



Good Practice Guide

Clinical Supply Systems

Data Standards

Functionality and Design

System Interfaces

- Packaged Box (1)
 - Booklet Label (1)
 - Carton (1)
 - Foam (2)
 - Foam (1)
 - Tamper Evident
- Packaged Vial (2)
 - Vial (1)
 - Booklet Label
- Packaged Vial in a Packa

- Packaged Blister Card (1)
- Tamper Evident Seal
- Blister Card (1)
- Packaged Blister Strip (1)
- Film (0)
- Foil (0)

Connecting a World of Pharmaceutical Knowledge





Good Practice Guide

Clinical Supply Systems

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.

Limitation of Liability

In no event shall ISPE or any of its affiliates, or the officers, directors, employees, members, or agents of each of them, or the authors, be liable for any damages of any kind, including without limitation any special, incidental, indirect, or consequential damages, whether or not advised of the possibility of such damages, and on any theory of liability whatsoever, arising out of or in connection with the use of this information.

© Copyright ISPE 2014. All rights reserved.

No part of this document may be reproduced or copied in any form or by any means – graphic, electronic, or mechanical, including photocopying, taping, or information storage and retrieval systems – without written permission of ISPE.

All trademarks used are acknowledged.

ISBN 978-1-936379-68-2

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.

Acknowledgements

The Guide was produced by a Task Team led by David Riege (Pfizer). The work was supported by the ISPE Investigational Products Community of Practice (IP COP).

Core Team/Chapter Leaders

The following individuals took lead roles and made valuable contributions in the preparation of this document and each managed one or more chapter teams made up of writers and contributors.

Petra Bielmeier	F. Hoffmann-La Roche AG	Switzerland
Anurag Gautam	Eli Lilly & Co.	USA
Matthew Gilson	GlaxoSmithKline	USA
Henryk Junker	Allergan Ltd.	United Kingdom
Douglas Meyer	Biogen Idec	USA
Greg Minogue	Fisher Clinical Systems	USA
Eddie Montoya	Fisher Clinical Systems	USA
David Riege	Pfizer Inc.	USA
Sandee Schroeder	AbbVie Inc.	USA
Andrew Scott	Almac Clinical Services	United Kingdom
Jeff Young	AbbVie Inc.	USA

Subject Matter Expert Input and Review

Particular thanks go to the following for their review and comments on this Guide:

Nicola Barnes	Pfizer Ltd.	United Kingdom
Ted Bradley	Pfizer Inc.	USA
Linda Burk	Pfizer Inc.	USA
Mike Webb	Pfizer Ltd.	United Kingdom

The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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

Table of Contents

1	Introduction	7
1.1	Background.....	7
1.2	Scope.....	7
1.3	Key Concepts/Terms.....	8
2	Data Standards	9
2.1	Introduction	9
2.2	Metadata	9
3	Functionality and Design Considerations	11
3.1	Material Requirements Planning.....	11
3.2	Drug Product BOMs/Material Masters	13
3.3	Packaging BOMs/Material Masters.....	17
3.4	Inventory Management	20
3.5	Drug Product Manufacturing Execution	24
3.6	Lot Genealogy.....	25
3.7	Kit Identification.....	26
3.8	Subject Randomization	28
3.9	Kit Lists (Randomized or Sequential).....	31
3.10	Blinding Controls.....	35
3.11	Labels (Translations, Design, and Printing)	39
3.12	Label Phrase Translations (including Approval and Controls)	39
3.13	Packaging Request.....	48
3.14	Packaging Work Orders and Execution	49
3.15	Drug Product and Finished Goods Dating	55
3.16	Regulatory and Quality Controls for Investigational Medicinal Products	57
3.17	Samples	66
3.18	Investigator Ethical Approval and Controls	67
3.19	Distribution Network Configuration	68
3.20	Shipment Requests and Orders.....	74
3.21	Shipment Pick/Pack/Ship.....	77
3.22	Controlled Temperature Management of Clinical Supplies	80
3.23	Shipment Invoice/Content.....	86
3.24	Shipment Tracking	87
3.25	Alignment with GAMP	88
3.26	Managing non-IRT Studies	89
4	System Interfaces and Considerations	91
4.1	Clinical Supply System and Clinical Trial Management Systems	91
4.2	Clinical Supply System and Supplier IRT System	92
4.3	Clinical Supply System and Courier Systems.....	95
4.4	IRT System and External Distribution System	96
4.5	Clinical Supply System and Laboratory Information Management System	97

5	Appendix 1 – Data Standards Information	99
6	Appendix 2 – Common EDI Data Elements	109
7	Appendix 3 – References	111
8	Appendix 4 – Glossary	113
8.1	Acronyms	114
8.2	Definitions	115

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.