LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guidelines on requirements and expectations for the qualified person in a pharmaceutical company

These guidelines describe 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 (Manufacturer's and Importer's 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.

These guidelines apply 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 and article 53 of Directive 2001/82/EC. The Danish Medicines Agency requires that a QP is in possession of a diploma, certificate or other evidence of qualifications awarded on completion of a university course extending over a period of at least four 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 directives, 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 programme at university level so that a diploma for a master's degree can be obtained.

The course must include one of the following basic subjects: Pharmacy, medicine, veterinary science, 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 directives stipulate that the QP must have studied the following basic subjects:

- Experimental physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- Basic 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.

If the applicant holds a foreign degree, the qualifications must be assessed by the Danish Ministry of Higher Education and Science (Danish Agency for Science and Higher Education). 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. The following requirements apply to the QP's experience from production, QA or QC in a pharmaceutical company, depending on the duration of the university course:

- After completion of a four-year university course, the candidate must have practical experience of at least two years
- After completion of a five-year university course, the candidate must have practical experience of at least one year
- After completion of a six-year university course, the candidate must have practical experience of at least six months

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)

Associated 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 in 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 permission to replace the relevant QP on the MIA. When the QP returns from the leave period, the company can apply for permission to authorise this person 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 Guide to 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 his/her 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.
- Diploma, including a list of completed subjects
- Training plan if the QP is newly employed in the company
- For consultants, the contract concluded 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 first page 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 the EU Guide to GMP, Annex 16, can be met.

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. However, if the requirements and expectations of these guidelines are met, the person concerned will be authorised as a QP.

Please note that it is not possible to obtain a general authorisation or certification of 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.

Delegated qualified persons

The delegated QP is described in the EU Guide GMP, Annex 16, and 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.

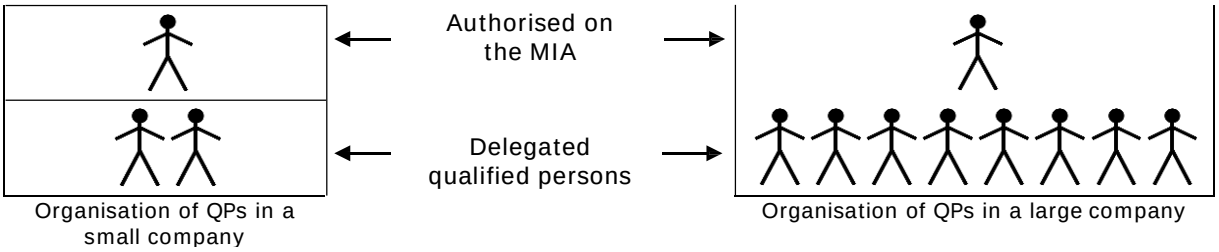

Figure 1. Example of organisation with one qualified person authorised on the MIA

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

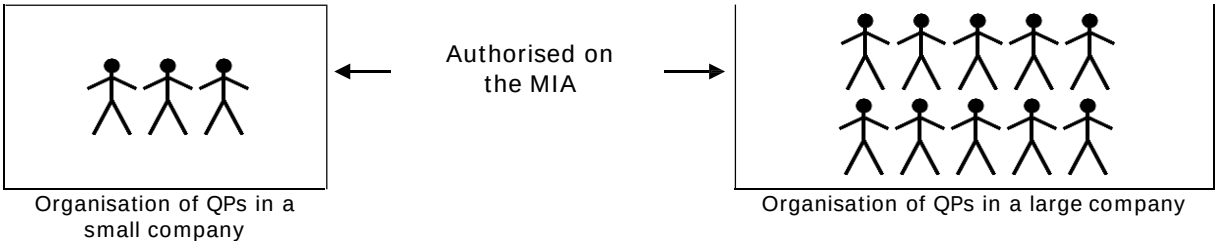

Figure 2. Example of organisation with several qualified persons authorised on the MIA.

Figure 2 shows the organisation with several authorised QPs and the scheme 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.

See also the Danish Medicines Agency's Questions and answers about procedure for authorisation of several qualified persons on the MIA for more information on the schemes.

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 our Guidelines on requirements and deadlines for applications for company authorisations.

These guidelines do not apply to QPs working in a pharmaceutical company holding an authorisation for wholesale distribution.

If you have questions to these guidelines, please contact Company Authorisations on telephone +45 4488 9779 or by email to virksomhedstilladelse@dkma.dk

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