



GXP SERVICES – MAPPING

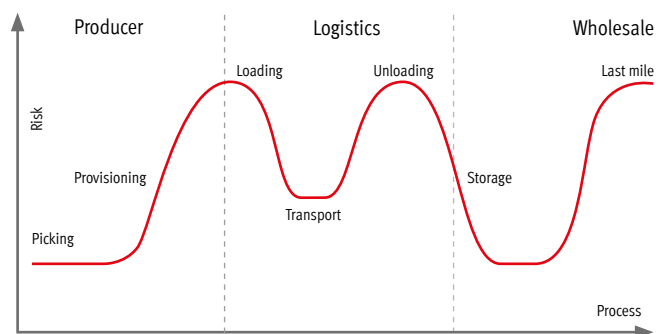
One important component of GxP directives is to safeguard the quality of products, for example medicines, during transport or storage. The basis for ensuring that the statutory regulations are observed is the GxP-compliant qualification of the transport or storage facilities. Rotronic specializes in these services and offers you efficient solutions tailored exactly to your needs.



Temperature/Humidity mapping in warehouses...

What are typical temperature mapping applications?

Mappings are the indispensable basis to meet product quality requirements and the necessary standards wherever temperature-sensitive products are manufactured, stored or transported.



Risk assessment of a pharmaceutical shipment



...cold stores



...climatic chambers



...production facilities



...trucks

How do we proceed?

Rotronic discusses the modules needed for qualification with you and then develops the optimal timetable with you. Thanks to the transparent structure of the service, you only pay for the qualification steps you need.

This approach, which has proven its worth many times, is welcomed by our customers around the world. A Rotronic qualification engineer will present the GxP-compliant data directly on customer request in the case of a possible audit.

What do you benefit from?

- Modular service structure from one provider
 - Transport qualification/validation
 - Temperature distribution study
 - Stress tests – findings
 - GDP training for handling of medicines
 - Upkeep and maintenance of the overall system
- Competent support by experienced qualification engineers
- Best test equipment accuracy and competence as prestigious manufacturer of measuring instruments





What do you receive?

- Exact climate data on the environment measured (room, vehicle, etc.)
- FDA and GxP-compliant mapping (basis for audits)
- Detailed evaluation of the data (provides information on critical areas)

What other GxP services does Rotronic also offer?

- Validation
- Calibration
- Engineering
- Personnel training

What parameters are monitored?

-  Temperature always
-  Humidity as required
-  CO₂ as required
-  Differential pressure as required

Typical mapping products



HL-1D data logger (humidity & temperature)

PDF logger (temperature)

CO₂ display (humidity, temperature & CO₂)

PF4 transmitter (differential pressure)