LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Requirements and expectations for the qualified person in a pharmaceutical company

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Generally

This document describes the Danish Medicines Agency's requirements and expectations for the qualified person (QP) in a pharmaceutical company authorised to manufacture and import medicinal products and intermediate products pursuant to section 39 of the Danish Medicines Act (Manufacturing and Importation Authorisation/MIA).

To obtain an MIA, the manufacturer must employ at least one QP who is authorised by the Danish Medicines Agency and named on the company's MIA. If there is a need for more than one QP, the manufacturer can choose to have several QPs authorised or use delegated QPs.

This document applies to all persons acting as QPs of a manufacturer; both QPs authorised on the MIA and delegated QPs appointed by the company. A delegated QP must meet the same requirements as to qualifications, experience, association etc. as a QP authorised on the MIA.

Educational background

The Danish Medicines Agency's qualification and experience requirements for a QP are based on article 49 of directive 2001/83/EC (human medicinal products) and Article 97 of regulation (EU) 2019/6 (veterinary medicinal products). The requirements in directive 2001/83/EC and regulation (EU) 2019/6 are not the same regarding education. Therefore, the educational requirements for human medicinal products and for veterinary medicinal products are listed separately below. If the MIA covers both human and veterinary medicinal products the educational requirements for human medicinal products are used.

Education – humane medicinal products

The Danish Medicines Agency's educational requirements for a qualified person who is to be responsible for human medicinal products are based on Article 49 of directive 2001/83/EC. The Danish Medicines Agency requires a qualified person to be in possession of a diploma, certificate or other evidence of formal qualifications for a university degree of at least 4 years.

A master's degree can be approved if it meets the below requirements for direction and subjects, also if the degree is made up of a separate bachelor's degree and master's degree. However, it is not possible to combine independent courses and act as a QP on the basis of two three-year university courses, because this

does not fulfil the requirement for a qualification certificate, e.g. a diploma of a degree at university level with a duration of minimum four years.

According to the directive, a university course of three and a half years may also be approved if the course is followed by a period of at least one year of theoretical and practical training and examination at university level. This one-year period must include a training period of at least six months in a pharmacy open to the public. It is also acceptable to combine a university course of three and a half years with a master's program at university level so that a diploma for a master's degree can be obtained.

The course must be in one of the following scientific disciplines: Pharmacy, medicine, veterinary medicine, pharmaceutical chemistry and technology, chemistry or biology.

The Danish Medicines Agency does not waive the requirements for the duration or direction of the course.

The directive stipulates that the QP must have studied the following basic subjects:

- Applied 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

However, the requirement that a QP must have studied all of the above-mentioned basic subjects can be waived. The specific subjects required will depend on the medicinal products which the applicant will be releasing. If, during the course, the applicant has not studied all of the above-mentioned subjects, the person concerned must provide evidence of how knowledge of the subject has been obtained subsequently or why the subject involved is not considered relevant for the release in question. You can use this document (in Danish only).

If the applicant holds a foreign degree, the qualifications must be assessed by the Danish Ministry of Higher Education and Science (Danish Agency for Higher Education and Science). This assessment must be enclosed with the application for authorisation.

Education – veterinarian medicinal products

The Danish Medicines Agency's educational requirements for a qualified person who is to be responsible for veterinary medicinal products are based on Article 97 of regulation (EU) 2019/6. The Danish Medicines Agency requires a qualified person to hold a diploma, certificate or other evidence of formal qualifications for a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology.

The Danish Medicines Agency does not waive the requirements for the direction of the course. Unlike for qualified persons for human medicinal products, regulation (EU) 2019/6 does not require a minimum length of the university education or specific basic subjects.

If the applicant holds a foreign degree, the qualifications must be assessed by the Danish Ministry of Higher Education and Science (Danish Agency for Higher Education and Science). This assessment must be enclosed with the application for authorisation.

Experience from production, QA or QC

A QP must have adequate experience from a pharmaceutical company holding an MIA. A minimum of two years of experience in manufacturing, QA or QC in a pharmaceutical company is required.
However, the duration of practical experience may be reduced if the duration of the education is 5 years or more:

- Upon completion of 5-year university degree, the candidate must have at least 1 year's experience

- Upon completion of 6-year university degree, the candidate must have a minimum of ½ years of experience

It is essential that the candidate has specific experience in the products to be released. If the position requires releasing e.g. medicinal products produced under sterile conditions, the QP must have specific knowledge of this area.

Exemptions

The Danish Medicines Agency does not waive any of the above-mentioned qualification and practical experience requirements for the QP, not even on the basis of:

- A quantitatively small production
- Geographical location of activities
- Release for export purposes only
- Production of medicinal products with low potency (e.g. homeopathic products)

Association with the company

The Danish Medicines Agency sets the following requirements for the QP's association with the company, on behalf of which the person is to be a QP:

- The QP must be permanently employed by the company or must have entered into a contract with the company.
- The QP must have sufficient knowledge of the quality system, including validation documentation.
- The QP must work at the company regularly and must be familiar with all facilities used for production and quality control.

The Danish Medicines Agency expects that the QP spends at least ten hours a week at the company. If the company's production is small or the company only produces in small campaigns, the presence of the QP can be reduced.

Due to the expectation of regular presence, a QP cannot be authorised on the MIA during leave. Consequently, the Danish Medicines Agency requires that the company, before a period of leave, applies for a change of the MIA so the relevant QP can be removed from the MIA. When the QP returns from the leave period, the company can apply for this person to be authorised as a QP on the MIA again.

Supplementary training

The Danish Medicines Agency expects an acting QP to participate in a course, seminar, conference or similar focusing on GMP at least once a year. This could either be related to general GMP compliance or be specific to the products released (cf. EU GMP, Annex 16).

If, during one year, the QP does not participate in any course etc., we expect the QP to meet with other people working with QA or QC to exchange experiences instead. This could be in the form of arranged theme meetings, experience exchange groups or similar private meetings.

Supplementary training or alternative meeting activities as mentioned above should be briefly described in a CV, so that the QP is able to document their participation to the Danish Medicines Agency.

Authorisation of a new QP on the MIA

Authorisation of a QP on the MIA requires an application for an MIA, both for new manufacturers and for companies wishing to change an existing MIA. The following documents should be enclosed with the application to the Danish Medicines Agency:

- CV listing relevant practical experience, relevant courses, etc. It should be clarified in the CV what experience is relevant for the specific application. See section Experience from production, QA or QC
- Diploma, including a list of completed subjects. If all subjects have not been completed in according to the above guide for education within the section for humane medicines, documentation for the knowledge obtained within the missing subjects must be submitted. You can use this document (in Danish only)
- Training plan if the QP is newly employed in the company

- For consultants, the contract between the company and the QP must be enclosed

According to the current practice, it is sufficient for the company – in addition to the above-mentioned documentation – to fill in the introductory pages of the application form and Annex 5 if the application only concerns a change of QP. Read our Guidelines on applications for authorisation to manufacture and import medicines and intermediates for more guidance on how to apply for an MIA.

When using consultants, the scope of the consultant's presence in the company should be considered so that the expectation as to the QP's knowledge of the medicinal product, the production etc. in EU GMP Annex 16 can be met. The Danish Medicines Agency expects that this is included in the contract between the consultant and the company. It is also expected that the QP is mentioned by name in the contract, and that it is clear when the consultant joins the company.

Please note that the Danish Medicines Agency can only assess whether a QP can be authorised once an application for a specific person and on behalf of a specific company has been received by the Danish Medicines Agency. The Danish Medicines Agency does not assess whether a candidate can be authorised without an application. However, if the requirements and expectations of these guidelines are met, the person concerned can be authorised as a QP.

Please note that it is not possible to obtain a general authorisation or certification as a QP in Denmark. When a QP is authorised on an MIA for a company, the authorisation only applies to the specific company. The authorisation cannot be transferred to other companies, and a QP listed on the MIA must therefore be authorised by the Danish Medicines Agency again if the person wants to be listed on another company's MIA. When a previously authorised QP is to be listed on the MIA of another company, the above-mentioned documentation must be submitted again.

As mentioned in the section about education, the requirements for a QP is not the same in the legislation for human and veterinary products. If an MIA only covers veterinary medicinal products and the company wishes to add human medicinal products to the MIA then it might be necessary for a new approval of the QP to make sure the legislation for human medicinal products is complied with.

Delegated qualified persons

The delegated QP is a person appointed by the company who can carry out releases on behalf of the authorised QP. A delegated QP does not need to be pre-approved by the Danish Medicines Agency. Please note that the QP authorised on the MIA is responsible for ensuring that the delegated QP has the competencies required to act as a QP. The delegated QP carries out a task on behalf of the authorised QP, and the authorised QP must be able to vouch for the delegated QP.

When an authorised QP delegates the release to a delegated QP, the authorised QP must countersign for all releases that the delegated QPs have made on behalf of the authorised QP. The authorised QP must randomly review the releases carried out by the delegated QPs.

Inspectors of the Danish Medicines Agency will randomly check whether the company's delegated QPs meet the requirements of these guidelines.

Number of QPs on the MIA

A manufacturer must decide whether they want to have (1) one authorised QP or (2) several authorised QPs. The following rules apply to the two schemes:

1. One qualified person authorised on the MIA.
In this scheme, the authorised QP of the company holds the ultimate responsibility for all the released medicine batches – even if they have been released by delegated QPs.

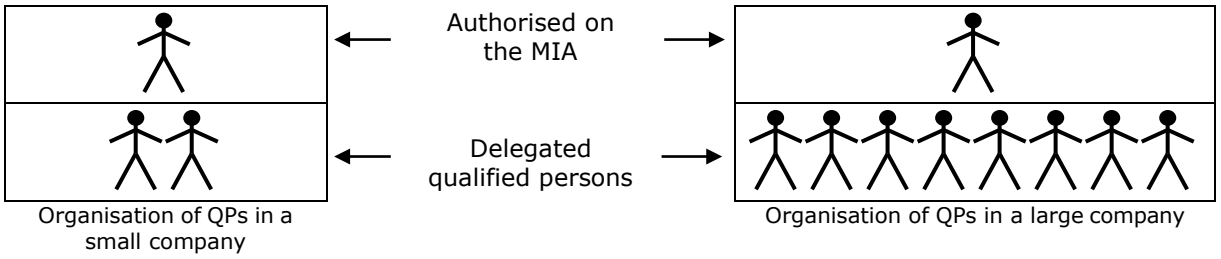

Figure 1. Example of organisation with one qualified person authorised on the MIA

Figure 1 shows the organisation with one authorised QP and the scheme covers:

- The company can only have one authorised QP on the MIA.
- Delegated QPs may release batches.
- The authorised QP must countersign the release of all batches.
- The authorised QP has the ultimate responsibility for all released batches.
- The authorised QP must be able to release all product types (manufactured by the company) to be authorised on the MIA.

2. Several qualified persons authorised on the MIA.
There are two scenarios for the authorisation of several QPs on an MIA:

A. The areas of responsibility are divided among the QPs, for example one QP is responsible for human medicinal products and the other is responsible for veterinary medicinal products. This should be described in the application for an MIA.
B. All of the QPs are authorised for all product types and activities on the MIA.

For scenario A, the same rules apply for each area as if only one QP is authorised on the MIA since only one QP is authorised for this particular area. See the description of this scheme above.

For scenario B, only the QPs authorised on the MIA can make the final certification in the batch release register; delegated QPs cannot do this.

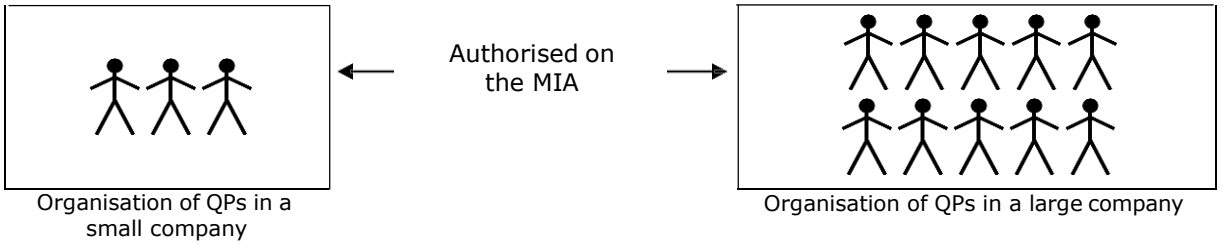

Figure 2. Example of organisation with several qualified persons authorised on the MIA.

Figure 2 shows the organisation with several authorised QPs and scenario B covers:

- The company can decide how many authorised QPs they want to list on the MIA.
- An authorised QP must make a release (by way of a signature in the batch register) before a medicine batch can leave the custody of the manufacturer; countersigning is not possible.
- Parts of the release (such as the review of batch documentation) can be delegated to other adequately qualified employees, with the exception of the signing of the batch register.
- A QP can be authorised on the MIA to release only some of the product types manufactured at the company.

More information about MIAs

You can find more information about MIAs on our website under Applications for authorisation to manufacture and import medicines and intermediates, where you can also find guidance on how to apply for an MIA. General requirements and deadlines for applications for MIAs are described in Requirements and deadlines for applications for company authorisations.

This document does not apply to the responsible person (RP) working in a pharmaceutical company holding

an authorisation for wholesale distribution.

If you have questions to this document, please contact Authorisations & Security of Supply at virksomhedstilladelse@dkma.dk.

Change log

Dato	Version	Change
01-12-2022	Guide-QP-12	Section about QP as responsible management person has been removed as the responsible management person no longer will be on the MIA. It is mentioned that a new approval of a QP might be necessary if human medicinal products is added to an existing MIA for the first time.
28-01-2022	Guide-QP-11	Changed the name of the document to "Requirements and expectations of the qualified person in a pharmaceutical company". Amendment of requirements for the approval of qualified persons for the veterinary field due to the rules laid down in Regulation (EU) 2019/6, which entered into force on 28 January 2022. New section on qualified person who is responsible manager. Inserted link to missing subjects form (the human field only). Stated that it must be clarified in the CV what experience is relevant to the specific application. Inserted information about the Danish Medicines Agency's expectations for the contract between a consultant QP and the company. Described scenario (scenario A) where the use of delegated persons is possible when several qualified persons are approved on the MIA. Deleted reference to questions-answers about several qualified persons on the MIA. General update including the insertion of the change log.