



Code of Conduct/Data Governance

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- **Introduction and Purpose**
 - Understanding the need for Code of Conduct for Data Integrity and Data Governance arrangements
- **PDA Code of Conduct for Data Integrity in the Pharmaceutical Industry**
 - Understand the contents and the possible application of the document



Introduction and Purpose

Code of Conduct for Data Integrity/Data Governance

- Data Integrity has been and currently is a **major global concern** of Health Authorities and the pharmaceutical industry
- Although **not a new issue**, numerous recent Health Authority enforcement actions such as Warning Letters, Import Alerts, Product Detentions, and suspension or revocation of Marketing Authorizations has focused attention on Data Integrity
- **Data Integrity issues** can result from ...
 - lack of awareness of regulatory requirements,
 - employee errors,
 - failure to check accuracy of data,
 - software or system malfunction,
 - or configuration problems with electronic data handling,
 - or malfeasance by employees



PDA Code of Conduct for Data Integrity

Application of the document

- This document is written for easy adoption, in part or in its entirety, by companies, if they so choose, without the need for extensive rewriting of the document
- Therefore, the terms 'shall' and 'must' have been used to permit the code to be enforceable by a company, if adopted
- This document is intended to reinforce a culture of quality and trust within the pharmaceutical industry. It is not intended to be a regulatory standard or guidance, nor is it intended to supersede any country specific or local laws and regulations governing labor, privacy and/or employee rights
- PDA is providing this document and these concepts as a service to members and an example of best practices to the pharmaceutical industry
- Link: <https://www.pda.org/scientific-and-regulatory-affairs/regulatory-resources/code-of-conduct/elements-of-a-code-of-conduct-for-data-integrity-in-the-pharmaceutical-industry> (Download)



PDA Code of Conduct for Data Integrity Elements





PDA Code of Conduct for Data Integrity Document Review



Microsoft Word
Document

*Live demonstration
of the document*



Parenteral Drug Association Points to Consider Elements of a Code of Conduct for Data Integrity

Introduction

Data Integrity has been and currently is a major global concern of Health Authorities and the pharmaceutical industry. Although not a new issue, numerous recent Health Authority enforcement actions such as Warning Letters, Import Alerts, Product Detentions, and suspension or revocation of Marketing Authorizations has focused attention on Data Integrity. Data Integrity can result from lack of awareness of regulatory requirements, employee errors, failure to check accuracy of data, software or system malfunction, or configuration problems with electronic data handling, or malfeasance by employees. To holistically address Data Integrity, the Parenteral Drug Association (PDA) is developing a set of tools in the form of PDA Technical Reports, PDA Training Program, Data Integrity Workshops, and Points to Consider documents that can be used by industry to address this serious issue. This document presents the views of the Parenteral Drug Association (PDA) on the benefits for companies to voluntarily adopt a Code of Conduct for assuring data integrity.

How to Use this Document

This document was developed by a team with expertise in the fields of quality, regulatory affairs, auditing, and manufacturing and reviewed by attorneys specialized in food, drug and labor law. This document is written for easy adoption, in part or in its entirety, by companies, if they so choose, without the need for extensive rewriting of the document. Therefore, the terms 'shall' and 'must' have been used to permit the Code to be enforceable by a company, if adopted. This document is intended to reinforce a culture of quality and trust within the pharmaceutical industry. It is not intended to be a regulatory standard or guidance, nor is it intended to supersede any country specific or local laws and regulations governing labor, privacy and/or employee rights.

Data Governance at its best...



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