

GDP: The critical link in maintaining quality from GMP to the patient



Cell and gene therapies are manufactured to good manufacturing practice (GMP) and administered, through clinical trials, under good clinical practice (GCP). To maintain a quality product they should also be transported, globally, under good distribution practice (GDP).

To achieve this, World Courier has attained global GDP certification throughout our office network against three major GDP standards, EU GDP, USP 1079 and WHO GDP¹.

"The quality of pharmaceutical products can be affected by a lack of adequate control over the numerous activities which occur during the distribution process." (WHO Technical Report 937, Annex 5, 2006)

Process

GDP guidelines regulate the distribution of medicinal products from the manufacturer to the patient. However, transport is generally not covered by national regulatory authorities. The accreditation is therefore awarded by DQS, a leading certification body for management systems worldwide, and is based on a six–month long evaluation process, during which a team of DQS auditors analysed World Courier's transportation, handling and storage processes, and tested them against the relevant guidelines.







CERTIFICATE

This is to certify that



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has implemented and maintains a system to fulfill the rec Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

WHO Good Distribution Practices for pharmaceutical products, Technical Report Series No. 957, Annex 5

USP 1079 Good Storage and Shipping Practices for Drug Products

The GDP compliance audit covered the following scope and found no critical nonconformities:

Temperature controlled management of pharmaceutical, biotech and related materials in a global supply chain

2017-12-01 Re-audit due date 2018-11-30 Certificate expiry date 2020-12-11 Certificate Registration No. 536777 GDF Frankfurt am Main 2017-12-12



DQS GmbH

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"Distribution is an important activity in the integrated supply-chain management of pharmaceutical products." (WHO Technical Report 957, Annex 5, 2010)

World Courier

World Courier connects therapies to patients. We comply with GxP standards, throughout our 140+ owned office network, have a cell and gene therapy dedicated business unit, and a track record of managing clinical and commercial scale therapies.

Building on successes in supporting cell and gene therapy developers, we have built a logistics platform that enables innovators to quickly utilise the capability of World Courier and distribute life changing therapies.

"The nature of risks involved is likely to be similar to that for risks encountered in the Manufacturing environment." (WHO Technical Report 957, Annex 5, 2010)

Beyond GxP

Our GxP (Good Practice) 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). GxP is more than a certificate, but a way of thinking and operating. World Courier, therefore, also operates to ICH Q10 – ISO certifications, SOP framework, a comprehensive training system, Overarching Management Review, Continuous Improvement, all supported by a Performance Review Program.

To learn more about how to evolve your supply chain please contact your local World Courier representative.

1 European Union (EU GDP Guidelines), United States Pharmacopeia (USP 1079) and World Health Organization (WHO GDP)

