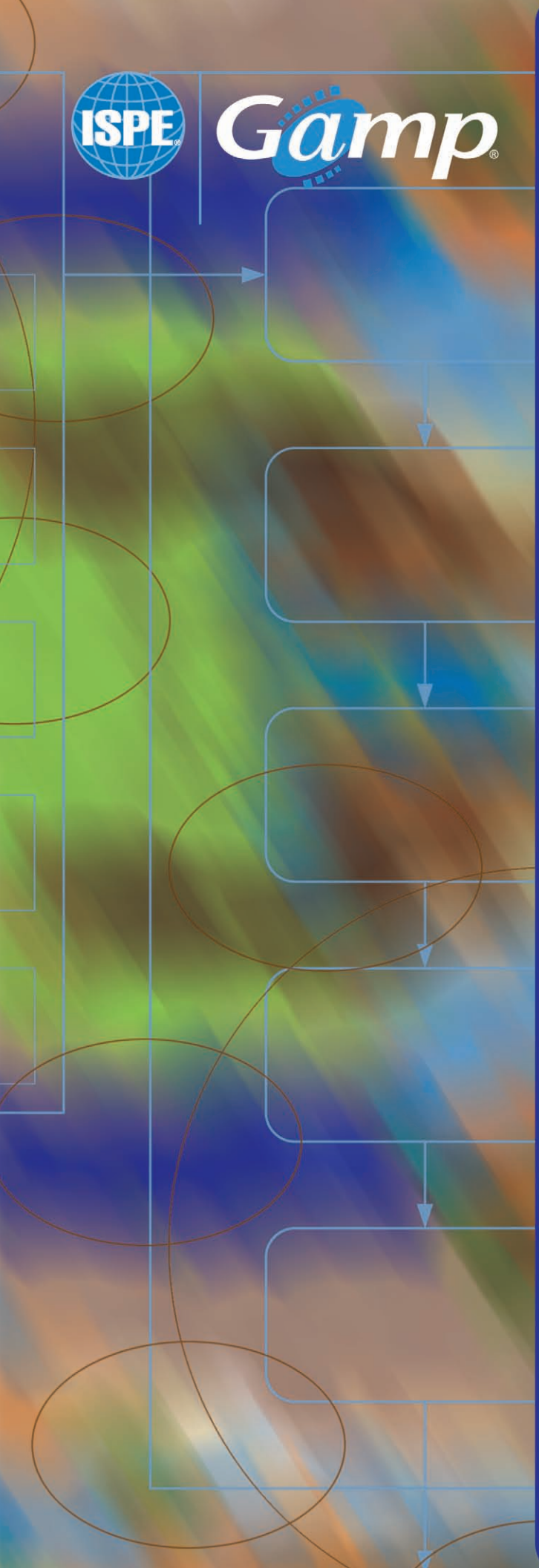

GAMP Good Practice Guide

Manufacturing Execution Systems – A Strategic and Program Management Approach

GAMP Good Practice Guide

Manufacturing Execution Systems – A Strategic and Program Management Approach

Disclaimer:
This Guide is meant to assist pharmaceutical organizations and related industry organizations in determining a common understanding of the concept and principles of Control and Compliance of Manufacturing Execution Systems. The International Society for Pharmaceutical Engineering (ISPE) cannot ensure and does not warrant that systems 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

The ISPE GAMP® Good Practice Guide: Manufacturing Execution Systems – A Strategic and Program Management Approach, was created to help to facilitate the planning, development, and testing of Manufacturing Execution Systems (MES) that may be used to support manufacturing in life sciences organizations.

This Guide is intended to help bridge the gap between the ISPE GAMP® Good Practice Guide: Global Information Systems Control and Compliance and the ISPE GAMP® Good Practice Guide: Validation of Process Control Systems for supporting and maintaining MES environments. The ISPE GAMP® Good Practice Guide: Manufacturing Execution Systems – A Strategic and Program Management Approach should be read in conjunction with these Guides.

GAMP® guidance aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner. This Guide has been developed by pharmaceutical industry professionals to meet these goals and principles.

This Guide takes a life cycle approach to examining MES, not as an application, but as a collection or domain of manufacturing related functions that integrates business and process controls, information flow, and human interaction to facilitate the operation of an organization.

As individual systems evolve to become broader in scope, a system considered to be business-oriented may have functionality which connects to Manufacturing Operations and potentially affects product quality. Therefore, the integration of functions may require the application of testing principles for process control systems to a system considered to be business-oriented. The definition of a ‘business system’ may become difficult, and it may become necessary to create logical boundaries around functionality across systems to define categories of use and criticality.

The domain approach presented in this Guide provides an approach to manage life cycles for the integrated manufacturing environment.

The authors of this Guide have built upon ANSI/ISA 95.00.01-2000, Enterprise-Control System Integration, Part 1; Models and Terminology, an industry independent standard for improved integration of manufacturing through communication that defines common terminology and a consistent set of models that emphasize good practices for integration of control systems with other enterprise systems.

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1 Introduction

1.1 Overview

Computerized systems are used widely throughout healthcare manufacture as a result of the substantial automation of business processes and equipment that has occurred during the 1980s and 1990s. This automation typically has occurred in an incremental system-by-system approach, over an extended period of time, which has left many organizations with islands of automation and little or no strategy for systems integration.

A traditional view of Manufacturing Execution Systems (MES) is of computerized systems designed to integrate with and extend the capabilities of other systems, e.g., by providing Recipe Management for process control equipment. The true potential of manufacturing execution lies in the integration of capabilities and functionality of systems through a well designed MES Domain, which can provide benefits, such as reduced cost, faster turnaround, and improved quality, through elimination of redundant data entry, transcription errors, etc.

This Guide uses the framework of GAMP 5, (Reference 5, Appendix 14), as a complete life cycle approach to the development and use of MES for regulated manufacturing. GAMP 5 provides a framework to:

- facilitate interpretation of regulatory requirements based on good practices
- define the approach for planning and project activities
- apply Risk Management to all aspects of the life cycle activities
- identify roles and responsibilities to execute the life cycle
- integrate existing and new systems
- scale activities and documentation appropriately
- leverage existing documentation and knowledge
- identify boundaries and interfacing among the installed systems
- develop an appropriate strategy for MES

This Guide has been developed by the Manufacturing Execution Systems Special Interest Group (MES SIG) of the GAMP Community of Practice (COP), a technical subcommittee of ISPE, to provide project teams with practical information to address the complex challenges of MES.

1.2 Purpose

This Guide is intended to provide regulated pharmaceutical organizations with the information to assist in achieving and maintaining compliant MES appropriate to the needs and capabilities of an organization.

It collects and integrates information and knowledge from many disciplines and sources into a comprehensive guideline. Regulatory requirements, industry standards, and GAMP guidance are leveraged, and references to sources of additional information are provided.

The intended audience of this document includes:

- systems and process development staff

- manufacturing technology staff
- information technology and engineering staff
- regulatory, compliance, and quality staff
- business process owners
- data owners
- suppliers of technology and systems to industry

1.3 Scope

This Guide focuses on regulated life science manufacturing industries, including:

- pharmaceuticals
- diagnostics
- biologics
- medical devices
- consumer products

It is intended to be applied to the development of new systems, to extensions of existing systems, and to the operation of systems.

Additional information about managing global IT systems may be found in the ISPE GAMP Good Practice Guide: Global Information Systems Control and Compliance (Reference 6, Appendix 14).

Although applications and examples in this document may refer to batch manufacture, the concepts, strategies, approach, and implementation presented in this Guide are applicable to manufacturing found in the medical device industry, consumer products, and packaging operations.

1.4 Benefits

The potential benefits of integrated manufacturing systems for recipe-driven operations include:

- improved scheduling and resource utilization
- improved manufacturing flexibility and process changeover
- reduced Work in Progress (WIP) and improved material tracking
- shorter production cycles
- enforced sequence of operations
- reduced production record errors, electronic or hybrid

- improved visibility, accuracy and consistency of manufacturing data, enhancing decision support, Process Analytical Technology (PAT), and investigations capabilities
- minimized product recalls
- increased plant reliability
- realize paperless manufacturing
- automated Key Performance Indicator (KPI) generation and reporting, such as an Overall Equipment Efficiency (OEE) calculation
- support knowledge management and PAT
- reduce Quality Unit resources required for day to day operations by providing functionality, such as Electronic Production Records (EPR) and Review By Exception (RBE)

This Guide aims to enable organizations to:

- shorten development and implementation times by leveraging industry experience
- implement design and testing methods that improve life cycle activities
- build compliance into the process
- provide improved understanding and coordination of the complete manufacturing environment
- reduce the risk of project failure
- better balance costs of implementation and operation
- clarify Quality Unit resources required for ongoing system operational support

1.5 Objectives

This Guide aims to provide guidance for the effective and efficient development and operation of MES by:

- providing an understanding of MES
- providing a practical framework for applying the principles and concepts of GAMP 5 to MES
- identifying regulatory and compliance aspects of MES
- providing guidance for MES suppliers
- addressing MES technical considerations

1.6 Key Concepts

1.6.1 MES Operational Definition

In this Guide, MES is considered to be the complete interactive system of human, electronic, and mechanized functionality to execute Manufacturing Operations. This includes the necessary business and manufacturing computer applications and systems to optimize operations, manage data, and control information flow.

This section further defines MES in the context of this Guide. These concepts have been developed from industry standards (see Appendix 13).

1.6.2 MES Domain Concept

This Guide considers the word 'domain' to be a method for organizing and documenting computerized systems and functions into groups or 'domains', based on common attributes, business and manufacturing goals, intended use, or risks.

The MES Domain is composed of computer systems, applications, and equipment functionality, along with any related data and information, which is used to produce desired intermediate results and final products.

The MES Domain is constructed by defining functionality necessary for production, then determining which existing or new systems or functionality are needed for implementation. An MES domain includes functionality relevant to the intended scope of manufacturing activities; this may incorporate only the necessary functionality from systems components or applications as necessary to support the domain defined by an organization. See Figure 1.1.

Figure 1.1: An Example View of MES Domain