VAISALA

Staying Current in Cold Chain Management

Changes to USP, EU GDPs and Storage and Shipping Practices for Drugs

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Terms to Know

Ambient Temperature
The temperature of the surroundings.

API
Active Pharmaceutical Ingredient

Cold Chain Management
Management of all processes in temperature-controlled transfer of materials from original manufacture, to suppliers, to a consumer. This includes processes of storage and transit.

Cold Chain
The continuous profile of a temperature-controlled product throughout its phases of manufacturing, packaging and distribution.

CRT
Controlled Room Temperature – generally defined as 20°C – 25°C.

Deviation
The variance from an average.

Distribution Temperature
Specified temperature at which a product must be distributed.

EMA
European Medicines Agency

Excursion
Deviation from a specified limit.

Excursion Limit
A defined allowable deviation from a specified limit.

GDP
Good Distribution Practice regulates the movement of drugs from the manufacturer to the end user, including all intermediate points and transport methods.

IQ/OQ/PQ/CQ
Installation Qualification, Operational Qualification, Performance Qualification, Component Qualification

Qualification
Testing that provides reasonable assurance that the qualified product or process will produce similar results under stated conditions.

Stability
The ability of a substance to maintain efficacy under various conditions: i.e. temperature, humidity, etc.

Storage Temperature
The temperature at which a product is stored.

Temperature-Sensitive Product
A product for which stability is affected by temperatures outside a prescribed range (e.g., vaccine).

Thermal Mapping
Defining the thermal properties throughout a storage area or container over time. Thermal mapping refers to the collection of temperature (and often humidity) data with the purpose of analyzing the environmental conditions of an area.

USP
United States Pharmacopoeia

Validation/Mapping Study
A study that provides documented evidence that a specific process or system will consistently meet predetermined specifications.

Recent Changes and New Outlooks

USP <1079> Responds to a Complex Supply Chain

by Paul Daniel, *Senior Regulatory Compliance Expert, Vaisala*

Introduction

Our aim with this article is to explore the latest revision of Chapter <1079> from the U.S. Pharmacopeial Convention (USP) and to address questions that Vaisala, as a creator of systems used in cold chain applications, receives from customers and contacts who manage temperature-controlled supply chains. We will look at Good Distribution Practices (GDP) and outline salient points in the ongoing discussion of how to apply the guidance and recommendations.

USP 36 <1079> Good Storage and Distribution Practices for Drug Products

The new Chapter <1079> is 40% longer, indicating the increased importance and complexity of cold chain in the eyes of the USP. For this article, we examine four basic themes in the changes:

1. Scope and responsibility (the scope has drastically changed)
2. Risk-based flexibility (more GDP choices)
3. Quality management system (QMS)
4. Specific tools – a "temperature tool kit"

Changes: Scope, Focus and Language

There has been a clear shift in focus, starting with the title, which has changed from "Good Storage and Shipping Practices" to "Good Storage and Distribution Practices for Drug Products." The new title ensures the focus is on drugs regardless of environmental storage or distribution requirements. The purpose of this chapter changed from providing *general guidance to describing good practice*. Stated explicitly is the expectation that while firms are responsible for determining the means by which they will fulfill the guidance in the chapter. It also means that firms must be prepared to justify the means they chose, including any alternatives to explicit guidance and accepted standards.

The earlier version of this USP chapter referred to "pharmacopeial preparations," which was a bit vague. It now refers to "drug products," which are clearly defined in the chapter, and includes items a lay person would recognize as medicines. Excluded are several substances such as API's and excipients. However, the chapter states that the principles of good distribution can be applied to those products as well. The language was also modernized and simplified to align chapter <1079> with other pertinent international regulations.

Broadening <1079>

The chapter's breadth has also changed, and the first indicator is the removal of the simplified cold chain diagram, and its replacement with a simple and direct statement (See: USP <1079> "Background" to the right).

This statement could mean that the USP recognizes the complexity of the modern cold chain and allows that each distribution case is unique. Because of this variability and complexity, the best approach is to generalize. Specificity would limit the application of the guidance.

Recent Publications

In 2011

- Health Canada – GUI-0069: Guidelines for Temperature Control of Drug Products during Storage and Transportation
- ISPE – Good Practice Guide: Cold Chain Management

In 2012

- PDA – Technical Report 58 – Risk Management for Temperature Controlled Distribution
- CDSCO (India) – Guidelines on Good Distribution Practice for Biological Products
- USP 36 – Chapter <1079> Good Storage and Distribution Practices for Drug Products

In 2013

- CFDA (China) – Good Supply Practices for Pharmaceutical Products
- EMA (Europe) – (2013/C 68/01) Good Distribution Practice of Medicinal Products for Human Use
- EMA (Europe) – (2013/C 343/01) Good Distribution Practice of Medicinal Products for Human Use (corrected version)

"Storage and distribution processes may involve a complex movement of product around the world, differences in documentation and handling requirements, and communication among various entities in the supply chain. The translation of best practices into good storage and distribution meets these challenges and sets forth a state of control."

From USP <1079> "Background"

Assigning Responsibility

While the previous version did not discuss responsibility, it did offer general guidance. In this revision, responsibility is clearly assigned to all cold chain entities – that is, anyone involved in the distribution of drugs. Anyone who touches the product is now responsible for adhering to GDP.

The USP assigns overall responsibility to the application holder, manufacturer, or repackager. This is equivalent to the European GDP, where they refer to the "wholesale distributor," and may represent a step towards harmonization. The clear assignment of responsibility is a major step in modernization, and will help to achieve and maintain compliance. Why would any company allocate time, effort, and money to complying with guidance that didn't specifically apply to them?

> *GDP applies to "…all organizations and individuals involved in any aspect of the storage and distribution of all drug products…"*
>
> *From USP <1079> "Scope"*

Risk-Based Flexibility

The USP provides a general framework, rather than tightly defined requirements. The basic rule of GDP is that solutions be practical, practicable, and suitable to their processes (see: 21 CFR 211). However, the complex GDP environment needs more, such as the "new approach," typified by the <1079> revisions. The revisions provide smart, agile, and modern tools and techniques, such as Risk Assessment. Risk Assessment tools provide a better understanding of the costs and benefits of our distribution choices.

In the case of label storage specifications, the previous recommendations suggested using standard definitions, such as controlled room temperature (CRT). But these tight definitions became a hindrance. Now, instead of standard definitions, USP encourages industry stakeholders to develop their own clear definitions that resist interpretation. This provides more flexibility.

As another example of the shift toward flexibility, the old revision consistently stated two hours as a standard transfer time for any product. The new revision recommends that transfer times align with product specifications and exposure risks.

QMS and SLAs

To take advantage of this new risk-based flexibility industry stakeholders must create and implement a Quality Management System (QMS). The QMS provides a sensitive feedback loop for continuous improvements in quality-related processes, such as risk-based solutions. The Quality Management System itself is a new mention in this revision of <1079>. The QMS has already been well described in ICH guidelines (ICH Q9 and Q10) including such familiar items as change and deviation management processes.

One key tool in a modern GDP QMS, and new to <1079>, is the Service Level Agreement (SLA). The SLA is a contract between partners along a product's distribution chain that allows for the implementation of complex processes with multiple participants. This is another example of risk-based flexibility in cold chain. The agreement will usually have provisions for yearly review and improvement based on operational needs of both entities in the SLA. Without reviews, there is no formal method for continual improvement of agreements. (Hint: If your SLAs don't already leave room for review, you may want to change that.)

<1079> QMS Elements

Storage Management System

- Focuses on static **facilities**, such as warehouses & cold rooms.

Distribution Management System

- Targets the **transport** part of the cold chain, including ships, trucks and airplanes.
- Emphasizes communication between the entities.
- Supports development of packaging and storage solutions.

Environmental Management System

- Maintenance of the **product environment** through storage and distribution phases.
- Focus is on mapping/ validation, monitoring, and excursion-handling processes.

Risk Management System

- **QMS** – keeps distribution processes appropriate to both the product and the route.
- Ensures that procedures are followed by partners through the SLA.

Temperature Tool Kit

Proactive Tools

There are several tools and techniques available to help us avoid new problems, both proactive and reactive. The first proactive tool is **thermal validation** (a.k.a: temperature mapping), which is a standard practice. However, USP <1079> breaks new ground by making distinct recommendations on how to map, including specifying a 3-dimensional model of a space for sensor placement. In this model, we map a space with sensors placed in three planes and in three dimensions.

In addition, Chapter <1079> says to only map areas where product is actually stored. These two ideas are not new practices, but USP 36 <1079> is the first guidance that actually articulates them.

The second proactive tool is **continuous monitoring**. Obviously monitoring is also a standard practice in drug manufacture, but <1079> now expects it by default, and all the way along the cold chain.

The third proactive tool is **qualification.** Again, this is not a new tool, but the revised <1079> takes a deeper dive, and includes certain specific practices, such as qualifying packaging for temperature-sensitive transport.

Reactive Tools

Deviation management is a reactive tool. We are required to explain temperature deviations during shipping, and then discern whether quality has been affected. Again, this is nothing new, but the new <1079> advocates the use of Stability Data and Mean Kinetic Temperature (MKT) as suitable data for managing temperature deviations specifically in transport.

These data are acceptable internationally for deviation management at static sites such as cold rooms and warehouses, but are not internationally accepted in transport. It should be mentioned that USP 36 <1079> only recommends **MKT analysis** where existing data shows extreme temperature to be *within known stability limits*. While this is the direction industry is moving, it is new to see it in guidance. Industry is evolving quickly, and GDP guidance must keep pace.

It is important to note that these tools can only be used in conjunction with detailed data about the products and how they have been stored. A robust monitoring program is a necessary support to deviation management.

Staying Current

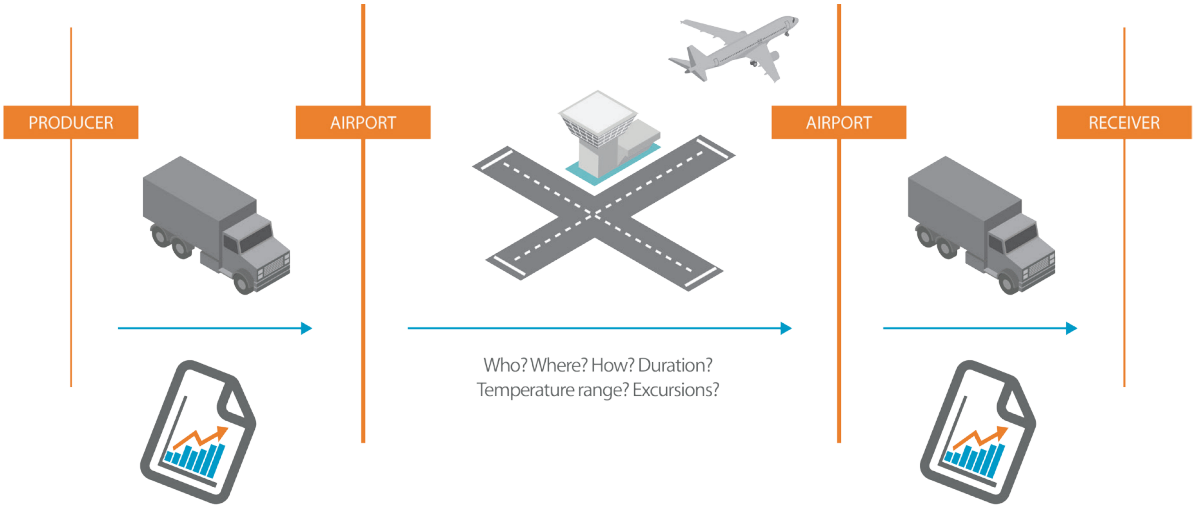
The USP says "stay current," but perhaps that really means "stay tuned." Technology is changing fast and the regulatory environment is struggling to keep pace.

New publications are coming soon, for example from **PIC/S (Pharmaceutical Inspection Cooperation Scheme)**, which is expected to further enhance GDP. Moreover, the new <1079> is already under revision.

The USP's new General Chapter <1083> Good Distribution Practices (GDP) will soon replace Chapters <1079> "Good Storage and Distribution Practices" and <1197> "Good Storage and Distribution Practices for Bulk Pharmaceutical Excipients." General Chapter <1083> will include pharmaceuticals, medical devices, and bulk ingredients and will be divided into four sections:

- *Quality Management System <1083.1>*
- *Environmental Conditions (Supply Chain Temperature) Management <1083.2>*
- *Good Importation and Exportation Practices <1083.3>*
- *Supply Chain Integrity and Security <1083.4>*

Check out www.uspf.org to learn more about these coming chapters.



USP <1079>

Frequently Asked Questions

Q. USP <1079> assigns **"Specific responsibility"** to the manufacturer. In the case of contract manufacturing, who is regarded as the manufacturer?

A. In the case of true contract manufacturing, the owner of the application has the final responsibility and accountability for the drug product. The contractor is accountable to the owner of the application. The applicant holder becomes the most responsible entity.

The entity with ultimate GMP responsibility is the entity that contracted out the manufacture, which is likely the application holder or license holder for the product.

According to <1079>: *"The holder of the drug product application, the drug product manufacturer (in the case of many OTCs, where there is no application) and the repackager bear primary responsibility and accountability…"*

In <1079> it seems the "manufacturer" is only mentioned for cases where there is no application.

Q. Does USP <1079> apply to **Investigational Products in Clinical Trials?**

A. All drug products are covered in this chapter, from investigational drugs to finished dosage forms. The new chapter that is currently under revision (Summer 2014) will include a sub-chapter in clinical trial material because there are specific processes that are unique to clinical trial drugs.

The definitions section of <1079> defines drug products as: *"Medicines, including marketed human and veterinary prescription finished dosage medications, in-process/intermediate/bulk materials, drug product samples, clinical trial materials, over-the-counter products (OTC)".* It does not apply to clinical trial materials for which storage definitions have not been determined yet.

Q. This does not apply to **Medical Devices**, but some have temperature control requirements. Do you see the addition of devices to <1079> in the future?

A. <1079> does not apply to medical devices, but it says: *"Although this chapter is not intended to address the storage and distribution of… medical devices... the general principles outlined here may be useful if applied selectively or comprehensively."*

It makes sense to follow the <1079> recommendations for a temperature sensitive device. These recommendations do create an expectation that will become part of the GMP culture, and it may therefore become an expectation in the mind of auditors.

If you know a particular device has temperature control requirements, then it is prudent and reasonable to provide the necessary environment in storage and transport regardless of *whether or not* guidance (or regulation) applies specifically to medical devices.

Q. A question from the United Kingdom: Do **U.S. Wholesalers** need to comply with <1079>? Who monitors compliance to the standard?

A. Technically speaking, no one needs to comply with <1079>, because it is a guidance, *not* a regulation. As a guidance, it is a collection of strategies designed to meet the actual regulatory requirements, which for the US are mainly in 21 CFR Parts 11, 211, and 820. From these regulations, any GDP requirement can be deduced. In addition, other chapters of the USP are enforceable by the FDA, and this does tend to create the expectation of compliance.

Therefore, the short answer is, yes, U.S. wholesalers do need to comply, and the FDA would be the agency monitoring and enforcing compliance. However, the regulation being enforced would be 21 CFR Part 211, etc. <1079> just outlines good strategies for compliance to regulations like 21 CFR Part 211.

Q. **Why not just use the EU GDPs?** (It's an actual regulation) to develop your QMS vs. a non-regulation…

A. Both regulations and guidance exist to help us do what we should be doing anyway – ensuring the quality of products. Creating procedures (or developing QMS) with the primary goal of fulfilling regulations will not necessarily result in creating the best set of processes for the quality of a product; however, focusing on the quality of the product as the primary goal will create a better set of procedures (QMS or otherwise).

In the case of <1079> you are actually in agreement with the USP. <1079> refers to the ICH publications, which are the backbone of the EU GDP regulations. USP just goes a little further to develop the parts of the QMS that are specific to GDP. In any case, it's better to have multiple points of view contributing to the development of our procedures and QMS in order to select the best fit for our products' safety and business needs.

Q. Is it not so that a USP standard would only apply to **USP monograph products?**

A. If you look in the earlier revision of <1079> it said that it was to provide guidance *"concerning storing, distributing, and shipping Pharmacopeial preparations."* So, they originally meant that it was for preparations described in the pharmacopeia, i.e. a USP Monograph product.

However, the new <1079> clearly states something quite different. It now says: *"This general information chapter describes good storage and distribution practices to ensure that drug products (medicines) reach the end user with quality intact."* And they define "drug products" as *"Medicines, including marketed human and veterinary prescription finished dosage medications, in-process/intermediate/bulk materials, drug product samples, clinical trial materials, over-the-counter products (OTC)."*

A Short Description of EU GDP

EMA <2013/C 343/01> Good Distribution Practice of Medicinal Products for Human Use

by Piritta Maunu, ***Regulations Expert, Vaisala***

Introduction

In the European Economic Area (EEA) appropriate storage and distribution practices of medicinal products are covered under GDP regulation. Following the GDP guideline <2013/C 343/01> in the EU is mandatory. The Commission published EU Guidelines on Good Distribution Practice (GDP) in 1994. Revised guidelines <2013/C 68/01> were accepted for use in March 2013, but because factual mistakes were found, the final version of guidelines on GDP <2013/C 343/01> was published 5th of November 2013.

In <2013/C 343/01> GDP is defined as that part of quality assurance which ensures that the quality of medicinal products is maintained **throughout all stages of the supply chain,** from the site of manufacture to the pharmacy or person authorized to supply medicinal products.

The wholesale distribution of medicinal products is: "all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public…"

From <2013/C 343/01 "Introduction">

Need for the Improvements

It is well known that distribution networks are increasingly complex and involve many stakeholders. Because the Guidelines on Good Distribution Practice published in 1994 were found to be inadequate and lacking the new requirements for wholesale distributors and brokers relating to medicinal products for human use, several changes were included in GDP <2013/C 343/01>. One of the main goals was to clarify the regulations so that the risk of counterfeit medicines entering the legal supply chain, as well as adulteration, cross contamination and any other negative impact of quality and integrity of the medicinal product, would be avoided. The intention of these improvements was to ensure control of the distribution chain, and consequently maintain the quality and the integrity of medicinal products.

"…in this context procuring refers to obtaining, acquiring, purchasing or buying medicinal products from manufacturer, importers or other wholesale distributors…"

From <2013/C 343/01 "Glossary of terms">

Major Improvements

In the revised GDP regulation clear emphasis on the following items was introduced:

- ***Quality Management*** *including Quality Risk Management (QRM)*
- ***Sufficient competent personnel*** *to carry out all the tasks for which the wholesale distributor is responsible*
- ***Adequate premises, installations and equipment*** *to ensure proper storage and distribution of medicinal products*
- ***Suitable documentation*** *that prevents errors from spoken communication*
- ***Qualification*** *of suppliers and customers – as well as brokers*
- *Appropriate* ***management of complaints,*** *returns, suspected falsified medicinal products and recalls*
- ***Outsourced*** *activities correctly defined to avoid misunderstandings*
- *Specific rules for* ***transport*** *(in particular to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport)*
- *Specific rules for* ***exporting***
- *Specific rules for* ***brokers*** *(person involved in activities in relation to the sale or purchase of medicinal products).*

When exporting medicinal products to third countries, the person exporting:

- *must hold a wholesale distribution authorization or a manufacturing authorization.*
- *shall ensure that such supplies are only sent to persons who are authorized or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country concerned.*

Remember! Manufacturers performing any distribution activities with their own products must also comply with GDP.

Other Relevant EU Guideline Updates

A Summary of EU GMP Vol. 4 <Chapter 1 Pharmaceutical Quality>

- *"Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials, the selection and monitoring of suppliers and for verifying that each delivery is from the approved supply chain."*

- *"Arrangements are in place for the prospective evaluation of planned changes and their approval prior to implementation taking into account regulatory notification and approval where required."*

  This means that the potential effect of the forthcoming changes has to be carefully evaluated before implementation.

- *"An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems. This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked, if present. Appropriate corrective actions and/or preventative actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles."*

  It is now clearly defined that when investigating deviations, suspected product defects or other problems, these issues can't be solved just by retraining to Standard Operating Procedures (SOP). More advanced methods must be used.

- **Product Quality Reviews** should be introduced in quality reviews of **all authorized medicinal products**, including export only products (existing process, current specifications, trends and improvements). It should also include **the review of contractual arrangements.**

A Summary of EU GMP Vol. 4 <Chapter 7 Outsourced Activities>

- The roles of the Contract Giver and the Contract Acceptor as well as the content of the Contract have been carefully identified.
- The Contract Giver is responsible **for reviewing and assessing the records and results** related to the outsourced activities. He should also ensure that outsourced activities are performed in accordance with GMP and the marketing authorization.
- The Contract Acceptor should **not subcontract to a third party...** without the **Contract Giver's prior evaluation and approval...** Arrangements made between the Contract Acceptor and any third party should ensure that **information and knowledge,** including those from assessments of the suitability of the third party, are **made available** in the same way as between the original Contract Giver and Contract Acceptor.
- Outsourced activities may be subject to **inspections.**
- The Contract should permit the Contract Giver to **audit** outsourced activities.

Note: The "site of release" is viewed as the actual Contract Giver, and all the other players as Contract Acceptors and Subcontractors.

GDP <2013/C 343/01>

Frequently Asked Questions[1]

Q. Concerning Chapter 3 – *Premises and Equipment*, 3.2.1, how many probes are necessary to monitor the temperature?

A. The number of probes and their placement depend on the risk analysis performed on the site and the placement should be in agreement with the mapping results.

Q. Concerning Chapter 3 – *Premises and Equipment*, 3.2.1.(2), what is meant by 'initial temperature mapping'?

A. An initial temperature mapping is an exercise in which temperature sensors are placed on the points identified as most critical through a risk analysis (e.g. at different heights, near a sunny window, next to the doors, etc.). Once placed, a measurement is taken over a period of time and with the results obtained, the temperature sensors will be places where greater fluctuation occurred. The mapping should be performed in different seasons where highest and lowest temperatures are reached.

Q. Concerning Chapter 3 – *Premises and Equipment*, 3.3.(3), what are appropriate settings for the alarm levels?

A. Alarm settings should be chosen as to guarantee a timely alert of personnel when there are excursions from predefined storage conditions.

Q. Concerning Chapter 3 – *Premises and Equipment*, 3.3.2.(1), is it required to have only equipment with a CE certificate of conformity?

A. No. The CE marking is mandatory only for products dating from 1993 or later. It should be noted that the presence of a CE certificate of Conformity doesn't exempt from equipment validation/qualification.

Q. Concerning Chapter 3 – *Premises and Equipment*, 3.3.2.(1), Is it required to record all deviations or can they be limited to significant deviations having an impact on product security and integrity?

A. All deviations from established procedures should be documented.

Q. Concerning Chapter 6 – *Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product* Recalls, 6.3.(2)(iii), how should the customer demonstrate that the medicinal products have been transported, stored and handled in compliance with specific storage requirements?

A. The customer needs to provide records showing that the medicinal products have been transported, stored and handled in compliance with their specific storage requirements.

Q. Concerning Chapter 9 – *Transportation*, 9.2.(1), can we deviate from storage conditions if the manufacturer agrees to the transportation of the product within a certain temperature range (2°-25°C) for a limited time frame of 6 hours?

A. No. Storage temperature limits as described by the manufacturer or on the outer packaging need to be maintained through the entire distribution chain.

[1] *From: "Good Distribution Practice for Medicinal Products for Human Use - Questions and Answers Version 1.0" http://ec.europa.eu/health/files/gdp/2014-04_qas_.pdf*

Resources & Further Reading

WHO Technical Report Series No. 957, 2010.
Annex 5: WHO good distribution practices for pharmaceutical products.

WHO Technical Report Series No. 908, 2003.
Annex 9: Guide to Good Storage Practices (GSP) for pharmaceuticals.

WHO BS/10.2129, 2010.
Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products.

PIC/S PS/INF 20, 2011.
Questions & Answers document regarding Distribution Activities for Active Pharmaceutical Ingredients (APIs).

IPEC, 2011.
IPEC Europe Good Distribution Practices Audit Guideline for Pharmaceutical Excipients.

GDP <2013/C 343/01>
Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use.

USP 36 <1079>
Good Storage and Distribution Practices for Drug Products.

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