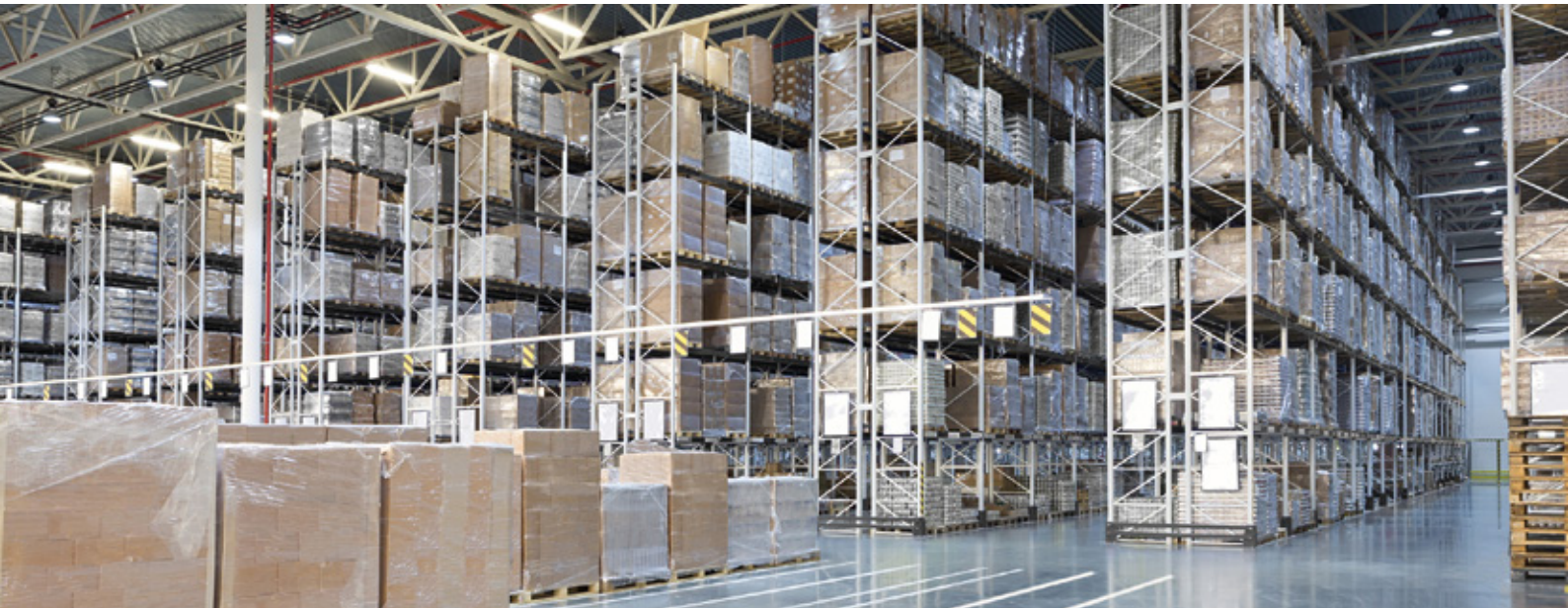


GXP SERVICES MAPPING

Temperature is a crucial parameter for many products, including medicines, drugs, vaccines, active pharmaceutical ingredients, body samples, medical devices and food/feed, where temperature can have effects on the product quality. The GxP quality guidelines were created to ensure product quality. As of such, it is important to qualify areas where these products are located (manufacturing areas, storage, warehouses, transport...). Rotronic specialises in offering temperature mapping services, tailor made to your requirements.



Temperature/humidity mapping in warehouses...

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.



Trucks



Cold stores



Climatic chambers /fridges

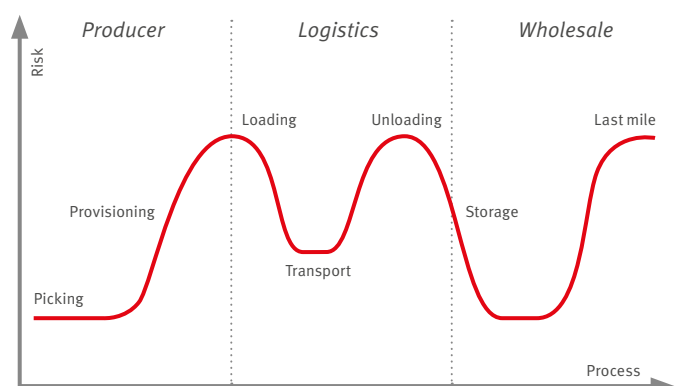


Production facilities



Warehouses

RISK ASSESSMENT OF PHARMACEUTICAL SHIPMENT



HOW DO WE PROCEED?

The user defines the protocol as well as the area acceptance criteria. Rotronic will analyse the qualification requirements and develop a specific timetable with the user. After the mapping process, Rotronic will present the GxP compliant data to the customer with optimisation recommendations.

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
 - Overview of various guidelines
 - World wide experience
 - Physical mapping
 - Qualification of the various areas
 - Recommendations
 - Possibility to integrate an Environmental Monitoring 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)
- Valid calibration certificates

WHAT OTHER GXP SERVICES DOES ROTRONIC ALSO OFFER?

- Validations (from the URS to IQ/OP/PQ)
- Calibration (ISO 17025 & ISO 9001)
- Training
- Service Level Agreements
- Project Management
- Engineering

WHAT PARAMETERS ARE MONITORED?

Rotronic can help monitor all critical control parameters, including but not limited to:

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

A COMPLETE RANGE OF PRODUCTS FOR YOUR BMS/EMS AND MAPPING REQUIREMENTS

