

Qualified Person (QP)

- flexible QP Service by Eltronic Pharma Engineering



Eltronic

PHARMA ENGINEERING

Flexible QP service for release of medicinal products

To be able to release medicinal products for commercial use or use in clinical trials, the products must be approved by a Qualified Person (QP).

Eltronic Pharma Engineering offers a flexible QP service giving you the option of hiring a Qualified Person for a specific task or period of time.

The QP will be named on your authorisation and take over the legal responsibility for release of the product in question.

3 flexible QP areas

Having a temporary Qualified Person in your team for a defined period of time or for a specific task may often be the most optimal solution.

We have defined 3 areas where the advantages of a flexible QP significantly outweigh the disadvantages.

How it works

1 Identification of scope

We help you identify the needs and requirements connected with the release of your product.

We use verified models for cost calculation and ensure that all relevant aspects are considered.

2 Project execution

The QP takes over full responsibility for the product release and ensures that all requirements regarding Good Manufacturing Practice (GMP) are in place.

Based on solid practical experience and our holistic project approach, all projects are executed in the most effective manner.

3 Involvement of stakeholders

To ensure a smooth product release, the QP ensures that relevant stakeholders at all levels of the organisation are involved in the process.

Roles and responsibilities are clearly defined and communicated.

4 Product release

When the required authorisation has been obtained and all prerequisites and requirements for batch release have been met, the product can be released for the specified purpose.

The QP stays in touch in case any issues arise.

Flexible QP Service

When to consider flexible QP service?



Few Batch Releases

You are in a situation where you only release a few batches each year and the review load is low.

We offer to take over all tasks in connection with each single batch release to ensure that no details are missed.

When hiring a QP resource from us for specific batch releases, we always aim at sending out the same resource for any future releases, to ensure that already gained know-how and experiences can be reused.

Release of Products from 3rd Countries

You need to have medicinal products from a country outside the EU released for sale on the European market or for clinical trials in the EU.

According to EU regulations, a Qualified Person must verify that the product has been manufactured in compliance with EU laws and regulations. Eltronic Pharma Engineering QP's are widely experienced in this area and are able to ensure a smooth and timely product release.



Temporary Need of QP Resource

You are in need of a Qualified Person for a limited period of time.

Eltronic Pharma Engineering can provide a QP resource with short notice. Our QP's continuously undergo training to ensure that they meet all requirements from the medical authorities and are up-to-date with the most recent rules and regulations.

A Holistic Project Approach

No matter what type of project we take on at Eltronic Pharma Engineering, we use a holistic project approach.

The approach integrates aspects from 3 main areas - Quality Management, Change Management and Lean Management.

All members of our team have extensive experience working with all 3 areas. Using the approach, we are able to ensure that:

- + **Quality Management**
All requirements are met - but redundant requirements are eliminated. Focus on “need-to-have” instead of “nice-to-have”.
- + **Change Management**
Changes are implemented at all relevant levels of the organisation.
- + **Lean Management**
Projects are carried out as efficiently as possible both with regard to time and cost.



About Eltronic Pharma Engineering

Eltronic Pharma Engineering is a team of highly specialized and experienced GMP consultants and IT and automation specialists. We help our customers with all aspects of quality management and GMP compliance and processes.

www.eltronic.dk/markets/pharma-engineering

Eltronic Pharma Engineering is a part of Eltronic A/S - an engineering company focused on increasing the productivity, flexibility and efficiency of its customer's business.

Eltronic employs more than 260 highly professional engineers and technicians covering competencies within a wide range of disciplines.

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