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# Support for USP <797> Compliance From Helmer Scientific

Helmer products and services provide features, technology, and performance aligned to updated USP standards, including updated USP <797>.

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## Company Background

Helmer Scientific is a U.S.-based manufacturer and worldwide distributor of medical-grade cold storage and laboratory processing equipment. We have over 45 years of experience in providing high-quality temperature-controlled environments, with our products used in more than 125 countries. Precise temperature performance and control are essential to the successful storage of pharmaceuticals, and Helmer cold storage products are designed and developed with these considerations.

## Product Overview

Updates to USP <797> become fully enforceable on November 1, 2023. USP <797> provides updated guidance related to sterile compounding practices. Products and services from Helmer Scientific can help support USP <797> compliance.

### ■ Gx Solutions Pass-Thru Refrigerators

Pass-thru equipment is commonly used in USP <797> validated clean rooms. Pass-thru chambers and refrigerators provide efficient workflows that allow cleanrooms to be stocked without direct access. Limiting cleanroom access reduces the risk of contamination. It also reduces the time and materials required for garbing.

The updated USP <797> chapter requires that if a pass-thru chamber is in use the cleanroom and anteroom doors never be opened simultaneously. USP recommends the use of interlock technology to support this requirement. The GX Solutions Pass-Thru Refrigerator from Helmer Scientific is available with i.Lock™ interlock technology which prevents cabinet doors from being opened simultaneously, supporting USP <797> standards.

Along with interlocking doors, GX Solutions Pass-Thru Refrigerators are equipped with the i.C3® Advanced Information Center which provides comprehensive temperature performance data and intelligent diagnostic information directly from the unit. Additionally, detailed event logs related to system alarms and the i.Act™ Event Acknowledgment function capture corrective actions, including signatures and completion dates.

As with all GX Solutions products from Helmer, the GX Solution Pass-Thru Refrigerator utilizes OptiCool™ cooling technology which delivers world class temperature performance as well as reduced noise output and reduced energy consumption compared to traditional medical-grade cold storage equipment.

OptiCool™ technology pairs a variable capacity compressor (VCC) and natural hydrocarbon (HC) refrigerants to deliver temperature uniformity, stability, and recovery while also reducing greenhouse gas emissions. GX Solutions Cold Storage Equipment can reduce global warming potential up to 99% per unit, compared to traditional medical-grade cold storage.

### ■ Controlled Room Temperature Cabinets

Helmer Controlled Room Temperature (CRT) Cabinets can be used in USP <797> environments to store medications that required controlled storage between 20°C and 25°C.

CRTs may also support updated testing and sampling requirements outlined in USP <797>. Glove testing, media-fill testing, active air sampling, and surface sampling all require incubation at CRT temperatures for between five and seven days.

## Ordering Information

Contact a Helmer Scientific sales representative at [sales@helmerinc.com](mailto:sales@helmerinc.com).