

GxP Compliance in the World Courier Network

About GxP

“GxP” is a collective term for the *Good Practice* quality guidelines and regulations used in many fields, encompassing such internationally-recognized standards as GMP (Good Manufacturing Practice), GCP (Good Clinical Practice), GSP (Good Storage Practice) and GDP (Good Distribution Practice). These guidelines are designed to ensure that products are safe, meet their intended use and, in regulated industries such as drugs, food, medical devices and cosmetics, adhere to quality processes during manufacturing, control, storage and distribution.

Our Position

World Courier acknowledges the critical role that *Good Practice* plays in servicing its biopharmaceutical customers. It remains dedicated to ensuring company GxP compliance at a worldwide organizational level as it relates to the transport and storage of investigational drugs, biological samples and additional supplies used in global clinical trials.

Policy Governing Transport/Courier Business

As a courier company, guidance documents dealing with Good Distribution Practice (GDP) have been identified as being most relevant to World Courier’s transport-related business. GDP governs the proper distribution of medicinal products for human use and regulates the movement of products from the manufacturers’ premises (or other central point) to the end user (or other intermediate point).

As such, World Courier’s *Good Practice* policy is based on, but not limited to, the following guidance documents that deal with GDP:

- *WHO Good Distribution Practice*, Annex 5 to Technical Report Series, No. 937, 2006
- *Health Canada Guidelines for Temperature Control of Drug Products during Storage and Transportation*, 2005
- *Irish Medicines Board Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances*, 2006
- USP chapter <1079> *Good Storage and Shipping Practice*
- *EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use* (94/C 63/03)

In addition, World Courier’s policy covers Quality Management elements listed in the following documents:

- ICH Q10, *Pharmaceutical Quality System*
- *FDA Guidance for Industry, Quality Systems Approach to Pharmaceutical cGMP Regulations*
- *EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use*, Part I, Chapter 1, Quality Management

Although GDP compliance is defined as the main driver for the company's GxP policy, World Courier also embraces elements of GMP (Manufacturing), GSP (Storage) and GCP (Clinical) as they relate to World Courier's core transportation business.

Quality Management

Quality Management is of paramount importance to World Courier. Quality Coordinators have been set in place locally, regionally and globally to develop, implement and maintain World Courier's Quality Management System (QMS) which is based on its internal GxP policy as well as the following pillars:

- Corrective and Preventive Actions (CAPA) program
- Change Management Program
- Management Review Program
- Process Performance/ Product Quality Monitoring Program

Although GDP compliance is defined as the main driver for Quality within the company's regulated environment, World Courier also complies with other quality systems such as the ISO 9000 series.

Clinical Trial Supply Chain Services

As a provider of logistics services, various guidance documents dealing with Good Manufacturing Practice (GMP) have been identified as being most relevant to World Courier's clinical trial materials storage business. While GMP governs primarily the manufacturing and quality control of pharmaceutical products, it also ensures that drug storage is efficiently carried out without compromising product quality.

As such, World Courier's Clinical Trial Supply Chain Services is based on, but not limited to, the following GMP guidance documents:

- *EU Good Manufacturing Practice (GMP) Guidelines*, Volume 4 of "The rules governing medicinal products in the European Union"
- *US FDA current Good Manufacturing Practice (cGMP) for finished pharmaceuticals*, 21 CFR, 210 and 211
- *WHO Good Manufacturing Practices for pharmaceutical products*, Annex 4 to WHO Technical Report Series, No. 908, 2003

Information

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November 2009

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