

- GxP-compliant service
- Modular and cost-effective



SERVICE DESCRIPTION

ELPRO GMP Services

Qualification Services for pharmaceutical storage facilities

Quality assurance during pharmaceutical storage is essential for product quality and an integral part of cGXP regulations. In order to demonstrate regulatory compliance, storage facilities must be qualified, but this is often a challenging and time consuming task.

Here's how we can help:

Using ELPRO's services helps you overcome internal resource constraints associated with time-consuming qualification projects. Our experienced and qualified experts assist and guide you completely through the qualification process from the initial risk assessment to thermal mappings and the final validation report.

How it works:

ELPRO's qualification services are designed in a modular way, allowing you to choose the activities where you need assistance most, such as:

- Risk assessment
- Templates for validation plans and reports
- Thermal mappings and stress tests

All qualification activities are designed tailor-made according to your requirements, using a state-of-the-art validation approach compliant to cGxP regulations.

Your benefits:

- Full storage facility validation service executed by experienced professionals
- Transparency and cost efficiency through modular validation approach

Typical Qualification Challenges:

- Shortage of validation engineers
- Shortage of data loggers for thermal mappings
- Deadlines to meet



From guidance and expertise ...



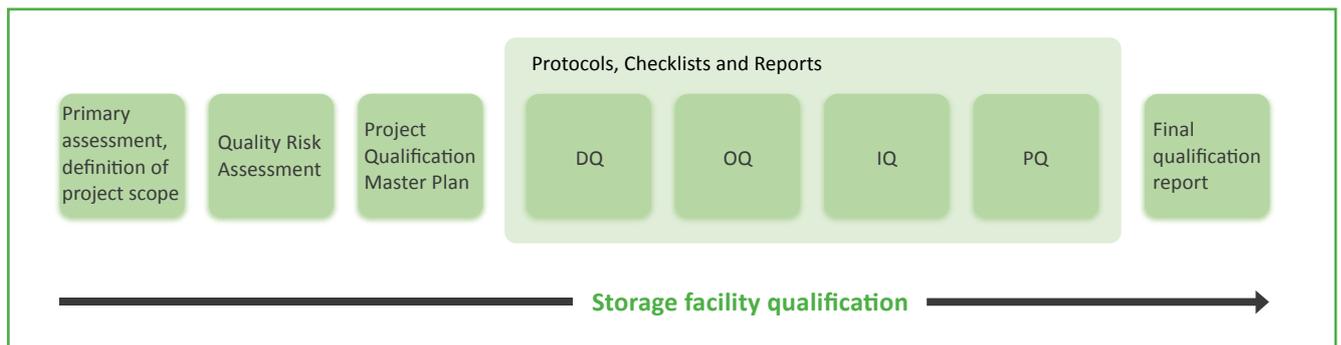
... to the complete Qualification Documentation.

we prove it.

«Wholesale distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products.»

EU GDP Guideline

ELPRO GMP Services: A modular qualification concept



Complete and thorough – The ELPRO GMP Services offer a comprehensive service package for a complete qualification of pharmaceutical storage units, including an assessment of the risk involved in the storage process, working through qualification steps from DQ to PQ, and writing the final report.

Customized according to your requirements – Different storage facilities require different qualification approaches based on their current qualification state, the type of storage, or the sensitivity of the product stored. To accommodate these different needs, the ELPRO qualification system is designed in a modular way, allowing you to choose only the qualification modules required. This customized approach allows maximum transparency and cost efficiency.

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