GAMP Good Practice Guide:

A Risk-Based Approach to Compliant Electronic Records and Signatures

Preface to the GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures

The appropriate management of electronic records and signatures is of current concern to both the regulated life science industry and its regulators. This *GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures* provides timely and much needed guidance on meeting current regulatory expectations for compliant electronic records and signatures, which include the need for record integrity, security, and availability throughout the required retention period.

It describes how a risk management approach may be used to ensure the compliance of regulated electronic records and signatures, through the application of appropriate controls commensurate with the impact of records and signatures and the identified risks. The Guide covers:

- New automated systems
- Existing automated systems
- Those systems that have already been subject to electronic record and signature assessments

This Guide is intended as a supplement to the *GAMP Guide for Validation of Automated Systems (GAMP 4)*. It has been designed so that it may be used in conjunction with guidance provided in GAMP 4 and other ISPE publications.

Disclaimer:
This Guide is meant to assist pharmaceutical manufacturing companies in managing systems which use and maintain regulated electronic records and signatures. The GAMP Forum 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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1 Introduction

1.1 Overview

The increased use of information technology and computer systems in all aspects of business is leading to the automation of more and more processes. Key decisions and actions are routinely being taken using automated systems, with regulated records being generated electronically. Increasingly, confirmation and approval of these actions and decisions is also being provided electronically.

As a result, the appropriate management of electronic records and signatures is a very important topic for the life science industries.

This Guide has been developed by the GAMP Forum, a technical subcommittee of ISPE, to provide timely and much needed guidance in this area. It supplements the existing *GAMP 4, GAMP Guide for Validation of Automated Systems* (see Appendix 13, reference 1).

Good Automated Manufacturing Practice (GAMP) guidance aims to achieve validated and compliant automated systems meeting all current life science regulatory expectations, by building upon existing industry good practice in an efficient and effective manner.

1.2 Purpose

This Guide provides comprehensive new guidance on meeting current regulatory expectations for compliant electronic records and signatures, which includes the need for record integrity, security, and availability throughout the required retention period. This is achieved by well-documented, validated systems, and the application of appropriate operational controls.

The main drivers for this Guide are:

1. An increasing emphasis on the assessment and management of risk within the regulated environment

2. The need to consider and comply with all applicable international regulations

3. Recent regulatory activity and guidance, such as FDA guidance on 21 CFR Part 11 Scope and Application (see Appendix 13, reference 3).

This Guide supersedes previous guidance published jointly by ISPE and PDA, Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures (see Appendix 13, reference 2).

The guidance is intended primarily for regulated companies, but will also be useful for suppliers of systems, products, or services in this area.

The intended audience for this Guide includes:

- Quality assurance (QA) and computer validation professionals responsible for defining and managing validation practices in regulated life science industries

- IT personnel, including IT compliance, who manage and support these systems

- Business owners, data owners, and system users
- System developers, engineers and suppliers

Some familiarity with GAMP and current international regulations is assumed.

1.3 Scope

This Guide addresses compliance with international regulations and guidelines for electronic records and signatures covering automated systems used within the regulated life science industries including pharmaceutical, biological, and medical devices. While not specifically targeted as such, this Guide may also be useful in other regulated areas such as cosmetics and food. Specific guidance is given for:

- New automated systems
- Existing automated systems
- Those systems that have already been subject to electronic record and signature assessments

Current international GxP life science requirements related to electronic records and signatures have been taken into account, and the following publications have been specifically considered:

- US Codes of Federal Regulations (CFRs) covering GCP, GLP, GMP, and medical devices
- US CFR regulation 21 CFR Part 11, and associated guidance documents
- Relevant sections of EU regulations
- PIC/S (Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme) Guidance
- Proposed Japan MHLW (Ministry of Health, Labour and Welfare) guidelines
- European Medicines Agency (EMEA) guidance
- World Health Organization (WHO) guidelines
- International Conference on Harmonization (ICH) guidelines
- International Society of Blood Transfusion (ISBT) guidelines
- Relevant ISO documents, such as ISO 14971 Medical devices - Application of risk management to medical devices and ISO 17799:2000 Information technology - Code of practice for information security management

This Guide covers electronic records, electronic signatures, handwritten signatures captured electronically, and handwritten signatures applied to electronic records. The Risk Management approach described applies to records generally. While paper, electronic and hybrid situations are considered, the detailed activities described are focused on the electronic aspects.