BRIEFING

〈 **1083.3** 〉**Good Importation and Exportation Practices.** A new series of general informational chapters describing various aspects of the pharmaceutical supply chain replaces *Good Distribution Practices—Supply Chain Integrity* 〈 1083 〉, which appeared as an *In-Process Revision* in *PF* 38(2) but since then has been canceled. USP is proposing a new series of Good Distribution Practices (GDP) General Chapters, which were developed based on a review of three existing general chapters covering storage, shipment, distribution, and transportation of pharmaceutical components and products: *Good Storage and Distribution Practices for Drug Products* 〈 1079 〉, *Good Distribution Practices* 〈 1083 〉, and *Good Distribution Practices for Bulk Pharmaceutical Excipients* 〈 1197 〉. A review of these chapters showed overlapping and complementary items, highlighting the need for an overarching perspective. The series of new general chapters will cover pharmaceutical components and products, medical devices, and dietary supplements beginning with material flow at initial procurement and continuing throughout the supply chain through delivery to the end user. The suite of chapters—*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 〉— will address four main GDP topics, highlighting best practices and principles.

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Add the following:

〈 1083.3 〉 GOOD IMPORTATION AND EXPORTATION PRACTICES

INTRODUCTION

Importation and Exportation Management (IEM) is a set of basic principles that should be followed to ensure the quality, safety, and security of imported and exported materials and products. Organizations involved in the importation and exportation of materials or products or both should be aware of local, national, and international regulations; risks associated with material or product handling; and have controls in place to mitigate the likelihood that the material or product quality, safety, or security is compromised.

This chapter does not cover importation or exportation laws and customs procedures, because they are country specific. Instead, this chapter covers business-to-business (B2B) and business-to-government (B2G) importation and exportation processes.

Importation and exportation are the international procurement and sales of materials or products or both. These processes are discussed in the *Operations* section in general chapter *Quality Management System* 〈1083.1〉. International donations of samples or products for health programs are also within the scope of importation and exportation and should also follow these basic principles.

This chapter is structured in three sections, as shown in *Figure 1*.

Figure 1. Chapter structure of 〈1083.3〉.

GENERAL REQUIREMENTS

Organizations dealing with importation or exportation of materials and products should have the appropriate licensing and authorizations. Hence, their quality management system (see 〈1083.1〉) should include the provisions/protocols to support international procurement, sales, and distribution. All regulatory and legal requirements for importation and exportation should be followed for the particular material or product and for the country or countries that the organization is dealing with. Organizations should have knowledge of the country's customs policies and procedures and international conventions before importation and exportation, because they are country specific. The organization should comply with relevant intellectual property laws and regulations, such as patent and trademark registration.

The organization should perform a risk assessment, taking into account:

- The material or product
- Supply chain partners (including brokers, agents, carriers, and customs authorities) involved in the importation or exportation or both and their licensing, authorizations, and certifications, such as International Standards Organization (ISO) and U.S. Customs-Trade Partnership Against Terrorism (C-TPAT)
- Physical modes of transportation (air, sea, rail, or truck)
- Transactional mode of ownership
- Transportation routes and country-specific regulations

Listed below are general criteria for conducting this risk assessment.

- Identifying the business partners involved and mapping a product's cargo movement throughout the supply chain
- Conducting both a quality and security threat audit or assessment to identify potential gaps
- Developing an action plan to address potential gaps

With respect to ensuring material and product quality, all necessary environmental conditions and other vulnerability should be accounted for during material and product importation and exportation (see *Environmental Conditions Management* 〈 1083.2 〉), which includes storage in bonded warehouses and during transportation (in-transit storage). Delays in port clearance can potentially lead to deterioration in material or product quality or both.

Organizations should have written procedures for importation and exportation, for all processes, including but not limited to (see 〈 1083.1 〉):

- Responsibilities
- Communication between the supply chain partners and within an organization, such as quality, regulatory, legal affairs, and security
- Operations (order; pro forma or invoice issue; and port and customs clearance, storage, and transportation)
- Origin, authentication, and quality control of imported materials and products
- Applicable documentation, forms, and records (e.g., manifest, air waybill, bill of lading, certifications, batch record, certificate of analysis, and others)
- Identifying forbidden, restricted, controlled, or hazardous materials and products
- Traceability and security of material and product (see general information chapter *Supply Chain Integrity and Security* 〈 1083.4 〉)

MATERIAL OR PRODUCT KNOWLEDGE

Organizations importing or exporting should have adequate knowledge of the material or product, including but not limited to:

- Product or material identification and characteristics: international identification name (if available), code and brand and any other classification intended to identify the material or product (e.g., dosage form for medicines), regulatory classification, and presentation (primary and secondary packaging)
- Intended use of the material and product, including the country in which it will be sold and used
- Storage conditions (e.g., for temperature- and time-sensitive materials or products such as vaccines, cell therapy products, and others)
- Potential hazards: the organization should be aware of both environmental hazards and hazards to personnel (e.g., hormones, cytotoxic drugs, radiopharmaceuticals, and radiolabeled materials, and others)
- Potential risks: e.g., due to the likelihood of cargo theft; materials and products with high potential for abuse; and likelihood of counterfeiting, tampering, adulteration, and diversion
- Source of material or product
- Contractual agreements in place to ensure quality, safety, and security of the material and product

GLOBAL SOURCING KNOWLEDGE

Importation and exportation are the international procurement and sales of materials and products, generally involving supplier, customer, freight forwarders and carriers, and customs. The basic steps for importation and exportation could be summarized as:

1. Business requirements, involving the negotiation between the stakeholders (e.g., supplier, customer, banks, brokers), which includes financial requirements and the flow of information
2. Material or product holding and transportation, taking into consideration all of the environmental factors that can have an affect on the material or product being distributed
3. Customs clearance and, regarding documentation, duties and ports authorities charges necessary to deliver the order from the port warehouses to the customers' receiving sites

Organizations should be aware that business or financial transactions related to importation and exportation could be different from the physical movement of material or product being imported or exported, and these transactions may affect the accountability of the material's or product's quality, safety, and security.

Supplier, service provider, and customer requirements should be established to meet business needs and be monitored to ensure an acceptable level of performance and compliance with importation and exportation regulations (see 〈 1083.1 〉). Organizations should develop a list of approved/not approved suppliers, service providers, and customers. For those approved suppliers, service providers, and customers, their performance should be measured and assessed on an ongoing basis.

Organizations should have agreed-upon responsibilities and contractual terms between the freight forwarder, carrier, supplier (e.g., exporter), and customer (e.g., importer) to handle the inland freight, temporary storage, and overseas shipment; import/export documentation (e.g., licenses, certificates, letter of credit, and others); customs clearance arrangements; and cargo insurance. Depending on the mode of transportation used, additional information and documents may be required (e.g., importer security filing for vessels).

If a contract for port and customs clearance is in place, the organization should define in writing the scope of work and service requirements (e.g., arranging clearance, documentation to be provided by the supplier and by the consignee, security, deviation remediation, and others).

Organizations should have written procedures for port clearances, including the actions the organization or that third-parties should take, including but not limited to communication of expected arrival date of shipments and obtaining the documents necessary for clearance and warehousing (see 〈 1083.2 〉). Re-exportation should not happen, and the organization should require a warranty against this (e.g., statement of non-re-export of product).

Any computer system used for placing orders, order processing, supplier and customer registration, information tracking regarding licenses, product information, regulatory status, denied countries, controlled substances (names and allowed amount),

and others should be validated. Procedures should be in place to identify suspicious orders, including but not limited to whether contact information is different from that filed with the authorities, whether unusual instructions for payment or delivery are included, whether unusually large amounts of controlled substances are involved, and other similar situations. The organization's legal affairs or security department should be notified of any suspicious orders, and the health authority or law enforcement agency or both should be notified as appropriate.

APPENDIX

In the context of this chapter, the following definitions are used.

Air waybill: The shipping document used for the transportation of air freight that includes conditions, limitations of liability, shipping instructions, and description of the material or product being shipped.

Bill of lading: A document that establishes the term of a contract between a shipper and a transportation company under which freight is to be moved between specific points for a specific charge. Because it is usually prepared by the authorized agent on forms issued by the carrier, the bill of lading serves as a document of title, a contract of carriage, and a receipt for product.

Bonded warehouse: An approved private warehouse used for the storage of products until duties and taxes are paid and the goods are properly released by the competent customs authorities.

Exportation: The act of sending or transporting materials or products out of a country.

Importation: The act of bringing materials or products into a country.

Manifest: A collection of documents, including forms such as the cargo declaration and annotated bills of lading, that lists and describes the cargo contents of a bulk transport, container, or warehouse.

Re-exportation: The act of bringing materials or products into a country and then sending or transporting them outside that country.