

Technical Report No. 52
Guidance for Good
Distribution Practices (GDPs)
For the Pharmaceutical
Supply Chain



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PDA Guidance for Good Distribution Practices for the Pharmaceutical Supply Chain Task Force Members

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Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain

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1.0 Introduction

This technical report describes the overall quality system for distribution of pharmaceutical products and is meant to assist manufacturers in assuring that quality, integrity, and efficacy of the product are not compromised in the distribution channels.

The document summarizes both regulatory requirements and industry best practices. However country-specific regulations should be followed, as applicable.

1.1 Purpose and Scope

The purpose of this guidance is to provide direction for distribution practices, including handling, storage, transportation and distribution. This document is intended for use as guidance for the pharmaceutical industry and their supply-chain partners.

Good Distribution Practices (GDPs) can be divided into seven different categories or pillars, as depicted in **Table 1.1** below. Each product should be evaluated against the pillars of GDPs to identify the individual categories that apply within each pillar. This Technical Report provides guidance on the first four pillars: Stability, Distribution Control Management, Performance Management, and Supply Chain Partner Management.

More specific guidance on the first pillar, Stability, is provided in *PDA Technical Report No. 53: Guidance for Industry: Stability Testing to Support Distribution of New Drug Products*. Separate PDA Technical Reports will provide guidance on the other GDP pillars: Qualification/Validation, Continuous Improvement, and Import/Export Compliance.

Table 1.1 Seven Pillars of Good Distribution Practices; this Technical Report covers the first 4

Stability	Distribution Control Management	Performance Management	Supplier/Chain Partner Management	Qualification/Validation	Continuous Improvement	Import/Export Compliance
Storage Temperature	Qualification and Training of Personnel	Performance Measurement and Reporting	Partner Selection	Ambient Temperature Profiles	Industry Trends	Customs Release
Shipping Temperatures	Premises and Equipment	Self Inspections	Quality Audit	Passive Shipping Systems	Regulatory Trends	Documentation Control
Stability Testing to Support Distribution	Material Handling	Management Review Meetings	Quality Agreements	Active Shipping	Requalification	Product Tracking
	Storage and Inventory Control		Business Review Meetings	Facility Qualification		
	Transportation			Warehouse Management System Validation		
	Product Disposition and Distribution			Distribution Validation Master Plans		
	Product Protection					
	Returns Management					
	Exception Management					

1.2 Responsibility

This guidance applies to all parties that are involved in the handling, storage and/or transportation of regulated products, including, but not limited to, the manufacturer, the holder of the marketing authorization, third party Logistics Service Providers (termed 3PLs), wholesale distributors, and transportation carriers.