



A Guide to WHO Good Distribution & Good Storage Practices for Healthcare Products

UNDERSTANDING THE CHALLENGES, IMPLEMENTATION, CERTIFICATION & BENEFITS



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Background

With the continuous development and production of healthcare products around the world, such as pharmaceuticals and medical devices, supply has become more complex. Supply chain quality and safety have become more difficult during the life cycle of healthcare products.

Government regulators and their suppliers have also increased the scrutiny and complexity of healthcare product storage, trade and distribution, as well as audits of logistics companies in the supply chain, such as wholesalers and distributors.

In addition, with the internationalization of healthcare product trade, imports and exports have intensified competition between domestic and foreign counterparts. Furthermore, healthcare product quality and safety incidents in circulating the products across the globe have also increased.

To better regulate the process and, ultimately, protect consumer rights, the World Health Organization (WHO) has the most representative and universal guidelines on healthcare product storage, transportation, distribution and trade – Good Distribution Practices (GDP) and Good Storage and Distribution Practices (GSDP).

Safety & quality

The safety of healthcare products is a concern while the quality is also increasingly demanding.

The quality of healthcare products must be guaranteed during transportation and storage. In these situations, international healthcare product buyers have put forward higher technical management requirements for the healthcare products supply chain that cover storage, trade and distribution.

Choosing a reliable partner that establishes or improves their management system and level of healthcare product storage and distribution management, as well as keeps pace with common international requirements, will become inevitable for healthcare industries. Simultaneously, the customer requirements enhance competitiveness and should win you more markets.





Overview of our services

Our WHO GDP and GSDP audit services are based on the basic requirements and compare other national practices, such as the Australian Code of Good Wholesaling Practice (GWP) for Medicines in Schedules 2, 3, 4 and 8, to enable continuous improvement for our customers.

WHO GDP & GSDP basic requirements

WHO GDP and GSDP guidelines cover all aspects of healthcare products, from procurement to distribution:

- Introduction
- Document scope
- Glossary
- General principles
- Regulation of pharmaceutical product distribution
- Organization and management
- Quality risk management
- Management review
- Personnel
- Quality system, including activities and operations
- Premises, warehousing and storage
- Vehicles and equipment
- Qualification and validation
- Shipment containers and container labeling
- Dispatch and receipt, including stock control and rotation
- Transportation and products in transit
- Documentation
- Repackaging and relabeling
- Complaints
- Recalls
- Returned products
- Counterfeit products
- Importation
- Contract activities
- Self-inspection

WHO GDP & GSDP operational map



The specifications involved

WHO GDP (Technical Report Series, No. 957, Annex 5) and GSDP (Technical Report Series, No. 1025, Annex 7) specifications apply to any organization that wishes to demonstrate its compliance with the stated management system guidelines for storing, transporting, distributing and trading healthcare products.

Storing, selling and distributing healthcare products is often carried out by various companies, institutions and individuals. WHO GDP and GSDP certification sets out appropriate steps to assist in fulfilling the responsibilities involved in the distribution process within the supply chain, as well as avoid introducing counterfeits into the marketplace via the distribution chain.

WHO GDP and GSDP certification can apply to:

- Wholesalers and other parties, such as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents of healthcare products with functioning storage and distribution areas, and warehouses
- Healthcare product manufacturers that own warehouses or provide distribution
- Healthcare product manufacturers that use external distribution





WHO GDP & GSDP certification benefits

WHO GDP and GSDP certification has many benefits, including:

- Assisting identification of WHO GDP and GSDP specifications in the regulatory authorities or insufficient findings before the sponsor's inspection
- Ensuring that healthcare products are manufactured, including relabeling, repacking, storing, distributing and handling, in compliance with WHO GDP and GSDP requirements
- Demonstrating that all parties involved in the operation and supply chain meet WHO GDP and GSDP requirements
- Increasing the management level and visibility of enterprises
- Ensuring that healthcare product quality in the supply chain is consistent, so that enterprises receive greater economic benefits
- Supporting the removal of trade barriers and access to international markets
- Enhancing a product's competitiveness and its market, including field occupancy

Our services in detail

We are a trusted global partner that specializes in Quality Management System (QMS) audits and certifications, and have a firm base in WHO GDP and GSDP.

We can handle the volume, complexity and breadth of today's regulatory environment in a globally consistent manner, which has never been needed more.

A RELIABLE PARTNER

We can help all stakeholders across healthcare supply chain management and improve the quality of their products in a globally consistent, reliable and efficient way, through services and solutions tailored to the healthcare industries.

REGULATORY OBLIGATIONS FOR HEALTHCARE INDUSTRIES

We can support you with various national practices, including the Australian Code of GWP for Medicines in Schedules 2, 3, 4 and 8, among others.

Case study – the first in Australia

As Australia is a vital origin and destination market for pharmaceuticals, in vitro diagnostic and medical devices, dnata wanted to improve its services, efficiency, position in the market and healthcare supply chain, and expand across the country.

We worked closely with the company to help them achieve these goals by becoming the first cargo terminal operator in Australia to receive WHO GDP certification.

During the certification process, our highly qualified auditors analyzed dnata's processes, policies and supply chain partners to ensure consistent delivery of quality products.

Through certification, dnata can offer partners the highest operating standards for time-critical and temperature-sensitive shipments, including temperature-controlled zones of 2–8°C and 15–25°C for healthcare acceptance and storage.

The certificate demonstrates dnata's commitment to the global healthcare airfreight supply chain. It also shows their dedication to quality in every aspect of their service and them as a vital partner in the healthcare supply chain.

The process has also seen dnata swiftly expand and certify across Australia, with services at multiple airports.





About SGS?

SGS is the world's leading testing, inspection and certification company. We are recognized as the global benchmark for quality and integrity.

With more than 96,000 employees, we operate a network of over 2,600 offices and laboratories around the world.

Enhancing products, processes, systems and skills is fundamental to your ongoing success and sustained growth.

We enable you to continuously improve, transforming your products, services and value chain by increasing performance, managing risks, better meeting stakeholder requirements, and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

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WHEN YOU NEED TO BE SURE

