1 简介

1 Introduction

GAMP 指南旨在在使用 GxP 计算机化系统时保障患者安全、产品质量和数据完整性。它旨在通过以高效和有效的方式建立现有的行业良好实践，实现适合预期用途并满足当前监管要求的计算机化系统。

GAMP guidance aims to safeguard patient safety, product quality, and data integrity in the use of GxP computerized systems. It 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.

GAMP 提供了以下实用指南：

GAMP provides practical guidance that:

- 便于解释监管要求

  Facilitates the interpretation of regulatory requirements

- 建立通用语言和术语

  Establishes a common language and terminology

- 广基于良好实践的系统生命周期方法

  Promotes a system life cycle approach based on good practice

- 明确角色和责任

  Clarifies roles and responsibilities

它不是一种规定性的方法或标准，而是为从业者提供实用的指导、方法和工具。

It is not a prescriptive method or a standard, but rather provides pragmatic guidance, approaches, and tools for the practitioner.

当运用专业知识和良好判断力时，本指南提供了一种稳健、经济高效的方法。

When applied with expertise and good judgment, this Guide offers a robust, cost-effective approach.

本文档中描述的方法旨在与广泛的其他模型、方法和方案兼容，包括：

The approach described in this document is designed to be compatible with a wide range of other models, methods, and schemes including:

- 质量体系标准和认证计划，例如 ISO 9000 系列 [1]

  Quality systems standards and certification schemes, such as the ISO 9000 Series [1]

- ISO 14971 [2]：医疗器械－风险管理在医疗器械中的应用

  ISO 14971 [2]: Medical devices – Application of risk management to medical devices

- 评估和改进组织能力和成熟度的方案，例如能力成熟度模型集成® (CMMI) [3]

  Schemes for assessing and improving organization capability and maturity, such as Capability Maturity Model Integration® (CMMI) [3]

- 软件过程模型，例如 ISO 12207 [4]

  Software process models such as ISO 12207 [4]

- 迭代和增量（敏捷）软件开发方法和模型

  Iterative, and incremental (Agile) software development methods and models

- IT 服务管理方法，例如 ITIL [5]

  Approaches to IT service management, such as ITIL [5]

在可能的情况下，术语应与 ICH [6] 和 ISO [7] 等标准国际来源相协调。本指南旨在与 ASTM E2500 药品和生物制药制造系统和设备的规范、设计和验证标准指南 [8]中描述的方法完全兼容。

Where possible, terminology is harmonized with standard international sources such as ICH [6] and ISO [7]. This Guide aims to be fully compatible with the approach described in the ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment [8].

1.1 GAMP 5 第二版的基本原理

1.1 Rationale for GAMP 5 Second Edition

本第二版指南旨在通过促进和鼓励实现有效、可靠和高质量的计算机化系统来保护患者安全、产品质量和数据完整性。

This Second Edition Guide aims to protect patient safety, product quality, and data integrity by facilitating and encouraging the achievement of computerized systems that are effective, reliable, and of high quality.

尽管总体方法、框架和关键概念保持不变，但指南的技术内容已经更新，以反映包括云服务提供商在内的 IT 服务提供商日益重要的重要性，包括增量和迭代模型和方法在内的软件开发方法的演变，以及增加使用软件工具和自动化在整个生命周期内实现更好的控制、更高的质量和更低的风险。

While the overall approach, framework, and key concepts remain unchanged, technical content of the Guide has been updated to reflect the increased importance of IT service providers including cloud service providers, evolving approaches to software development including incremental and iterative models and methods, and increased use of software tools and automation to achieve greater control, higher quality, and lower risks throughout the life cycle.

与此相关的是信息的强化，即 GAMP 规范和验证方法本身不是线性的，但也完全支持迭代和增量（敏捷）方法。

Associated with this is the reinforcement of the message that the GAMP specification and verification approach is not inherently linear but also fully supports iterative and incremental (Agile) methods.

人工智能和机器学习 (AI/ML)、区块链、云计算和开源软件 (OSS) 等新兴技术领域的应用指南已被纳入或更新。

Guidance on the application of new and developing technological areas such as Artificial Intelligence and Machine Learning (AI/ML), blockchain, cloud computing, and Open-Source Software (OSS) has been included or updated.

批判性思维和应用以患者为中心、基于风险的方法（以质量和安全为目标）与主要以合规驱动的方法相比的重要性得到进一步强调。作为美国 FDA 设备和放射健康中心 (CDRH) 质量案例 [9]的一部分所讨论的计算机化系统保证的概念也得到了探索和应用。

The importance of critical thinking and the application of patient-centric, risk-based approaches (aimed at quality and safety) versus primarily compliance-driven approaches is further underlined. Concepts of computerized systems assurance as discussed as part of the US FDA Center for Devices and Radiological Health (CDRH) Case for Quality program [9] are also explored and applied.

已添加有关记录和数据完整性主题领域的 GAMP 指南的链接和参考。

Links and references to GAMP guidance on the topic area of record and data integrity have been added.

支持以下 ISPE 倡议和主题领域，并考虑与它们的联系和协同作用：

The following ISPE initiatives and topic areas are supported and links and synergies with them have been considered:

知识管理—关注组织如何在产品的整个生命周期中创建、管理和使用知识，使组织能够更好地将其知识作为关键资产进行管理，进而提高药品质量体系的有效性，并提供运营效益。[10]

Knowledge Management – focusing on how organizations create, manage, and use knowledge throughout the life cycle of a product, enabling organizations to better manage their knowledge as a key asset, in turn improving the effectiveness of the pharmaceutical quality system, and providing operational benefits. [10]

APQ（推进药品质量）—构建行业对行业的工具和计划，以帮助公司评估和改进其质量运营。[11]

APQ (Advancing Pharmaceutical Quality) – building industry-for-industry tools and programs to help companies assess and improve their quality operations. [11]

Pharma 4.0™ – 提供符合制药行业特定监管要求的指导，以加速 Pharma 4 .0 转型。Pharma 4 .0 也称为智能工厂，其目标是使参与产品生命周期的组织能够充分利用数字化的潜力，为患者提供更快的创新。[12]

Pharma 4.0™ – providing guidance, aligned with the regulatory requirements specific to the pharmaceutical industry, to accelerate Pharma 4.0 transformations. Also known as the Smart Factory, the objective of Pharma 4.0 is to enable organizations involved in the product life cycle to leverage the full potential of digitalization to provide faster innovations for the benefit of patients. [12]

设计的数字成熟度和数据完整性是有效数字化战略的推动力，并以管理良好的自动化和信息系统为基础。GAMP 指南旨在确保 GxP 计算机化系统适合预期用途，并在整个数据生命周期中管理 GxP 电子记录和数据，以确保数据完整性。请参见图 1.1。

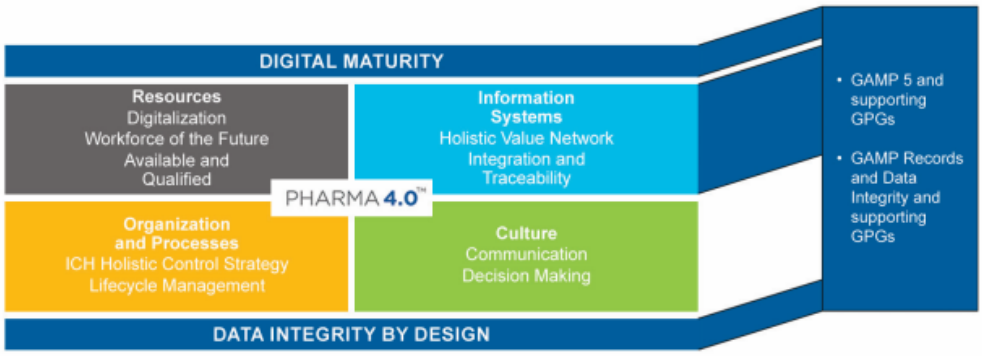
Digital maturity and data integrity by design are enablers to an effective digitalization strategy and are underpinned by well-managed automation and information systems. GAMP guidance aims to ensure that GxP computerized systems are fit for intended use, and that GxP electronic records and data are managed throughout the data life cycle in order to ensure data integrity. See Figure 1.1.

GAMP 指南采用以患者为中心、基于风险的方法，在证明符合监管要求的同时实现创新。Pharma 4.0 建立在基于 ISPE 指南的最佳实践之上，并通过实时数据驱动流程的数字化转型方法得到增强。

GAMP guidance adopts a patient-centric risk-based approach that enables innovation while demonstrating compliance with regulatory requirements. Pharma 4.0 builds on best practices based on ISPE Guidelines that are enhanced by the digital transformational approach to real time data driven processes.

图 1.1：制药 4.0 [13]

Figure 1.1: Pharma 4.0 [13]



1.2 新材料和修订材料

1.2 New and Revised Material

新指南已包含在以下主题中：

New guidance has been included on the following topics:

- 附录 D8 – 敏捷
  Appendix D8 – Agile
- 附录 D9 – 软件工具
  Appendix D9 – Software Tools
- 附录 D10 – 分布式账本系统（区块链）
  Appendix D10 – Distributed Ledger Systems (Blockchain)
- 附录 D11 – 人工智能和机器学习 (AI/ML)
  Appendix D11 – Artificial Intelligence and Machine Learning (AI/ML)
- 附录 M11 – IT 基础设施
  Appendix M11 – IT Infrastructure

- 附录 M12 – 批判性思维

  Appendix M12 – Critical Thinking

已包含以下主题的重大更新指南：

Significantly updated guidance has been included on the following topics:

- 附录 D1 – 指定要求

  Appendix D1 – Specifying Requirements

- 附录 S2 – 电子生产记录

  Appendix S2 – Electronic Production Records

由于上述添加和修订，本指南先前版本中包含的以下指南已被删除：

As a result of the above additions and revisions, the following guidance included in the previous version of this Guide have been removed:

- 附录 D2 – 功能规格

  Appendix D2 – Functional Specifications

- 附录 O7 – 维修活动

  Appendix O7 – Repair Activity

- 附录 S5 – 在外包 IS/IT 环境中管理质量

  Appendix S5 – Managing Quality within an Outsourced IS/IT Environment

总体 GAMP 5 框架、关键概念、系统生命周期、规范和验证方法以及质量风险管理 (QRM)流程（与 ICH Q9 [14] 一致）保持不变。

The overall GAMP 5 framework, key concepts, system life cycle, specification and verification approach, and Quality Risk Management (QRM) process (aligned with ICH Q9 [14]) remains unchanged.

1.3 目的

1.3 Purpose

本指南的目的是提供一个具有成本效益的良好实践框架，以确保计算机化系统是有效的和高质量的，适合预期用途，并符合适用的法规。 该框架旨在保障患者安全、产品质量和数据完整性，同时也带来商业利益。本指南还为生命科学行业的供应商提供遵循良好实践的系统开发和维护指南。

The purpose of this Guide is to provide a cost-effective framework of good practice to ensure that computerized systems are effective and of high quality, fit for intended use, and compliant with applicable regulations. The framework aims to safeguard patient safety, product quality, and data integrity while also delivering business benefit. This Guide also provides suppliers to the life-science industry with guidance on the development and maintenance of systems by following good practice.

患者安全受到关键记录、数据和决策的完整性以及影响产品物理属性的那些方面的影响。本指南通篇使用“患者安全、产品质量和数据完整性”这一短语来强调这一点。

Patient safety is affected by the integrity of critical records, data, and decisions, as well as those aspects affecting physical attributes of the product. The phrase “patient safety, product quality, and data integrity” is used throughout this Guide to underline this point.

本指南旨在供受监管的公司、供应商和监管机构使用。供应商包括受监管公司内部和外部的软件、硬件、设备、系统集成服务提供商、IT 服务 提供商和 IT 支持服务提供商。

This Guide is intended for use by **regulated companies, suppliers, and regulators.** Suppliers include providers of software, hardware, equipment, system integration services, IT service providers, and IT support services, both internal and external to the regulated company.

该指南旨在供广泛的学科和职责使用，包括：

The Guide has been designed for use by a wide range of disciplines and responsibilities, including:

- 管理

  Management
- 质量单位

  Quality Unit
- 研究

  Research
- 发展

  Development
- 生产

  Manufacture
- 实验室

  Laboratory
- 工程

  Engineering
- IT

  IT
- 技术支持人员

  Support Staff
- 所有相关供应商

  All associated suppliers

GAMP文件是指南而非标准。受监管公司有责任制定政策和程序以满足适用的监管要求。因此，受监管的公司、供应商或产品声称它们已获得 GAMP 认证、批准或合规是不合适的。

GAMP documents are guides and not standards. It is the responsibility of regulated companies to establish policies and procedures to meet applicable regulatory requirements. Consequently, it is inappropriate for regulated companies, suppliers, or products to claim that they are GAMP certified, approved, or compliant.

1.4 范围

1.4 Scope

本指南适用于以下受规管活动中使用的计算机化系统：

This Guide applies to computerized systems used in regulated activities covered by:

- 良好生产规范 (GMP)（药物，包括活性药物成分 (API)、兽药和血液）

  Good Manufacturing Practice (GMP) (pharmaceutical, including Active Pharmaceutical Ingredient (API), veterinary, and blood)
- 良好临床实践 (GCP)

  Good Clinical Practice (GCP)
- 良好实验室规范 (GLP)

  Good Laboratory Practice (GLP)
- 良好分销规范 (GDP)

  Good Distribution Practice (GDP)
- 良好药物警戒规范 (GVP)

  Good Pharmacovigilance Practices (GVP)

• 医疗器械法规（在适用和适当的情况下，例如，用于作为生产的一部分的系统或 质量体系，以及作为医疗设备的软件（SaMD）的一些示例）

Medical Device Regulations (where applicable and appropriate, e.g., for systems used as part of production or the quality system, and for some examples of Software as a Medical Device (SaMD[1]))

这些统称为 GxP 法规（完整定义见第 2 章）。

These are collectively known as GxP regulations (see Chapter 2 for full definition).

本指南提供了一种适用于所有类型的计算机化系统的方法，重点关注基于标准和可配置产品的系统，但同样适用于定制（定制）应用程序。

This Guide provides an approach that is suitable for all types of computerized systems, focusing on those based on standard and configurable products, but equally applicable to custom (bespoke) applications.

所描述的原理可以应用于范围广泛的计算机化系统。支持 ISPE GAMP 良好实践指南[15]中描述了这些原则在特定系统类型（例如，IT、基础设施、过程控制系统和分析实验室系统）中的详细应用。

The principles described can be applied to a wide range of computerized systems. Detailed application of these principles to specific system types (e.g., IT, infrastructure, process control systems, and analytical laboratory systems) is described in supporting *ISPE GAMP Good Practice Guides* [15].

并非本指南中定义的所有活动都适用于每个系统。采用批判性思维的可扩展方法使受监管的公司能够选择适当的系统生命周期活动。

Not all the activities defined in this Guide will apply to every system. The scalable approach, with application of critical thinking, enables regulated companies to select the appropriate system life cycle activities.

本指南还符合其他监管要求，例如 Sarbanes-Oxley (SOX)以及与数据隐私相关的要求。然而，本指南的使用并不保证符合或取代这些监管要求，这些要求将在适用的情况下定义附加要求。

This Guide is also consistent with other regulatory demands such as Sarbanes-Oxley (SOX)[2] and those associated with data privacy. The use of this Guide, however, does not guarantee compliance with, or replace, these regulatory demands, which will define additional requirements where they are applicable.

除了本指南中描述的方法之外，还有其他可接受的方法是公认的。本指南无意对新概念和技术的创新和发展施加任何限制。

It is recognized that there are acceptable methods other than those described in this Guide. This Guide is not intended to place any constraints on innovation and development of new concepts and technologies.

1.4.1 供应商方面

1.4.1 Supplier Aspects

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1 医疗器械有自己的监管框架和标准（例如，ISO 13485 [16]、ISO 14971 [17] 和 IEC 62304 [18]），通常需要单独批准，并且通常在软件验证后接受临床试验评估。本指南中讨论的 GxP 计算机化系统通常支持内部受监管的公司 GxP 业务流程，而 SaMD 通常是患者或医疗保健提供者手中的产品。

1 Medical devices have their own regulatory framework and standards (e.g., ISO 13485 [16], ISO 14971 [17], and IEC 62304 [18]), typically require individual approval, and are often subject to clinical trial evaluation after software verification. GxP computerized systems as discussed in this Guide usually support internal regulated company GxP business processes, whereas SaMD is typically a product in the hands of patients or health care providers.

2 美国萨班斯-奥克斯利法案 [19]，特别是第 404 节，要求控制生成财务记录的计算机系统。许多好的实践原则和电子记录管理控制与遵守本法有关。

2 The US Sarbanes-Oxley law [19], specifically Section 404, mandates control of computer systems that generate financial records. Many of the good practice principles and electronic records management controls are relevant to compliance with this law.

本指南中描述的受监管公司的计算机化系统生命周期不应与软件开发定义的方法或方法的需求相混淆，这是供应商的责任。

The computerized system life cycle described in this Guide for a regulated company should not be confused with the need for a defined approach or method for software development, which is the responsibility of the supplier.

本指南定义了供应商在提供产品和服务时所期望的活动和责任。 这些活动在支持受监管的公司活动方面发挥着重要作用。供应商可能是第三方或受监管公司的内部团体。 此类内部小组应遵循与受监管的公司质量管理体系 (QMS) 一致的流程。

This Guide defines activities and responsibilities expected of the supplier in the provision of products and services. These activities perform an important role in supporting regulated company activities. The supplier may be a third party or an internal group of the regulated company. Such internal groups should follow processes consistent with the regulated company Quality Management System (QMS).

本指南使用各种图表来表示系统生命周期。这些图通常以线性表示形式呈现关系。这并不是要限制开发方法和模型的选择。供应商应使用最合适 的方法和模型，其中可能包括迭代和增量（敏捷）、进化、探索和原型技术，或使用 DevOps 方法（另见附录 D8）。

This Guide uses various diagrams to represent the system life cycle. These diagrams often present relationships in a linear representation. This is not intended to constrain the choice of development methods and models. Suppliers should use the most appropriate methods and models, which may include iterative and incremental (Agile), evolutionary, exploratory, and prototyping techniques, or the use of DevOps approaches (see also Appendix D8).

现代系统可能具有涉及多个供应商的复杂供应链。本指南旨在满足每个群体的需求。

Modern systems may have a complex supply chain involving multiple suppliers. This Guide aims to meet the needs of each group.

1.5 商业利益

1.5 Business Benefits

有效、可靠和高质量的计算机化系统有助于实现患者安全、产品质量和数据完整性的主要目标，也需要有一个明确的流程以按时交付适合预期用途的系统，以及在预算之内。明确定义和指定的系统更易于支持和维护，从而减少停机时间并降低维护成本。采用本指南中描述的方法将有助于受监管的公司管理业务风险和质量风险。

Effective, reliable, and high-quality computerized systems assist in achieving the primary objectives of patient safety, product quality, and data integrity, but there are major business benefits in having a defined process that delivers systems fit for intended use, on time, and within budget. Systems that are well defined and specified are easier to support and maintain, resulting in less downtime and lower maintenance costs. Adoption of the approaches described in this Guide will assist regulated companies in managing business risk as well as quality risks.

对受监管公司和供应商的具体好处包括：

Specific benefits to both regulated companies and suppliers include:

- 减少实现和保持合规所需的成本和时间

  Reduction of cost and time taken to achieve and maintain compliance

- 早期缺陷识别和解决，从而减少对成本和进度的影响

  Early defect identification and resolution leading to reduced impact on cost and schedule

- 高性价比的运维

  Cost-effective operation and maintenance

- 有效的变更管理和持续改进

  Effective change management and continual improvement

- 促进创新和采用新技术

  Enabling of innovation and adoption of new technology

- 为用户/供应商合作提供框架

Providing frameworks for user/supplier cooperation

- 协助供应商制作所需的文件

  Assisting suppliers to produce required documentation

- 推广通用系统生命周期、语言和术语

  Promotion of common system life cycle, language, and terminology

- 提供实用指南和示例

  Providing practical guidelines and examples

- 促进对法规的务实解释

  Promoting pragmatic interpretation of regulations

1.6 结构

1.6 Structure

1.6.1 GAMP 文档结构概述

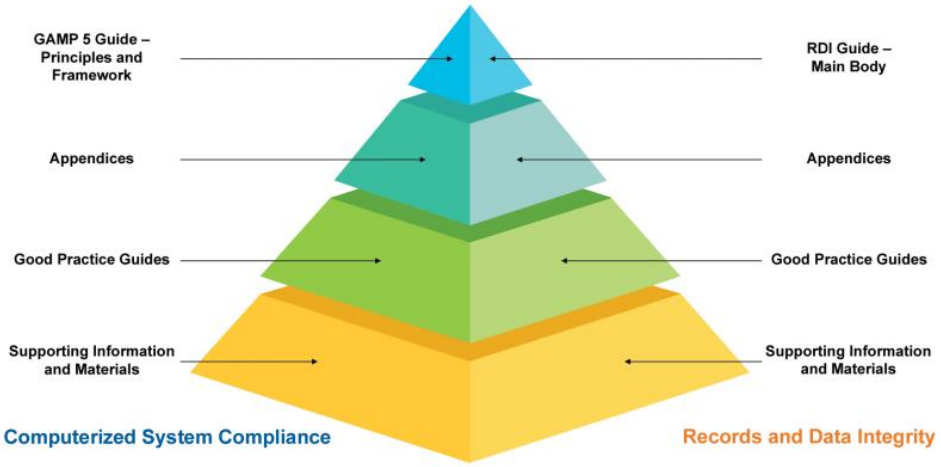
1.6.1 Overview of GAMP Documentation Structure

本指南是一系列文档的一部分，这些文档共同提供了一个强大而全面的知识体系，涵盖了计算机化系统良好实践和合规性的各个方面，如图 1.2 所示。

This Guide forms part of a family of documents that together provide a powerful and comprehensive body of knowledge covering all aspects of computerized systems' good practice and compliance, as shown in Figure 1.2.

图 1.2：GAMP文档结构 [20]

Figure 1.2: GAMP Documentation Structure [20]



本指南包括一个主体和一组辅助附录。

This Guide comprises a main body and a set of supporting appendices.

主体提供了适用于 GxP 监管的计算机化系统的原则和生命周期框架。

The main body provides principles and a life cycle framework applicable to GxP regulated computerized systems.

支持附录中提供了有关广泛主题的实用指南。

Practical guidance on a wide range of topics is provided in the supporting appendices.

单独的 ISPE GAMP 良好实践指南[15] 涵盖了将这些一般原则和框架应用于特定类型的系统和平台。其他 GAMP GPG 提供了针对特定活动和主题的详细方法。有关可用的 ISPE GAMP 良好实践指南的信息，请参阅 www.ispe.org。

Separate *ISPE GAMP Good Practice Guides* [15] cover the application of these general principles and framework to specific types of systems and platforms. Other GAMP GPGs provide detailed approaches to specific activities and topics. For information about available *ISPE GAMP Good Practice Guides,* see www.ispe.org.

1.6.2 GAMP 5 主体结构

1.6.2 GAMP 5 Main Body Structure

正文介绍涵盖了本指南的目的、范围、益处和结构。正文的后续部分涵盖以下主题：

The main body introduction covers the purpose, scope, benefits, and structure of this Guide. Subsequent sections of the main body cover the topics:

• 关键概念

Key concepts

• 生命周期方法

Life cycle approach

• 生命周期阶段：

Life cycle phases:

- 概念

  Concept

- 项目

  Project

- 手术

  Operation

- 遗体

  Retirement

• QRM

  QRM

• 受监管的公司活动：

  Regulated company activities:

- 实现合规的治理

  Governance for achieving compliance

- 系统特定的活动

  System-specific activities

• 供应商活动

  Supplier activities

• 效率提升

  Efficiency improvements

第 2 章中描述的关键概念是支撑文档其余部分的五个概念，应该使用批判性思维来应用。

The **key concepts,** described in Chapter 2, are the five concepts that underpin the rest of the document and should be applied using critical thinking.

计算机化系统生命周期包括从初始概念、需求理解、开发或购买、发布和操作使用到系统退役的所有活动。第 3 章描述了这些活动以及它们之间的关系。

The computerized system **life cycle** encompasses all activities from initial concept, understanding of the

requirements, through development or purchase, release, and operational use, to system retirement. Chapter 3 describes these activities and how they are related.

第 4 章更详细地描述了项目生命周期阶段，包括：

Chapter 4 describes the **project life cycle phase** in more detail, including:

- 规划

  Planning

- 规范、配置和编码

  Specification, configuration, and coding

- 确认

  Verification

- 报告和发布

  Reporting and release

还介绍了风险管理、变更和配置管理、设计审查、可追溯性和文档管理的关键支持流程。

The key supporting processes of risk management, change and configuration management, design review, traceability, and document management are also introduced.

QRM 是一种用于识别、评估、控制、沟通和审查风险的系统方法 患者安全、产品质量和数据完整性。它是一个贯穿整个系统生命周期的迭代过程。第 5 章描述了这种方法以及这些活动应如何基于良好的科学和产品以及过程理解。

QRM is a systematic approach for the identification, assessment, control, communication, and review of risks to patient safety, product quality, and data integrity. It is an iterative process applied throughout the system life cycle. Chapter 5 describes this approach and how these activities should be based on good science and product and process understanding.

确保合规性和适用性是受监管公司的责任。针对各个系统的有效且一致的受监管公司活动需要明确的组织和治理框架，涵盖政策、职责、管理 和持续改进等方面。第 6 章介绍了治理和特定系统的受监管公司活动。

Ensuring compliance and fitness for purpose is the responsibility of the regulated company. Effective and consistent **regulated company activities** for individual systems require a defined organizational and governance framework, covering aspects such as policies, responsibilities, management, and continual improvement. Governance and system-specific regulated company activities are covered in Chapter 6.

虽然合规责任在于受监管的公司，但供应商可以发挥关键作用。第 7 章概述了典型的供应商活动。

While the responsibility for compliance lies with the regulated company, the supplier has a key role to play. An overview of typical **supplier activities** is given in Chapter 7.

本指南提供了一个灵活的框架，用于实现适合预期用途的合规计算机化系统，但只有在特定组织的环境中有效应用该框架，才能获得全部好处。第 8 章涵盖了导致效率提高的关键主题。

This Guide provides a flexible framework for achieving compliant computerized systems that are fit for intended use, but the full benefits can be obtained only if the framework is applied effectively in the context of a particular organization. Chapter 8 covers key topics leading to **efficiency improvements.**