ELPRO
GxP Services

For 100% GxP compliance across your facilities, devices, fleets and transportation processes

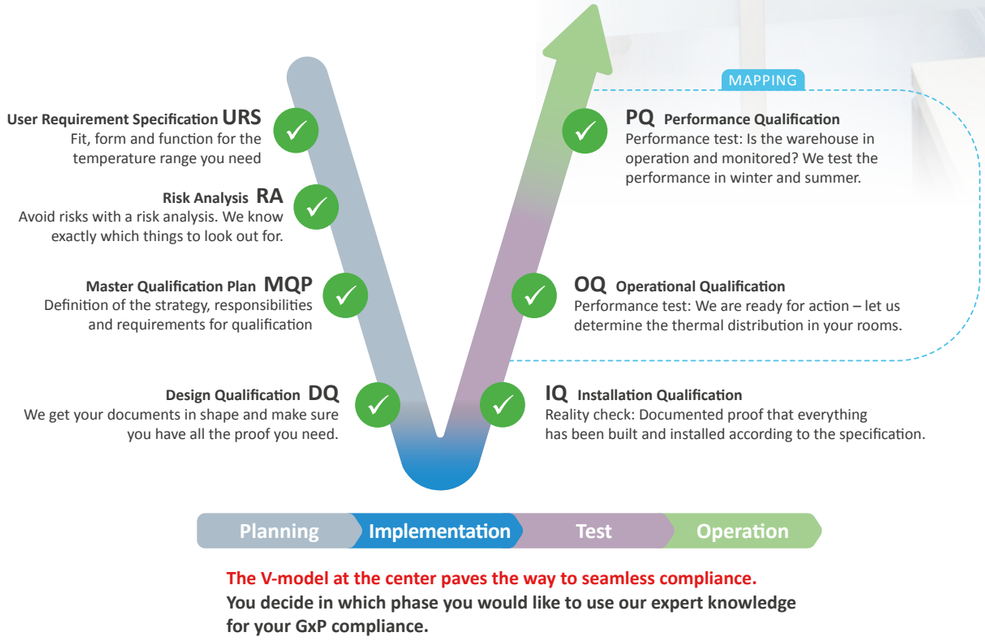
- Consulting
- Qualification and Validation
- Mapping

we prove it.

SWISS QUALITY

We focus on compliance for you: GxP Services from ELPRO

The complexity of regulatory requirements is what makes ensuring compliance tedious and time-consuming. With our GxP services, we take this burden off your shoulders. You can rely on our expert knowledge to ensure your company remains audit-proof and compliant at all times.



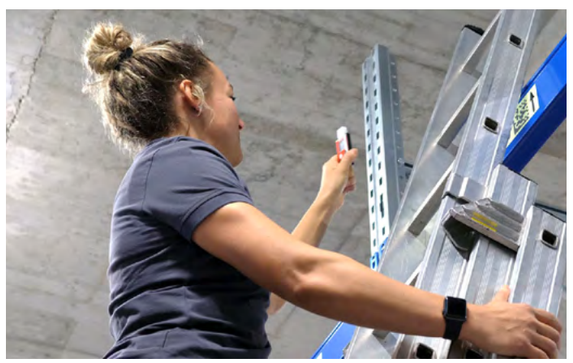
The V-model at the center paves the way to seamless compliance.
You decide in which phase you would like to use our expert knowledge for your GxP compliance.

Why monitoring?

Sensitive products can change their characteristics due to unfavorable environmental conditions during production, storage and transport. As a result, pharmaceuticals can become ineffective or harmful. To ensure maximum patient safety, quality must be maintained from the point of manufacture to dispensing, and environmental conditions must be monitored seamlessly and GxP compliant along the entire supply chain.

What is required for regulatory purposes?

Based on various national and international regulations, the monitoring of pharmaceuticals and other sensitive products is mandatory. Companies must keep a close eye on the requirements of FDA 21 CFR Part 210/211, the EU GMP, GDP, GLP and GCP guidelines, the ISPE and WHO guidelines, as well as specifications for quality risk management and sensor calibration (ISO 9001, ISO 17025) and implement them in their processes and systems.



GxP consulting

Our customers rely on our expertise in the pharmaceutical environment and in compliance with GxP regulations. We advise you on GDP/GMP regulations and ISO requirements and support you in improving processes while considering risk management. We develop URS, risk analyses and strategies for the qualification and validation/verification of rooms, equipment, processes, routes and vehicle fleets.

GxP qualification and validation

We offer complete qualification/validation according to the V-model, from risk assessments, DQ, IQ, OQ to PQ, to ensure the quality of active ingredients, APIs, packaging materials and medicinal products. Our offer:

- Qualification of your storage and transport units
- Validation/verification of transport processes
- Temperature and humidity mapping including stress tests
- Creation of individual qualification/validation documentation

GxP temperature and humidity mappings

Mapping is part of the qualification process. We support you in mapping your entire life science environment with complete, GxP-compliant documentation, including:

- storage or clean rooms
- containers
- thermal packaging or boxes
- refrigerators, freezers or ULTs
- trucks, vans or entire vehicle fleets
- lane studies

You have the choice between on-site or remote mapping as well as self-service mapping kits available for ULTs, small refrigerators and freezers as well as small rooms and large refrigerators/freezers. Do you only need data loggers or the corresponding evaluation? No problem! You can also carry out partial steps of the mapping together with us.

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Intelligent stability budget monitoring for pharmaceutical products

For over 35 years, ELPRO has been a leading global manufacturer of innovative environmental monitoring solutions for the pharmaceutical, life science and healthcare industries. Our end-to-end solutions provide data for analysis, decision-making and process automation. Sustainable thinking and action determine the development of our solutions and business models.

ELPRO's commitment to greater sustainability

ELPRO has been carbon-neutral since 2023. The building in Switzerland is certified to the Minergie™ standard and produces up to a third of its electricity each year using its own photovoltaic system. A reliable refurbishment process allows us to reuse data loggers or individual components and raw materials. Sophisticated technologies ensure a long service life for the products, many of which are suitable for multiple use.

Together for Sustainability: EcoVadis

ELPRO has been committed to the EcoVadis initiative "Together for Sustainability" for years in order to prove our strong commitment to sustainability, environmental protection and business ethics as well as our willingness to be transparent in this regard. Each year, in an independent EcoVadis assessment, we demonstrate how we meet the sustainability guidelines to achieve our rating. In 2023, ELPRO was awarded the EcoVadis Gold Medal.

About ELPRO-BUCHS AG

Founded in 1986, ELPRO is a globally acting Swiss provider of innovative monitoring solutions specifically designed for the highly regulated pharmaceutical, life science, and healthcare industries. As a leader in these fields, ELPRO is a "full service" organization offering state-of-the-art data loggers, cloud SaaS software platforms, including data analytics and a team of validation engineers to support the system integration into their customers' business processes. ELPRO is part of the Bosch Group.
Find more information at www.elpro.com

Leading Minds Network™
10 Years of Excellence

For more industry best practices and industry benchmarking opportunities, visit our Leading Minds Network online platform at leading-minds-network.com

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