms of the Directive. Once this is achieved, the status of this Qualified Person is recognized throughout the European Union and the person is eligible to be named as a Qualified Person in any Member State. Therefore the different standards applied by the different National Authorities, which have different educational and experience requirements to become a QP, contradict the concept of Freedom of Movement in Europe to some extent.

An additional element of the qualification and experience of Qualified Persons is the requirement for an ongoing training, as required in Annex 16 of the EU Guide (see Chapter C.6.16 *Annex 16 Certification by a Qualified Person and Batch Release*):

“8.3 A Qualified Person should maintain his knowledge and experience up to date in the light of technical and scientific progress and changes in quality management relevant to the products which he is required to certify.”

However, there are neither specific requirements regarding the content of the continuous training defined in the EU legislation nor harmonized expectations describing the frequency and the rigor of such an ongoing training. To ensure that appropriate standards of continuous training are maintained, the Qualified Persons in the UK and Ireland are subject to a Code of Practice, and the professional body of which the Qualified Person is a member of provides regular and continuous training.

The Compilation of Community Procedures on Inspections and Exchange of Information – set up by EMEA for GMP inspectors – states that a GMP inspector *“should preferably have the same level of qualification as the Qualified Person ...”* This implies that the recommendations given in this compilation may serve as a rationale for a continuous training of Qualified Persons.