

GMP Compliance Readiness Statement

The harmonized "Good Manufacturing Practice" or "GMP", according to the "Pharmaceutical Inspection Cooperation Scheme" or "PIC/S" is a set of quality management rules, regulated worldwide by many national pharmaceutical laws and applicable to manufacturing and testing of pharmaceutical and medical products.

Thermoguard develops turnkey products for computer aided monitoring of temperature, humidity and other environmental parameters, independent of human interaction and with real-time alarms.

Thermoguard is a de facto standard for online temperature and humidity control using computer networks.

Thermoguard Hard- and Software products are able to fulfill the relevant GMP requirements for IT based products and procedures, if properly implemented by the end user within a GMP compliant IT environment. Third party products might be necessary to fulfill all GMP relevant requirements like electronic signature and archival, depending on the capabilities of the existing IT environment.

Thermoguard delivers a full set of *Design, Installation, Operation and Performance Qualification* documents as well as templates for creating user specific *Corrective and Preventive Action Sheets* and *Standard Operation Procedures*.

In combination with appropriate and GMP compliant end user administrative controls and procedures, *Thermoguard* products comply with the requirements of the *Good Manufacturing Practice*.

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