FACTSHEET

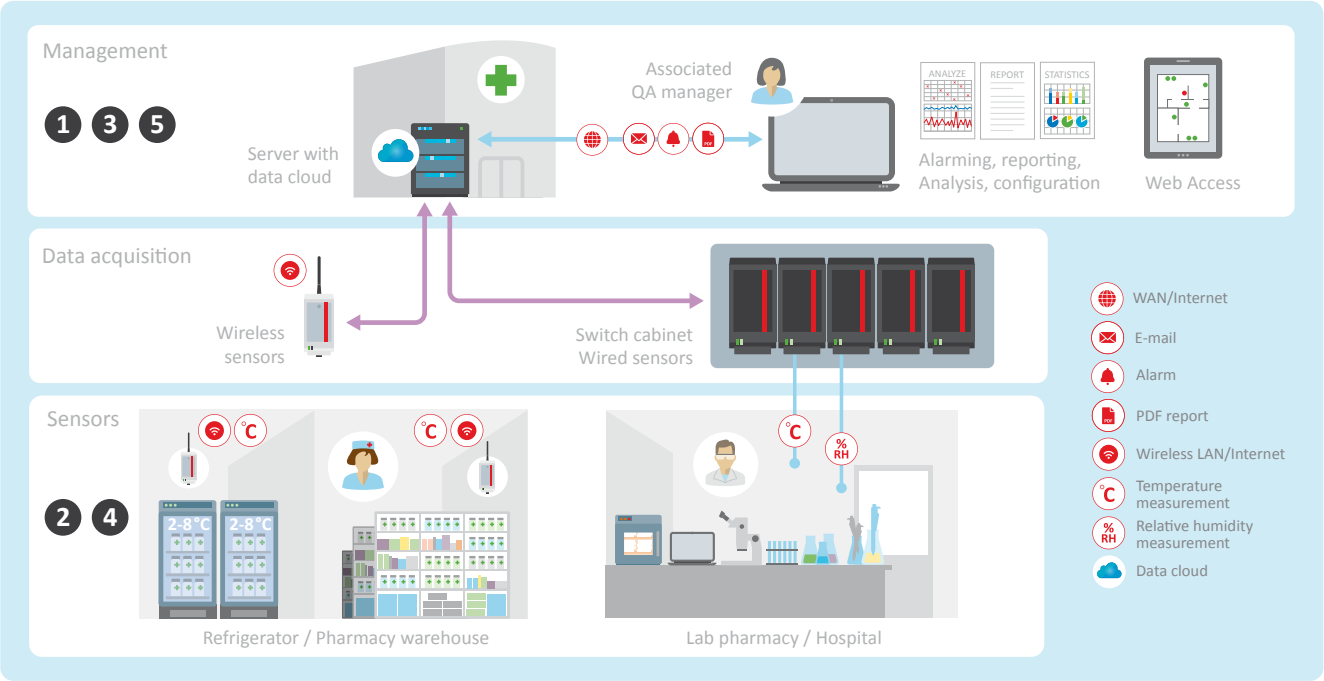
Regulations

Monitoring Pharmaceuticals and Samples in Pharmacies and Hospitals

Several authorities, interactive with one another, work towards universal standardization. There is a fair amount of redundancy, but some authors incorporate best practices and complementary information. Design your system to meet the most stringent requirements. And be able to reasonably justify your interpretation and implementation of regulations.

The graphic shows where the five main subjects authorities address fit into the monitoring process:

1. **Define acceptable environmental conditions.**
2. **Qualify and validate hardware and software.**
3. **Document all processes (audit trail).**
4. **Continuously monitor environmental conditions of products/samples.**
5. **Report deviations.**



A collection of regulations and guidelines for pharmacies and hospitals are listed on the next page. Since their original publication, some of the details in these standards have been revised, clarified, or expanded.

Quick Links* to Regulations and Guidelines

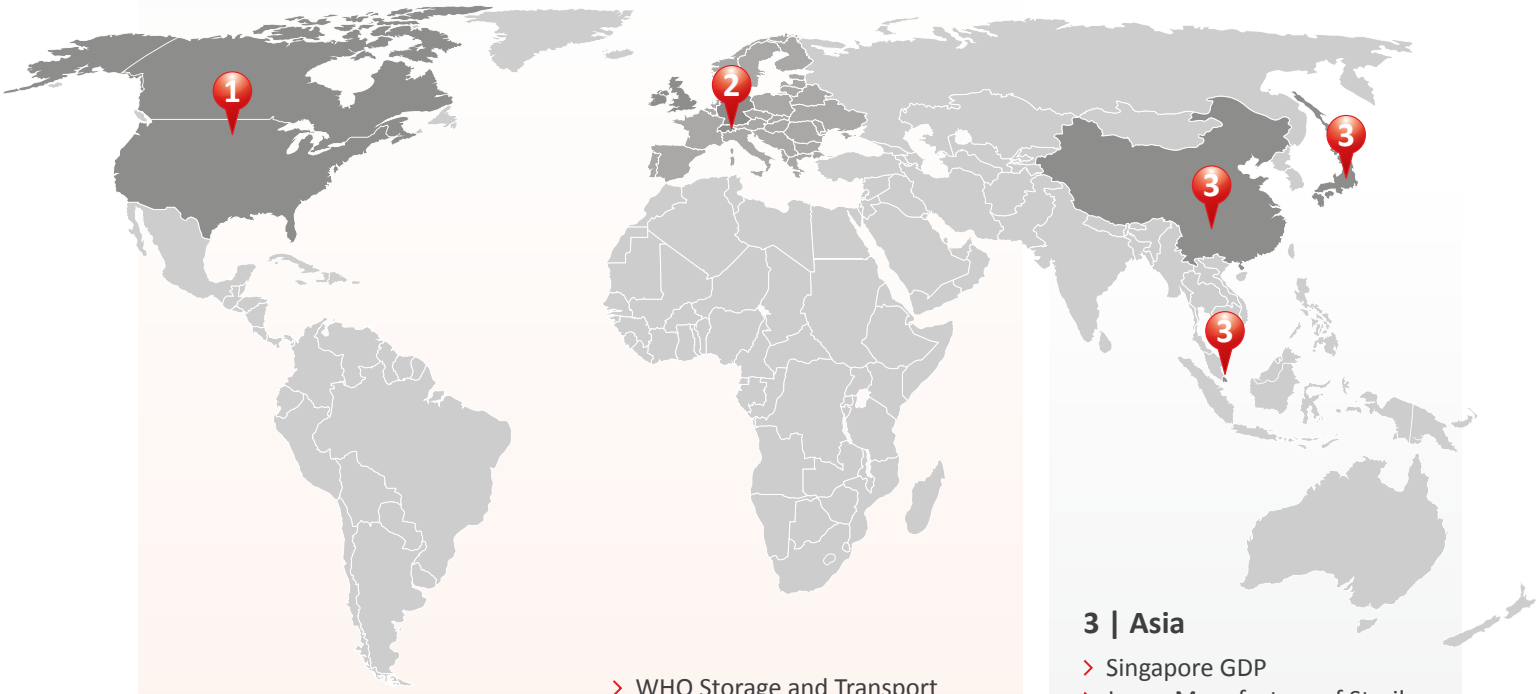
* This is not an exhaustive list of regulations, standards, and guidelines. Please reference regional authorities for regulations that are relevant to you.

1 | North America

- Health Canada GMP
- US FDA Quality System Regulation
- US FDA cGMP
- US FDA Electronic Records
- United States Pharmacopoeia
- AATB American Association for Tissue Banks

2 | Europe

- Swiss Federal Council Narcotics Control
- Federal Law on Medicinal Products and Medical Devices (Heilmittelgesetz – HMG)
- Pharmacopoea Helvetica
- Medicinal Products Act (Arzneimittelgesetz – AMG)
- Pharmaceuticals and Active Agent Manufacturing Ordinance (Arznei-mittel- und Wirkstoffherstellungs-verordnung – AMWHV)
- Pharmacy Act (Apothekengesetz – ApoG)
- Pharmacy Operations Regulations (Apothekenbetriebsordnung – ApBetrO)
- MHRA Medicines and Healthcare products Regulatory Agency
- HTA Human Tissue Authority
- HEPRA Health Products Regulatory Authority
- APIC for API producers and intermediates in Europe
- European Commission GMP
- European Commission GDP
- European Medicines Agency EMA Quality
- EMA Manufacture of Products derived from Human Blood or Human Plasma
- European Pharmacopoeia



International

- ISPE GAMP and GxP
- ICH GCP
- ICH GMP for Active Pharmaceutical Ingredients
- ICH Pharmaceutical Development
- ICH Quality Risk Management
- ICH Quality System
- ISO/IEC 17025 Testing and Calibration
- ISO 9001 Quality Management Systems
- AABB Association for the Advancement of Blood Banks
- WHO GDP
- WHO Storage and Transport of Sensitive Pharmaceutical Products
- WHO GDP for Pharmaceutical Products
- WHO Qualification of Temperature-Controlled Storage Areas
- WHO GMP for Blood Establishments
- WHO Temperature Mapping
- PIC/S GMP
- PIC/S GDP
- PIC/S Computerized Systems
- PDA Technical Reports
- iPEC GMP
- iPEC GDP

3 | Asia

- Singapore GDP
- Japan Manufacture of Sterile Pharmaceutical Products by Aseptic Processing
- Japan GMP Inspection for Foreign Manufacturers
- Japan Pharmacopoeia
- Japan Electromagnetic Records and Electronic Signatures
- Japan Computerized Systems
- Japan and other Asian Country Inspection Template
- China GMP for IMPs
- China GMP

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