Good Practice Guide

Clinical Supply Systems

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Disclaimer:
This Guide is intended to assist in the development of customized clinical supply applications and in assessing COTS systems for implementation. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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Preface

Many biopharmaceutical organizations have numerous internal systems that are used to manage and control clinical studies and investigational medicinal products, or use third party providers to perform at least some of their investigational medicinal product management activities. Currently, there are no standards or guidelines for system functionality that manage investigational medicinal products.

Lack of standards for data and functionality has resulted in varying terminology, data formats, and controls which can often make the selection, use, and/or interfacing of systems challenging. This Guide, the ISPE Good Practice Guide (GPG): Clinical Supply Systems, contains a list of proposed standard data terminology along with frequently used equivalent terms, definitions of the data terms, and data formatting standards.

The Guide also provides a detailed discussion of important areas of clinical supply system functionality touching on key business requirements to assist interested parties in developing customized clinical supply applications or assessing commercial off the shelf systems for implementation. The Guide provides examples and requirements for interfacing clinical supply systems involved in the management of investigational medicinal products with other internal or external systems.

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Company affiliations are as of the final draft of the Guide.

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1 Introduction

1.1 Background

A wide variety of computer systems are currently employed by biopharmaceutical organizations and third party service providers to manage Investigational Medicinal Products (IMPs) throughout their life cycle (e.g., planning, manufacturing, label design, packaging and labeling, distribution, Interactive Response Technology (IRT), drug accountability, returns, destruction).

A survey conducted by the ISPE Investigational Products Community of Practice (IP COP) indicates that many of the applications in use are either fully customized applications or Commercial off the Shelf (COTS) applications developed specifically for IMPs, or highly customized COTS applications developed for the management of commercial products.

Most biopharmaceutical organizations utilize multiple third party providers to perform at least some of their IMP management activities. Additionally, most biopharmaceutical organizations have numerous internal systems that are utilized to manage and control clinical studies and IMPs. There is often a significant benefit in interfacing the internal clinical supply chain system with other internal or external systems to maximize process efficiencies, to provide full visibility of inventory and lot genealogy to each individual patient, and to ensure robust quality and regulatory controls of IMPs.

Currently, there are no standards or guidelines for system functionality that manage IMPs. Lack of standards for data and functionality has resulted in varying terminology, data formats, and controls which can often make the selection, use, and/or interfacing of systems challenging.

1.2 Scope

This Guide, the ISPE Good Practice Guide (GPG): Clinical Supply Systems, contains a list of proposed standard data terminology, as well as equivalent terms which are frequently used, definitions of the data terms, and data formatting standards.

The Guide also provides a detailed discussion of important areas of clinical supply system functionality touching on key business requirements to assist interested parties in developing customized clinical supply applications and/or assessing COTS systems for implementation. Examples and requirements for interfacing clinical supply systems involved in the management of IMPs with other internal or external systems is provided.

This Guide will be useful for individuals with a foundational background in clinical supplies, who are involved in evaluating or designing clinical supply systems which meet operational, quality and regulatory requirements.

This Guide also may be useful to personnel in smaller biopharmaceutical organizations to assess the systems that their suppliers use to support the clinical supply services they provide. This Guide is also meant to help companies adopt common data standards to make working across company boundaries more seamless.

It is important to note that this document is a Guide. Each company should determine requirements for their systems based on business priorities and their interpretation of current regulatory and quality requirements.