World Courier
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GxP Compliance

A higher standard of flawless execution.

World Courier's customers rely on us for product safety and integrity. Quite frankly, they deserve nothing less than unsurpassed expertise and flawless execution. That's why all parts of our business, from transport and storage processes to our depots themselves, comply fully with GxP standards.

Our GxP policy is founded on the established precepts of Good Distribution Practice (GDP), Good Storage Practice (GSP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP). World Courier associates have extensive knowledge of international GxP and quality management standards. These practices are just one part of how World Courier expedites and enhances the global clinical trial process, ensures product quality and integrity, minimizes risk, increases efficiency and optimizes the supply chain for our customers.

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Good Practice

It's just one piece of the World Courier way.

Policy Governing Transport/Courier Business

As a trusted transport partner for the pharmaceutical industry, the documents dealing with Good Distribution Practice (GDP) are 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. 957, 2010
- Health Canada Guidelines for Temperature Control of Drug Products during Storage and Transportation, 2011
- Irish Medicines Board Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances, 2011
- USP chapter <1079> Good Storage and Shipping Practices
- EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)

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.

For more information, visit worldcourier.com.

Quality Management

World Courier has also put in place an independent quality management system (QMS) that complements our GxP policy and conforms to leading international quality management and oversight programs. Quality coordinators have been set in place locally, regionally and globally to develop, implement and maintain this QMS, which is based on 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 ISO 9001.

Clinical Supply Solutions

World Courier holds our operations and logistics services to a higher standard, which enables customers to view us as their partner in advancing medicine. As a provider of logistics services, various guidance documents dealing with Good Manufacturing Practice (GMP) are also relevant to World Courier's clinical supply solutions. While GMP governs primarily the manufacturing and quality control of pharmaceutical products, it also ensures that drug storage is efficiently carried out without compromise to product quality. As such, World Courier's clinical supply solutions are 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 2 to WHO Technical Report Series, No. 986, 2014