BRIEFING

〈 **1083** 〉 **Good Distribution Practices,** *PF* 38(2) [Mar.–Apr. 2012]. A new series of informational chapters describing various aspects of the pharmaceutical supply chain replaces that which appeared as an *In-Process Revision* in *PF* 38(2) but since then has been canceled. USP is proposing this new series of Good Distribution Practices (GDP) general chapters, which were developed based on a review of two existing general chapters, *Good Storage and Distribution Practices for Drug Products* 〈 1079 〉 and *Good Distribution Practices for Bulk Pharmaceutical Excipients* 〈 1197 〉, and the previously proposed general chapter *Good Distribution Practices—Supply Chain Integrity* 〈 1083 〉. These three general chapters provide information related to the storage, shipment, distribution, and transportation of pharmaceutical components and products. The review showed overlapping and complementary items among these general chapters and highlighted the need to revisit *USP* chapters on GDP from an overarching perspective. These new general chapters will cover material flow beginning with initial procurement and continuing throughout the supply chain to delivery to the end user for pharmaceutical components and products, medical devices, and dietary supplements. The chapters will address four main GDP topics—*Quality Management System* 〈 1083.1 〉, *Environmental Conditions Management* 〈 1083.2 〉, *Good Importation and Exportation Practices* 〈 1083.3 〉, and *Supply Chain Integrity and Security* 〈 1083.4 〉—highlighting best practices and principles.

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Add the following:

〈 1083 〉 GOOD DISTRIBUTION PRACTICES

INTRODUCTION

Sourcing and distribution are critical activities in an integrated supply chain covering packaging materials, active pharmaceutical ingredients, excipients, and final products (including clinical trial materials), such as pharmaceuticals, medical devices, combination products (e.g., drug-eluting stents), and dietary supplements. With the globalization of the pharmaceutical industry, various individuals and organizations from locations around the world are responsible for the handling, storage, and distribution of such products. It is thus critical to have adequate control over the entire supply chain from manufacture to delivery to the patient or customer. To maintain the original quality of materials or products, every party involved in the supply chain should understand and comply with the applicable requirements. Each activity in the distribution of a material or

product should be carried out according to the principles of good distribution practices (GDP).

Four GDP topics covering quality management system, environmental conditions management, importation and exportation management, and supply chain integrity and security will serve as the foundation for the GDP chapters. Generally, they apply to all materials and products, regardless of their regulatory category. These topics include the basic principles that provide guidance on how to establish and maintain a quality management system that ensures the quality, integrity, safety, and efficacy of materials and products during sourcing and distribution (e.g., personnel, storage buildings, transportation vehicles, and others). Aspects related to temperature and humidity control during product holding and transportation are also addressed. Information is provided on how to maintain supply chain integrity from importation and exportation procedures to minimizing counterfeiting, cargo thefts, and diversion, and improving traceability of individual products and shipments throughout the supply chain. The intent of the chapters is to be aligned with global directives where possible.

SCOPE

GDPs apply to all organizations and individuals involved in the storage and distribution of packaging materials, active pharmaceutical ingredients, excipients, and final products, such as pharmaceuticals, medical devices, and dietary supplements, including but not limited to the following:

- Manufacturers of active pharmaceutical ingredients, excipients, packaging material, drug products, radiopharmaceuticals, medical devices, dietary supplements, biological and biotechnological products, and cell and gene therapy products
- Packaging operations by the manufacturer or a designated contractor for the application holder or marketing authorization holder
- Repackaging operations in which the product may be owned by an organization other than the primary manufacturer
- Laboratory operations at the manufacturer's site or at the contractor's site
- Physician, dentistry, and veterinary offices
- Pharmacies including but not limited to retail, compounding, specialty, mail order, hospital, and nursing home and hospice
- Importers and exporters
- Wholesale distributors
- Distribution organizations involved in road, rail, sea, and/or air services
- Third-party logistics providers, brokers, freight forwarders, and consolidators
- Health care professionals storing medicinal products prior to dispensing or administering to patients
- Mail distributors that offer expedited or controlled temperature shipping services
- Technical assistance providers for medical devices

The information contained in the subsequent chapters is intended to apply to all supply chain partners regardless of the product's environmental storage or distribution requirements; however, it does not supersede or supplant any applicable national or

international storage and distribution requirements. The chapters are divided into those that contain general information (*Quality Management System* 〈 1083.1 〉, *Environmental Conditions Management* 〈 1083.2 〉, *Good Importation and Exportation Practices* 〈 1083.3 〉, and *Supply Chain Integrity and Security* 〈 1083.4 〉) generally applicable to all materials and products, and chapters containing specific information deemed important for certain materials and products as shown in *Figure 1*.

It is recognized that there may be special cases, and alternative means of fulfilling the intent of this chapter. If applicable, such means should be scientifically justified.

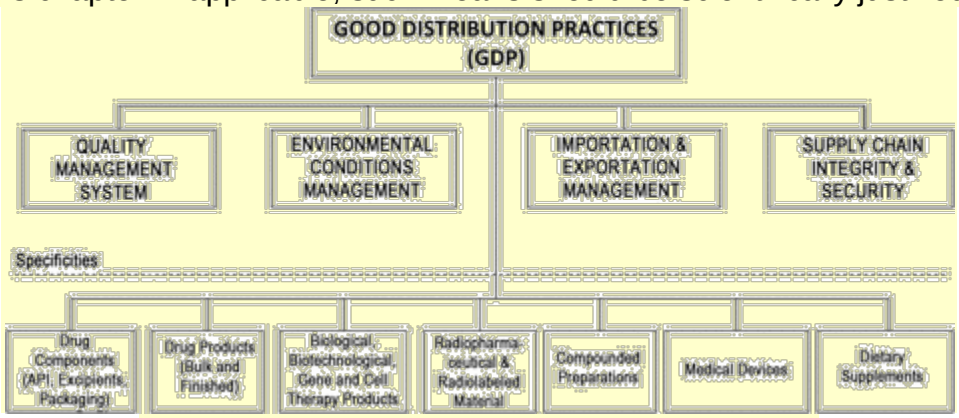

Figure 1. Structure of GDP overarching chapter.

■ 1S (*USP38*)