ECA QP ASSOCIATION
An ECA Foundation Interest Group

ECA Foundation
Fostering harmonisation of GMP/GDP regulations

EQPA Code of Practice for QPs

– Duties and Responsibilities for Qualified Persons in the EU –
Annex on National QP Implementation

A guidance document by the ECA Foundation
Version 2; December 2024

Annex on national QP implementation
Annex to EQPA Good Practice Guide
Version 2.0

Contents

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EQPA Code of Practice – Annex

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Version

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Technical Review

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Comment Form

This form should be used to send comments to the QP Association.

Country	Comment	Alternative Proposal

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1 Introduction/Scope

Implementation of the QP role is defined in national law. The different national laws have some differences which we want to share in this document as far as we are aware of them.
While QPs in their country may have deviating personal experience with inspectors or their organizations this document intents to limit its statements to legally binding national rules.

We have collected such information from the following countries. The individual QP is asked to always verify this information locally where relevant.

EQPA - Countries							
Countries addressed							
EU member states							
AT	Austria	EE	Estonia	IE	Republic of Ireland	PL	Poland
BE	Belgium	ES	Spain	IT	Italy	PT	Portugal
BG	Bulgaria	FI	Finland	LT	Lithuania	RO	Romania
CY	Cyprus	FR	France	LU	Luxembourg	SE	Sweden
CZ	Czech Republic	GR	Greece	LV	Latvia	SI	Slovenia
DE	Germany	HR	Croatia	MT	Malta	SK	Slovakia
DK	Denmark	HU	Hungary	NL	The Netherlands		
EEA member states							
IS	Iceland	NO	Norway	LI	Liechtenstein		
EU candidate states							
MK	Republic of North Macedonia	TR	Turkey				
states holding MRA/ACCA with EU							
CH	Switzerland	IL	Israel				
others							
BA	Bosnia and Hercegovina	N-IE	Northern Ireland	UK	United Kingdom		

Table 1: List of countries and used abbreviations covered by this document.

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National QP Information

The following overview sorted by country is built from feedback received mainly from Qualified Persons and/or inspectors operating in respective countries. They reflect the current state of knowledge of EQPA. Implementation of rules and regulations may change over time and personal experience may differ from the information shown. Please feel free to comment at any time on the information listed. Your comments will make this knowledge base more comprehensive, valuable and useful.

Analysed countries		European Union																							EEA		MRA		
		AT	BE	BG	CY	CZ	DE	DK	ES	FI	FR	GR	HR	HU	IE	IT	LV	MT	NL	PL	PT	RO	SE	SI	SK	IS	NO	CH	IL	UK
pharmacy	accepted																												
medicine	accepted																												
veterinary medicine	accepted										?										?								
chemistry	accepted																												
pharma. chemistry + technology	accepted																												
biology	accepted																												
other university degree	accepted																												
non-university degree	accepted				?																								
addtl. Formal education for others than pharmacists																													

Table 2: Accepted diplomas and degrees per country

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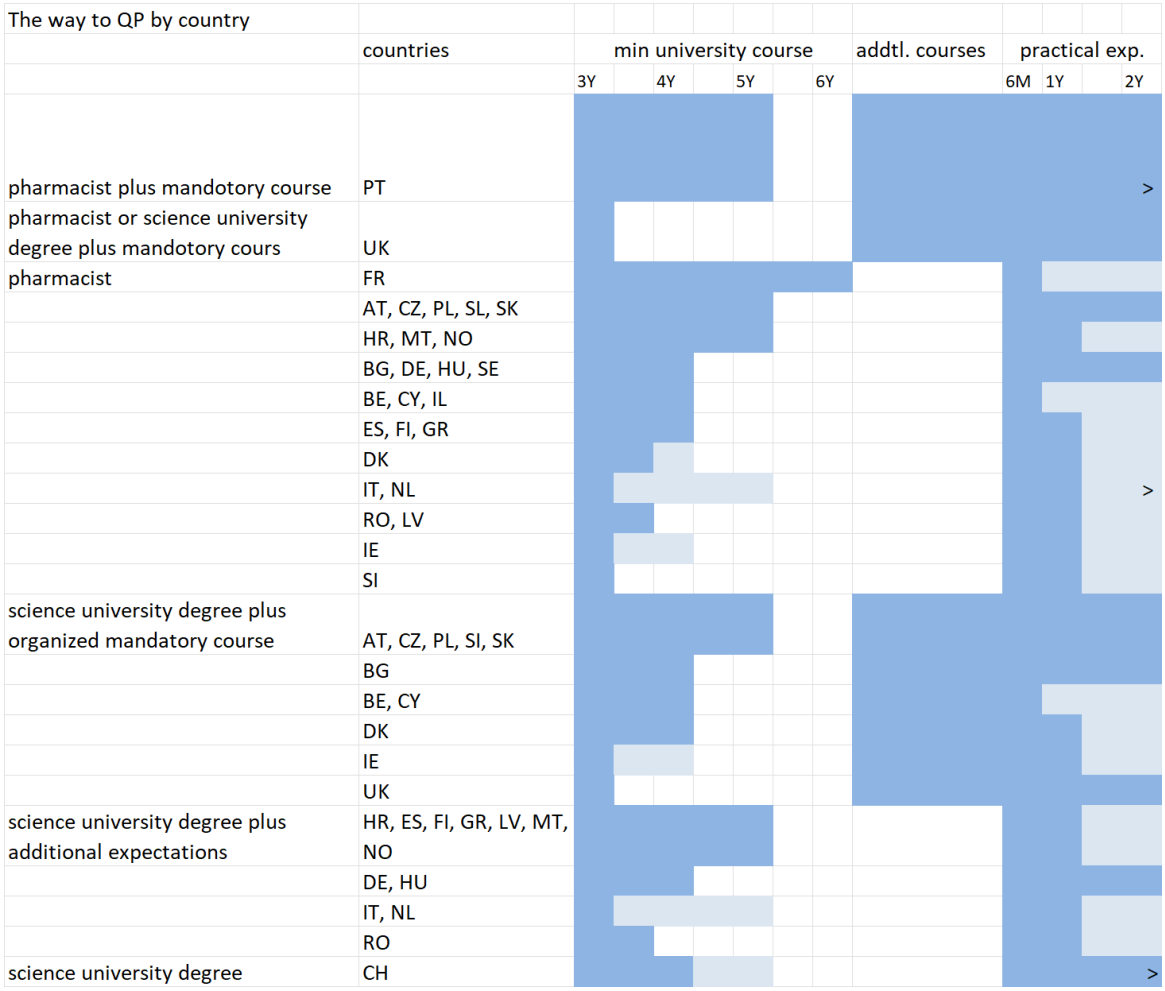

Figure 2: The route to become a QP – light blue shading means flexible application; > means duration can be longer

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EU Member States

Austria (AT)★

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Official Authority certifying QPs Address (Web Address)	Bundesamt für Sicherheit im Gesundheitswesen (BASG) – AGES MEA Traisengasse 5 A-1220 Wien Austria www.ages.at
Name	Sachkundige Person
Educational Requirements for becoming a QP	• Minimum 5 years of university courses • Pharmacists (approx. 40 % of all QPs). • Doctor or Veterinary or Chemist or Biologist with complementary academic training • To be recognized as QP additional training for non-Pharmacists. Can be obtained by university course "Pharmazeutisches Qualitätsmanagement"
Experience requirements for becoming a QP	• Minimum 2 years in Quality Control • The practical experience has to be demonstrated in one or more undertakings which are authorized to manufacture or control medicinal products in the EEA or Switzerland. • The practical experience is strictly limited to QC laboratory related activities.
QP Functional Area Requirements / Specifics	Each manufacturing authorization holder can nominate several QPs.
Interest Groups	AQPA /Austrian QP Association www.austria-qp.at
Applying for QP confirmation	https://www.basg.gv.at/inspektionen/formulare/gmpgdp/ FI220 Antrag auf Ausstellung einer Bestätigung Sachkundige Person
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Approve the Product Quality Review • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve Re-work and Re-processing
Other relevant information	• No contract QP possible; QPs need to hired • Head of QC ("Kontrolllaborleiter") or Head of Production ("Herstellungsleiter") may act as Sachkundige Person • Defined education and experience required for Head of QC and Head of Production

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Belgium (BE)★

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Official Authority certifying QPs Address (Web Address)	Agence Fédérale des Médicaments et des Produits de Santé Département Production et Distribution Eurostation, bloc II, 8è étage, bureau 8D11 Place Victor Horta 40, boîte 10 1060 Brussels Belgium www.afmps.be
Name	Bevoegde Persoon, Personne qualifiée, Qualified Person
Educational Requirements for becoming a QP	• Conditions for being approved are described in article 84 of the Royal Decree • Minimum 4 years of university courses • Master in industrial pharmacy (approx. 90 % of all QPs) • Doctor or Veterinary or Chemist or Biologist with complementary academic training as defined in the law
Experience requirements for becoming a QP	• Experience in pharmaceutical industry from 6 to 24 months f(production and QC experience). Time depends on academic qualification. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• FAGG/FAMHP only considers one QP per MIA • Additional QPs are regarded as back-up or deputy QPs. • The name of the QP is listed in Annex 5 to the MIA. • Annex 5 is an optional Annex which is not issued by the FAGG and as such the QP is not listed on the MIA issued by the FAGG
Interest Groups	Vereniging der Apothekers van de Pharmaceutische Industrie - Union des Pharmaciens de l'Industrie Pharmaceutique Nievelveldweg 1 9310 Aalst Belgium www.upip-vapi.be
Applying for QP confirmation	Applicants are asked to provide a copy of the university degree(s), the original internship certificate (signed by the QP of the company where

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	the internship was completed), a copy of ID and a fully completed Form 65 (which is the request form to be added to the List of QPs). More details can be found: https://www.famhp.be/en/human_use/medicines/medicines/production/qualified_person
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Sign Quality Agreements • Approve the Product Quality Review • Participate in audits • Approve Audit reports • Approve Deviation Investigations
Other relevant information	• (eligible) QPs are listed in a national QP register • QP and QP certification of biotech APIs required

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Bulgaria (BG)★

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Official Authority certifying QPs Address (Web Address)	Bulgarian Drug Agency Str 26 Janko Sakazov Sofia Bulgaria National Veterinary Service 15A Pencho Slaveikov 1606 Sofia Bulgaria
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 4 years of university courses • Pharmacists (approx. 20 % of all QPs) • Doctor or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • Quality Assurance activities can replace QC laboratory related activities (only partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs. • Named on manufacturing licence
Interest Groups	Not known
Applying for QP confirmation	Not known
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP requirement known.
Other relevant information	• Identical requirements apply to Head of QC

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Croatia (HR)★

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Official Authority certifying QPs Address (Web Address)	HALMED (Croation Agency for Medicinal devices) Ksaverska Cesta 4 10000 Zagreb Croatia www.halmed.hr
Name	Responsible Person
Educational Requirements for becoming a QP	• Minimum 5 years of university courses • Pharmacists (approx. 50 % of all QPs) • Doctor or Veterinary or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 1 - 2 years of practical experience • Quality Assurance activities can replace QC laboratory related activities (only partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Head of QC or Head of Production may act as Responsible Person
Interest Groups	Not known
Applying for QP confirmation	Not known
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP requirement known.
Other relevant information	• No contract QP possible; QPs need to be hired DECISION PROMULGATING THE MEDICINAL PRODUCTS ACT (NN 76/2013) 56. Qualified person for the release of a medicinal product batch shall mean a person who meets the conditions laid down in Article 49 of Directive 2001/83/EC, ORDINANCE ON THE CONDITIONS FOR ISSUING MANUFACTURING AUTHORISATIONS, ON THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICE AND ON THE CERTIFICATE OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (NN 83/2013) Article 11 (1) The person responsible for batch release of medicinal products shall be a person with undergraduate and graduate university qualifications or integrated undergraduate and graduate university qualifications with the specialisations in one of the following: pharmacy, medicine, veterinary medicine,

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	chemistry, pharmaceutical chemistry and technology, and biology. (2) The study programme shall include the proficiency in the following 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). (3) If the study programme does not include the proficiency in some of the subjects referred to in paragraph 2 of this Article, the responsible person shall provide evidence of adequate proficiency in the subjects involved. (4) The person responsible for the batch release of medicinal products shall have at least two years of experience with one or more legal or natural persons, who are holders of the manufacturing authorisation, to obtain practical experience in the area of analysis of medicinal products, quantitative analysis of active substances and all the other tests of the quality of medicinal products. Practical experience may be reduced by one year if the university study programme lasted for at least five years, or by a year and a half if the university study programme lasted for at least six years. (5) The person responsible for batch release of medicinal products may also be the person responsible for quality control or for the manufacturing of medicinal products. (6) The Agency shall have a procedure in place for the review of evidence of the fulfilment of conditions by the person responsible for batch release of medicinal products.

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Cyprus (CY)*

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Official Authority certifying QPs Address (Web Address)	The Drugs Council, Registrar Drugs Council Pharmaceutical Services Ministry of Health 1475 Lefkosia CYPRUS Website: http://www.moh.gov.cy/moh/phs/
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 4 years of university courses • Pharmacists (approx. 50 % of all QPs) • Pharmacist or Doctor or Veterinary with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • 1 year of practical experience if university lasted 6 years • Quality Assurance activities can replace QC laboratory related activities (only partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	Not known
Applying for QP confirmation	12 courses required as indicated in local law
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP requirement known.
Other relevant information	• Law No 70(I) of 2001, articles 42 – 47B • QPs get assessed and qualified based on their education and experience. They are becoming registered QP in the national "QP registry" independent from the manufacturing authorization holder.

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Czech Republic (CZ)★

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Official Authority certifying QPs Address (Web Address)	State Institute for Drug Control Srobarova 48 100 41 Prague 10 Czech Republic Institute for State Control of Veterinary Biologicals and Medicaments Hudcova 56a 621 00 Brno-Medlánky Czech Republic
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 5 years of university courses • Pharmacists (preferred) • Doctor or Veterinary or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least six years. • Quality Assurance activities can replace QC laboratory related activities (only partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	Not known
Applying for QP confirmation	Notification to the ministry of health
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Approve Deviation Investigations
Other relevant information	• you must have experience in the field where you act as QP; i.e. if I want to act as QP for blood products, I must have experience in blood product production / testing. This experience can be gained by working at a different non-QP position, to learn the critical points, etc. so you enhance already gained QP experience by this new field. All QPs are approved by national HA, who checks the education and experience to approve QP for the new field (e.g. QP with long experience from non-sterile must have some practice in sterile to be approved by HA for sterile products).

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Denmark (DK)*

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Official Authority certifying QPs Address (Web Address)	The Danish Medicines Agency Axel Heidesgade 1 2300 Copenhagen Denmark
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum (3.5)4 years of university courses • Usually an industrial pharmacists (approx. 70 % of all QPs) • Doctor or Veterinary or Chemist or Biologist with complementary academic training. If not pharmacist, additional courses have to be taken, see https://laegemiddelstyrelsen.dk/da/godkendelse/virksomhedstilladelse-og-registrering/~/media/A524C592C7F64F41BF556D2F0664EC37.ashx#:~:text=L%C3%A6gemiddelstyrelsen%20kr%C3%A6ver%2C%20at%20en%20sagkyndig,af%20minimum%204%20%C3%A5rs%20varighed.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least 5 years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (only partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can decide to either nominate 1) One QP and several delegates or 2) Several QP's with description of responsibilities.
Interest Groups	Informal network groups for QPs are organised by both The Association of Danish Pharmacists and The Danish Association of the Pharmaceutical Industry.
Applying for QP confirmation	• Approved by Medicinal Products Agency based on resume
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP • Sign Quality Agreements • Approve the Product Quality Review

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	• Approve Audit reports • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve the Master Batch Records of all sites involved in the supply chain • Approve Re-work and Re-processing
Other relevant information	• QPs for Active Pharmaceutical Ingredients manufacturers required (Biotech API´s; API's under responsibility of R&D; Live Bio-therapeutic Pharmaceuticals; API for sterile dosage forms) • Mentioned in the manufacturing • No local requirements or guidelines for QP training programmes • Danish Medicines Agency expects each manufacturer to have laid down internal procedures for training of personnel with delegated QP responsibility, and the training records will be audited during the regular authority inspections. • The training records for the official QPs will be evaluated by the Danish Medicines Agency as part of the approval procedure

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Estonia (EE)★

Latest update prior to 2018 – we ask members for confirmation or commenting

Official Authority certifying QPs Address (Web Address)	Estonian State Agency of Medicines (Ravimiamet) Nooruse 1 50411 Tartu Estonia www.ravimiamet.ee
Name	Qualified Person
Requirements for becoming a QP	State Agency of Medicines, Estonia: Excerpts from national regulations: • Evidence on completion of a university course in pharmacy, medicine, veterinary medicine, chemistry or biology, or an equivalent course in another country. • Practical experience in the last 5 years, over at least one year for pharmacists, and at least two years for other qualifications, in undertaking(s) which are authorized to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and quality assurance of medicinal products, including implementation of good manufacturing practice; or, in case of a person coming from another member state, the right to perform as a qualified person in that member state. • (Partially different requirements in terms of medicinal gases, as well as blood components classified as medicinal products.) • Experience of a qualified person shall be appropriate for the manufacturing activities.
QP Functional Area Requirements / Specifics	
Interest Groups	
Comments	

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Finland (FI)★

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Official Authority certifying QPs Address (Web Address)	National Agency for Medicines Mannerheimintie 103b (P.O. Box 55) FI-00301 Helsinki Finland www.fimea.fi
Name	Qualified Person, Kelpoisuusehdot täyttävä henkilö
Educational Requirements for becoming a QP	• Minimum (3-)4 years of university courses • Pharmacists • Doctor or Veterinary or Chemist or Biologist with complementary academic training. If not pharmacist, additional courses have to be taken, see
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least 5 years. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.

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Other relevant information	• Not named on manufacturing authorization • If QP is not a pharmacist, the company needs a pharmacist for pharmacovigilance • (https://www.finlex.fi/fi/laki/ajantasa/1987/19870395 or more information in english https://www.finlex.fi/en/) • When the requirements are fulfilled, QP is appointed by employer/ MAH and a notice of appointment is sent to FIMEA. FIMEA does not respond to the notification unless there is a reason why they would reject the appointment. However the appointment of a new QP and his/her education, training and qualification are evaluated during next manufacturing site GMP inspection. • Only one QP can act as QP for one specific batch - if this QP rejects a batch another QP may not approve it. The duties of the QPs within a team have to be stated clearly.

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France (FR)*

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Official Authority certifying QPs Address (Web Address)	Le Conseil National de l'Ordre des Pharmaciens (the national professional association of the pharmacist; responsible for assigning a "responsible pharmacist") Ordre National des Pharmaciens 4 Avenue Ruysdaël 75379 Paris France Agence nationale de sécurité du médicament et des produits de santé (ANSM) https://www.ansm.sante.fr/Les-contacts-utiles-a-l-ANSM http://www.ordre.pharmacien.fr/ (describing the procedure for the inscription of a responsible pharmacist and the corresponding requirement from the French health code)
Name	Pharmacien Responsible
Educational Requirements for becoming a QP	The requirements for responsible pharmacist are stated in the French health code. • Must be a pharmacist by education • Minimum 6 years of university courses
Experience requirements for becoming a QP	• Proof of experience required (senior role) • The practical experience for the (deputy) QP role is strictly limited to QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate one Pharmacien Responsable.
Interest Groups	Le Conseil National de l'Ordre des Pharmaciens (the national professional association of the pharmacist; responsible for assigning a "responsible pharmacist")
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Sign Quality Agreements • Perform the recall decision • Approve the Product Quality Review • Approve Audit Plan • Approve Audit reports •

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Other relevant information	• Only one "Pharmacien Responsable" entitled per site/company. If more sites, delegation of responsibility to one site QP "Pharmacien Délégué" for each site where is no "Pharmacien Responsable". • "Pharmacien Responsable" and "Pharmacien Délégué" can delegate daily business to deputies. • Broad responsibilities for example including sales, advertising and pharmacovigilance: senior position – member of the managing board • one single person nominated as Responsible pharmacist (necessarily qualified as a QP). Besides ,other pharmacists may be identified as QP, reporting to the Resp Pharmacist

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Germany (DE)★

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Official Authority certifying QPs Address (Web Address)	Regional Authorities "Länderbehörde" of each *Federal Member State* separately
Name	Sachkundige Person
Educational Requirements for becoming a QP	• Pharmacist preferred (about 80 % of all QPs) • 4 years of university courses (see table 2) • Medicinal Doctor (human or veterinary) or Chemist or Pharmaceutical Chemist or Pharmaceutical Technologist or Biologist with complementary university training.
Experience requirements for becoming a QP	• 2 years of practical experience • The practical experience is strictly limited to QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing and/or import authorization holder can nominate several QPs
Interest Groups	German QP Association: https://www.german-qp.de
Applying for QP approval	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them. • Notified to and approved by local inspectorates
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP
Other relevant information	• §12 AMWHV defines roles of QP, Head of Quality Control and Head of Manufacturing, §16 and §17 AMWHV define duties of a QP performing a release • Manufacturers of APIs from human, animal, microbiological origin or manufactured by genetic engineering need a QP • Practical experience requirements may differ depending on type of product (see table 2)

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Table 2: QP professional requirement by German law (Arzneimittelgesetz) – **local law requirements (German Drug Lae = AMG) indicated in blue**

Product category	**Educational requirements Art. 49 (2)/§15 (AMG)**	**Professional experience Art. 49 (3) /§15 (AMG)**	**Professional Code of Conduct or appropriate administrative measures Art. 52/§15 (AMG)**
Category 1 – 3	State examination as a pharmacist (Approbation) or University diploma/certificate of either scientific discpline: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology plus with proven detailed list of formal qualification of subjects		Yes: Included in professional law system for Pharmacists, medical and veterinary doctors with state examination (Approbation) Others: Missing
Category 1 General range of Small Molecule and biotech Medicinal Products, Herbal Products, etc.	If studies covered (3-) 4 years	2 years practical experience in the activities of qualitative and quantitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products (at a MIAH holder).	
Category 2 Blood products, sera, plasma derived products, vaccines,test allergenes, etc.	If blood products derived blood plasma	3 years practical experience in manufacturing or control at a plasma manufacturer plus 6 months experience in transfusion medicine	

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		or medicinal microbiology, virology, hygiene or control
	If blood products derived from blood cells, etc.	2 years of general experience in manufacturing and control within transfusion medicines
	If autologuous blood products	6 months in transfusion medicines or 1 year in manufacturing of autologouos blood products
	If hematopoietic stem cell products	2 years of specific experience in this area including respective techniques
Category 3		
ATMPS, other medicinal products and biotechnological active substances	If gene therapeutics or in-vivo diagnostic using marker genes	2 years in a corresponding medicinal area
	If somatic cell therapeutics or biotechnologically modified tissue products	2 years in a corresponding medicinal area
	If xenogeneic products	3 years in a corresponding medicinal area
	If tissue based products	2 years in manufacturing or control in such products
	If radiopharmaceuticals	3 years of nuclear medicine or radiopharmaceutical chemistry
	If biotechnological active substances	2 years in manufacturing or control in such products

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Greece (GR)★

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Official Authority certifying QPs Address (Web Address)	Hellenic Organisation of Medicines 284 Messogion Ave 155 62 Athens Greece
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacist preferred • Minimum 4 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • Quality Assurance activities can replace QC laboratory related activities (fully or partly) • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Other relevant information	• No contract QP possible; QPs need to hired

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Hungary (HU)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	National Institute of Pharmacy Zrínyi u. 3 1051 Budapest (Mail: 1372 P.O. Box 450) Hungary ogyi@ogyi.hu
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacist preferred (near to 100 %) • Minimum 4 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly).
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Other relevant information	• Notification to Ministry of Health • Named on manufacturing licence

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Ireland (IE)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Health Products Regulatory Authority /Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Ireland https://www.hpra.ie
Name	Qualified Person
Educational Requirements for becoming a QP	• Only few industrial pharmacists (approx. 10 %) • Minimum (3-)4 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Perform the recall decision • Approve the Product Quality Review • Participate in audits • Approve Deviation Investigations
Other relevant information	• Appointment by Irish Medicines Board • Named on manufacturing licence • In Ireland, the individual must have a 4yr Science degree, followed by practice experience and then individually can complete an MSc in Pharmaceutical Sciences to be eligible to practise as a QP.

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Italy (IT)*

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Agenzia Italiana del Farmaco (AIFA) Via del Tritone, 181 00187 Roma Phone: +39 06 5978401 https://www.aifa.gov.it/ For veterinary medicinal products: Direzione Generale della Sanità Animale e dei Farmaci veterinari (DGSAF) Ufficio 5 Fabbricazione medicinali veterinari e dispositivi medici ad uso veterinario Viale G. Ribotta 5 00144 Roma
Name	Persona Qualificata
Educational Requirements for becoming a QP	• Only few pharmacists (approx. 20 %) • Minimum (3.5-)4 years of university courses
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	AFI: Associazione Farmaceutici dell'Industria Gruppo di studio delle Persone Qualificate Viale Ranzoni, 1 20149 Milano Tel: +39 02 E-mail: segreteria@afiscientifica.it
Applying for QP confirmation	• QPs get assessed and qualified based on their education and experience. They are becoming registered QP in the national "QP registry" independent from the manufacturing authorization holder. QP has a qualification certificate that doesn't have a due date.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP • Perform the recall decision • Approve the Product Quality Review • Approve Audit Plan

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	• Participate in audits • Approve Deviation Investigations • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve the Master Batch Records of all sites involved in the supply chain • Approve Re-work and Re-processing
Other relevant information	• Named on manufacturing licence • Contract QP not supported • QP should have an ongoing employment relationship with the company • Based on the provision of Italian Legislative Decree 24 April 2006, n. 219 and subsequent amendments: • QP is required for API manufacturers

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Latvia (LV)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	State Agency of Medicines Jersikas 15 St. Riga, LV-1003 Latvia www.zva.gov.lv
Name	Kvalificētā persona
Educational Requirements for becoming a QP	• Usually a pharmacist or chemist • Minimum 3.5 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience is strictly limited to QC laboratory related activities. • Quality Assurance activities can replace QC laboratory related activities (only partly)
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Latvijas Farmaceitu Biedrība (LFB) – Latvian Society of Pharmacists, Section of Industrial Pharmacists
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Other relevant information	• Approved by State Agency of Medicines based on evaluation of Diploma, training certificates and CV • Named on manufacturing licence • QP required for APIs manufactured by chemical synthesis • No contract QP possible; QPs need to hired

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Lithuania (LT)★

Latest update prior to 2018 – we ask members for confirmation or commenting

Official Authority certifying QPs Address (Web Address)	State Medicines Control Agency at the Ministry of Health of the Republic of Lithuania www.vvkt.lt
Name	Qualified Person
Requirements for becoming a QP	• Either pharmacist or other academic qualification – chemists, (micro)biologists
QP Functional Area Requirements / Specifics	• Named on manufacturing licence
Interest Groups	
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Comments	

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Luxembourg (LU)★

Latest update prior to 2018 – we ask members for confirmation or commenting

No information available yet

(As Belgian inspectorate covers Luxembourg, requirements may be similar)

Official Authority certifying QPs Address (Web Address)	
Name	
Requirements for becoming a QP	
QP Functional Area Requirements / Specifics	
Interest Groups	
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Comments	

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Malta (MT)*

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Medicines Authority 198 Rue D'Argens GZR 03 Gzira Malta
Name	Qualified Person
Educational Requirements for becoming a QP	• Usually a pharmacist or microbiologist • Minimum 5 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	The Malta Qualified Persons Association
Applying for QP confirmation	• QPs get assessed and qualified based on their education and experience. They are becoming registered QP in the national "QP registry" independent from the manufacturing authorization holder.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP • Sign Quality Agreements • Perform the recall decision • Approve the Product Quality Review • Approve Audit Plan • Participate in audits • Approve Audit reports • Approve Deviation Investigations • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve the Master Batch Records of all sites involved in the supply chain • Approve Re-work and Re-processing
Other relevant information	• Named on manufacturing licence

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	• Documented training to demonstrate adequate understanding of responsibilities • Code of conduct

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The Netherlands (NL)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Ministerie van Volksgezondheid, Welzijn en Sport Centraal Informatiepunt Beroepen Gezondheidszorg Unit Farmacie- en Geneeskundige Technologie (FARMATEC – CIBG) Ministerie van VWS Parnassusplein 5 2511 VX The Hague Netherlands Postal Address: PO Box 16114 2500 BC The Hague Netherlands www.farmatec.nl
Name	Gekwalificeerd Persoon
Educational Requirements for becoming a QP	• Pharmacist preferred (approx.. 70 % of all QPs) • Minimum 3 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Dutch Association for Industrial Pharmacists (NIA) (e-mail contact nia@knmp.nl)
Applying for QP confirmation	• Application to the acting agency of the Ministry of Health (Farmatec) -> Inspectorate (IGJ) for review -> advice back to Farmatec -> appointment on behalf of the Ministry of Health • QPs are nominated by the manufacturing authorization holder and stay QP as long as

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	they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Sign Quality Agreements • Approve the Product Quality Review • Approve Audit Plan • Involved in IGJ inspections of sites that are being inspected as part of marketing authorisation application approval process. • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve site procedures that govern the PQS at the site.
Other relevant information	• Named on manufacturing licence • Additional training courses by professional bodies or private organizations in the NL and other countries e.g. UK accepted • QP and QP certification of biotech APIs required

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Poland (PL)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	The Chief Pharmaceutical Inspectorate ul. Senatorska 12 00-082 Warszawa Poland https://www.gov.pl/web/chief-pharmaceutical-inspectorate
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacist (Master of Science) OR • Doctor or Veterinary or Chemist or Biologist with complementary academic training*.
Experience requirements for becoming a QP	• 2 years of practical experience in work for a manufacturing or importing of a medicinal product authorization holder ** • The practical experience must include QC laboratory related activities (Pharmaceutical Law Act, Art.. 48).
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	Not known.
Applying for QP confirmation	• The newly appointed QP is reported to the Chief Pharmaceutical Inspector. • During the inspection, with applicable regulations is verified. • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.

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Other relevant information	• *) professional title of master, master of engineering, medical or other equivalent or diploma referred to in art. 191a paragraph 1 point 2 or 3 or par. 2 of the Act of 27 July 2005 - Law on Higher Education, obtained in the area covering at least one scientific discipline in the field of biological, chemical, pharmaceutical, medical or veterinary sciences; Complementary academic training is required for non-Pharmacists to fulfil requirements of acquiring knowledge and skills in the following subjects: physics, general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry including the analysis of medicinal products, general and applied (medical) biochemistry, physiology, microbiology, pharmacology, pharmaceutical technology, toxicology and pharmacognosy. • **) speaks Polish to the extent necessary to perform QP duties. • The QP is entered into the SMF. • No contract QP possible; QPs need to be hired

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Portugal (PT)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Infarmed – Instituto Nacional da Farmácia e do Medicamento (The National Pharmacy and Medicines Institute) Parque de Saúde – Av. do Brasil, 53 1749-004 Lisboa Portugal
Name	Commonly Technical Director
Educational Requirements for becoming a QP	• Pharmacist (100 % of all QPs) • Minimum 5 years of university courses • Plus mandatory 6 months courses on industrial pharmacist (Specialist in Pharmaceutical Industy granted by the professional Association "Pharmaceutical Industry College) • including thesis in one appropriate subject • oral examination with a 3 senior QPs' jury.
Experience requirements for becoming a QP	• 5 years of practical experience • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	• Ordem dos Farmacêuticos (Association of Portuguese Pharmacists) • Colégio da Indústria Farmacêutica (Association of Portuguese Industrial Pharmacists; a group that belongs to the Ordem dos Farmacêuticos)
Applying for QP confirmation	• Certification of that is granted by the pharmaceutical professional body "Ordem dos Farmacêuticos – Colégio da Indústria Farmacêutica" • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.

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Other relevant information	• Compliance with the requirements in article 60 of National Law Decreto-Lei no. 176/2006 (Portuguese Pharmaceutical Legislation) • Includes a list of broader responsibility • Main QP Functional Requirements are listed in article 61 of National Law Decreto-Lei no. 176/2006 • QP for the release of APIs required

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Romania (RO)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	National Medicines Agency 48 Aviator Samatescu St., sector 1 011478 Bucharest Romania www.anm.ro secretariat@anm.ro
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacist (approx. 65 % of all QPs) • Minimum (3.5)4 years of university courses • Pharmacists or Doctor or Veterinary or Chemist or Biologist with complementary academic training.
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	• Not known
Applying for QP confirmation	• Evidence that QP meets the qualification and experience demands the certificate granted by the National Agency for Medicines and Medical Devices of Romania attesting to qualified person status.

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Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP • Sign Quality Agreements • Perform the recall decision • Approve the Product Quality Review • Approve Audit Plan • Participate in audits • Approve Audit reports • Approve Deviation Investigations • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve the Master Batch Records of all sites involved in the supply chain • Approve Re-work and Re-processing
Other relevant information	• Evidence that QP meets the qualification and experience demands of the certificate granted by the National Agency for Medicines and Medical Devices of Romania attesting to qualified person status. • Should be independent from Head of QC and manufacturing

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Slovakia (SK)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	State Institute for Drug Control Kvetná 11 82508 Bratislava Slovakia
Name	Responsible Person for quality assurance of medicinal products; Law No.: 362/2011 § 12 - (1) - e) - 1, 2
Educational Requirements for becoming a QP	• Pharmacist preferred • Minimum 5 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience is strictly limited to QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	• Not known
Applying for QP confirmation	• Appointed by the Ministry of Health.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Participate in audits
Other relevant information	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.

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Slovenia (SI)★

Latest update November 2021

Official Authority certifying QPs Address (Web Address)	Agency for Medicinal Products and Medical Devices of Republic of Slovenia Mali trg 6 SI-1000 Ljubljana Slovenia
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacist preferred • Minimum 5 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training; also Biomedicine
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience is strictly limited to QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	• Not known
Applying for QP confirmation	• Appointed by the Ministry of Health.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Other relevant information	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them. • No contract QP possible; QPs need to hired

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Spain (ES)*

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Generalitat de Catalunya Gran Via Corts Catalanes, 587, 3° 08007 Barcelona Spain Agencia Espanola de Medicamentos y Productos Sanitaros (AEMPS) C/ Alcalá 56 28014 Madrid Spain Agencia Espanola de Medicamentos y Productos Sanitaros (AEMPS) Parque Emp. Las Mercedes. Edif. 8/ Campezo, 1 E-28022 Madrid Spain
Name	Technical Director
Educational Requirements for becoming a QP	• Pharmacist preferred (approx.. 90 % of all QPs) • Minimum 4 years of university courses • Doctor or Veterinary or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs from which one is the QP the others equally qualified are accepted as deputy QP.
Interest Groups	• Asociación Española de Farmacéuticos de Industria (AEFI) (association that can take care of topics related to QP)
Applying for QP confirmation	• Approved by pharmaceutical professional body • Appointed by inspectorates

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Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• No national personal QP responsibility known.
Other relevant information	• QPs are required for API manufacturers (sterile, biotech APIs) • Specific qualification of QPs for radiopharmaceuticals required • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them. • No contract QP possible; QPs need to hired

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Sweden (SE)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Läkemedelsverket (Medical Products Agency – MPA) Dag Hammarskjolds väg 42(P.O. Box 26) SE-75103 Uppsala, Sweden www.lakemedelsverket.se
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 4 years (theoretical & practical studies) from a university education within any of the following scientifical areas: pharmaceutics, medicine, veterinary medicine, chemistry, technology or biology • Specific topics (similar to pharmacy education) are listed in the national legislation
Experience requirements for becoming a QP	• 2 years of practical experience from a company with a valid Manufacturing License • Practical experience from Production or QC laboratory including Quality Assurance activities or Quality Control in these areas • If the theoretical duration is minimum 5 years – the practical experience could be reduced by one year
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs
Interest Groups	• Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Additional responsibilities (other than the general obligations) are not specified in the national legislation
Other relevant information	• Proof of knowledge and product-specific experience required • Named on the manufacturing licence

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EU Candidates

Northern Macedonia (MK)★

Latest update February 2023 – we ask members for confirmation or commenting

Official Authority certifying QPs Address (Web Address)	Ministry of Health 50 Divizija bb Skopje 1000 Republic of Macedonia
Name	
Requirements for becoming a QP	According to Law on medicinal products and medical devices, from September 2007: "Manufacturers of medicinal products must have a qualified person responsible for batch release. He /she is to be pharmacist with additional knowledge and training in production and quality control of medicinal products, who assures that the batch has been manufactured and controlled according to law as well as marketing authorization."
QP Functional Area Requirements	
Interest Groups	
Comments	• No contract QP possible; QPs need to hired

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Bosnia and Hercegovina (BA)★

Latest update February 2023 – we ask members for confirmation or commenting

Official Authority certifying QPs Address (Web Address)	
Name	
Requirements for becoming a QP	
QP Functional Area Requirements	
Interest Groups	
Comments	• No contract QP possible; QPs need to hired

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Turkey (TR)*

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Ministry of Health-Directorate of Pharmaceuticals www.saglik.gov.tr
Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 4 years of university courses • Pharmacist or Doctor or Chemist
Experience requirements for becoming a QP	• 2 years of practical experience • The practical experience **does not need** to be demonstrated in one or more undertakings which are authorized to manufacture medicinal products. • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate one QP only.
Interest Groups	• Not known • Although no formal interest group exists as such, Qualified Persons network with each other on a regular basis, through seminars and related gatherings.
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Other relevant information	• Named on manufacturing licence • QP is required for API manufacturers • No contract QP possible; QPs need to hired

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EFTA Members

Iceland (IS)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Ministry of Health and Social Security Vegmula 3 150 Reykjavik Iceland Icelandic Medicines Control Agency (IMCA) Eioistorg 13-15/180 172 Reykjavik Iceland
Name	Qualified Person
Educational Requirements for becoming a QP	• (industrial) Pharmacists • Minimum 4 years of university courses • Pharmacist or Doctor or Veterinary or Chemist or Biologist with complementary academic training
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years. • The duration of expected experience is reduced to six months, where the university course lasts for at least six years.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	• Not known
Applying for QP confirmation	• Appointed by Medicinal Products Agency based on CV • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Other relevant information	• Proof of knowledge and product-specific experience required • Named on manufacturing licence

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Liechtenstein (LI)★

Latest update prior to 2018 – we ask member for confirmation or commenting

Official Authority certifying QPs Address (Web Address)	
Name	
Requirements for becoming a QP	
QP Functional Area Requirements / Specifics	
Interest Groups	
Comments	

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Norway (NO)★

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Statens Legemiddelverk (Norwegian Medicines Agency) Sven Oftedalsvei 8 N-0950 Oslo Norway
Name	Qualified Person
Educational Requirements for becoming a QP	• Pharmacists (also Pharamceutical Technolgy (100 % of all QPs) • Minimum 4 years of university courses
Experience requirements for becoming a QP	• 2 years of practical experience • The duration of expected experience is reduced to one year, where the university course lasts for at least five years.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	• Not known
Applying for QP confirmation	• Appointed by Medicinal Products Agency based on CV • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal QP responsibilities based on national legislation (feedback from this country´s QPs)	• Author the release and certification SOP • Sign Quality Agreements • Perform the recall decision • Approve Audit Plan • Participate in audits • Approve Audit reports • Approve Deviation Investigations • Approve the Validation Master Plan • Approve the Master Batch Record of the same site • Approve the Master Batch Records of all sites involved in the supply chain • Approve Re-work and Re-processing
Other relevant information	• Proof of knowledge and product-specific experience required • Named on manufacturing licence

★ The summarised information represents current knowledge and may be subject to change.

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Switzerland (CH)*

Latest update February 2023

Official Authority certifying QPs Address (Web Address)	Swissmedic Hallerstrasse 7 3000 Bern 9 Switzerland Swissmedic Erlachstrasse 8 3000 Bern 9 Switzerland
Name	Responsible Person (Fachtechnisch verantwortliche Person)
Educational Requirements for becoming a QP	• Only few pharmacists • Minimum 4 years of science based university courses
Experience requirements for becoming a QP	• 1 years (or more) of practical experience • Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate one RP per site (not per legal entity).
Interest Groups	• Not known
Applying for QP confirmation	• QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal RP responsibilities based on national legislation (feedback from this country´s QPs)	• Sign Quality Agreements • Perform the recall decision • Approve Audit reports • Approve Deviation Investigations • Approve Re-work and Re-processing

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Other relevant information	• RPs are required for API manufacturers • According to Technical Interpretation I-SMI.TI.17e: Diploma and minimum 1 year experience depending on type of activities Named on manufacturing licence • According to Technical Interpretation I-SMI.TI.17e: A dual role as RP and chairman of the board of directors or principal shareholder is normally not acceptable. However, a dual role as a member of the upper management and a RP is basically acceptable.

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ACAA Partner States

Israel (IL)★

Latest update March 2023

Official Authority certifying QPs Address (Web Address)	Ministry of Health Jerusalem Israel
Name	Qualified Person
Educational Requirements for becoming a QP	• must be a licensed pharmacist in Israel In a company engaged in the production of medical gases, the responsible professional will have a degree in chemistry or chemical engineering or is a pharmacist.
Experience requirements for becoming a QP	• Required experience in at least one of the following fields: production, QA, QC • The period of practical professional experience required depends on the academic degrees of the candidate. -A pharmacist with a bachelor's degree - two years of proven experience. -A pharmacist with a degree of Master of science (such as pharmacy, medicine, veterinary medicine, pharmaceutical chemistry and technology, chemistry or biology) - proven experience of six months. The QP must have professional knowledge regarding the preparations in his area of responsibility accordingly to the nature of the company's activity.

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QP Functional Area Requirements / Specifics	• The QP must be employed by the company permanently, or through a contract (contracting). • The QP will be employed by the company for the extent appropriate to the company's activityíes which will allow him to execute his duties according to the regulations, to devote appropriate time to all the aspects defined under his responsibility according to Annex 16 of European GMP. • At the disposal of a manufacturer/importer employing one QP, there should be an alternative QP that can replace the QP during his absence. The replacement QP will also be specified in the manufacturer/importer's approval (MIA). • In the event that the permanent QP goes on vacation for more than 45 days, the company must notify this to the GMP unit in MOH
Interest Groups	• There is a QP forum in Israel (mostly training)
Applying for QP confirmation	• Appointed by Ministry of Health based on CV (and supporting evidence of the experience) and declaration of knowledge of the provisions of the law and the procedures of the Ministry of Health • QPs are nominated by the manufacturing authorization holder and stay QP as long as they are nominated by at least one manufacturing authorization holder. If they leave the manufacturing authorization holder, they are not recognized QP until a new manufacturing authorization holder would nominate them.
Personal RP responsibilities based on national legislation (feedback from this country´s QPs)	• Release product batches to the market and clinical trials, manufactured in Israel or imported. • If the company manufactures APIs and employs a QP, the QP will release also API batches. • If the batch is intended for clinical trials: ensures that it is manufactured and tested according to clinical trial protocol • Perform the recall decision *The actions below are normally performed by site QP, but no official MOH regulation (e.g. QP that releases imported batches will not perform these actions)* • Approve the Product Quality Review • Participate in audits • Approve Audit reports • Approve Deviation Investigations • Approve Re-work and Re-processing
Other relevant information	• Named on manufacturing licence

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Countries not holding an MRA with EU

United Kingdom (UK)★

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Official Authority certifying QPs Address (Web Address)	Deciding whether a candidate nominated by a MIAH is suitable for adding to the manufacturing authorisation is solely the responsibility of: Medicines and Healthcare Products Regulatory Agency 10 South Colonnade London E14 4PU, UK www.mhra.gov.uk Veterinary Medicines Directorate Woodham Lane New Haw Addlestone KT15 3LS UK www.vmd.gov.uk Nevertheless in practice the above authorities rely, in most cases, on an assessment of the qualifications and experience of a candidate by the following 3 professional bodies: Royal Pharmaceutical Society 66 East Smithfield London, E1W 1AW UK www.rpharms.com The Royal Society of Chemistry Burlington House, Piccadilly London, W1J 0BA UK www.rsc.org The Royal Society of Biology 1 Naoroji Street London, WC1X 0GB UK www.rsb.org.uk

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Name	Qualified Person
Educational Requirements for becoming a QP	• Minimum 3 years (with conditions) of university study • Pharmacy, Pharmaceutical Chemistry and Technology, Medicine, Veterinary Medicine, Chemistry or Biology Mandatory core subjects identical to those laid down in EU legislation are transposed into UK law A study Guide produced by the 3 professional bodies mentioned above complements this list. Prospective QPs do a gap assessment against the mandatory core subjects and the study guide and may identify a need to undergo further study. A number of universities specifically cater for these needs.
Experience requirements for becoming a QP	• 2 years of practical experience but can be shorter in line with EU legislation • The practical experience requirements are in line with EU legislation but in practice members have reported some flexibility i.e. Quality Assurance activities can replace QC laboratory related activities (fully or partly). • Manufacturing related activities can replace QC laboratory related activities. • Other activities are accepted to demonstrate practical experience.
QP Functional Area Requirements / Specifics	• Each manufacturing authorization holder can nominate several QPs.
Interest Groups	• The three professional bodies listed at the top of this table. • Some universities
Applying for QP confirmation	• Unless choosing not to use the professional bodies, prospective QPs first need to be listed as "eligible to be a QP" on the respective professional body's website for which they are a member. Each candidate must have a sponsor that is a member of the same body and is also a QP. Once successfully assessed against the study guide the individual will then be listed. • Prospective QPs are nominated by the manufacturing authorization holder and if accepted as suitable for the MIA in question by the MHRA or VMD become and remain QPs only as long as they are listed on at least one manufacturing authorization. If they leave the manufacturing authorization holder they are no longer a QP until added to a new manufacturing authorization, although they may remain as "Eligible" on the professional body's website. In

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	practice QPs need to be experienced in the relevant area. e.g if experienced only with solid doses MHRA/VMD suitability assessment will likely require appropriate additional training before accepting them for vaccines or steriles. •
Personal QP responsibilities based on national legislation	None.
Other relevant information	• Named on manufacturing authorisation • QPs named on manufacturing authorizations in NI are accepted for batch certification to the EU/EEA market (NI protocol) • Temporary derogations are in place until at least 31 December 2024 that allow batches certified in Great Britain to be released in Northern Ireland (expected to become permanent), Republic of Ireland, Malta and Cyprus. • .All QPs in UK have an identification number issued by the MHRA. This is used in future applications to assess the individual's current work, experience and suitability.

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