计算机化系统和电子记录/电子签名合规范式

CS and ER/ES Compliance Examples

一条通往计算机化系统和电子记录/电子签名合规的路径

A Way to CS and ER/ES Compliance

刘振超◎著

经济日报出版社

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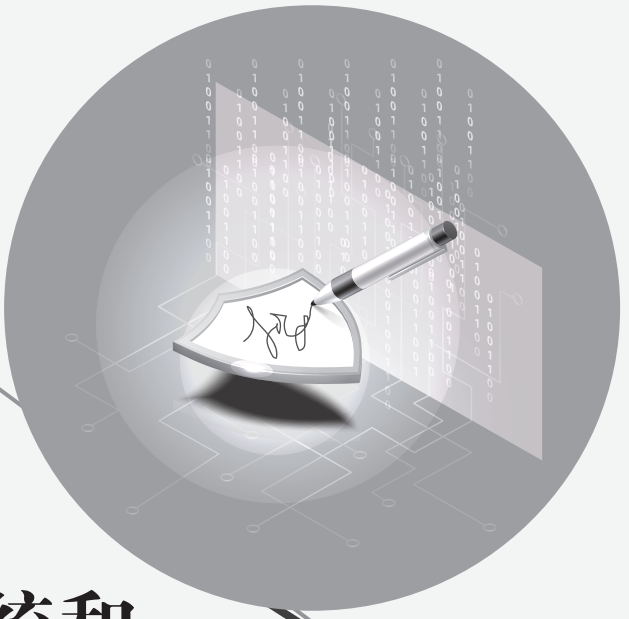

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序
Preface

本书并没有创造任何新的知识，只是根据当前比较具有影响力的法规和国际指南内的要求，并进行解读后写了这本书。作者著书过程中，参考和引用的法规和国际指南列表，见本书附录。如果非要说创造了点什么的话，那作者只是创造了一条自认为可以通往这些法规和国际指南要求的路。同世界上没有一双鞋使每个人穿上都合脚一样，也没有任何一条路可以适用于每家企业，使这家企业达到这些法规和国际指南的要求。尽管作者已经尽力把内容的可执行性写到很详尽，但本地化还是必要的。本书的内容只能被认为是一种提醒和建议，书的内容不能被认为可以取代任何法规和国际指南内的要求。在我们看这本书的时候，我们要感激这些法规机构和行业组织对医药相关行业做出的贡献，如果没有这些法规机构和行业组织，那我们用的药和医疗器械等相关产品的质量，可能只能看“广告”了。

书的内容大体上是中英文版的，但母语是中文，当中英文所表达的意思不一致时，请以中文为准。本书内的英文可以起到辅助理解的作用，因为书内的某些行业术语是从英文的法规和国际指南翻译过来的。为了更好地弥合理解上的差异，作者在本书的最后章节，做了一个常见英文词汇翻译惯例对照表。但这只是本书词汇翻译的一部分而不是全部。模板里的举例可能并不是来源于某个真实的系统，里面的内容也不一定完全正确，请不要生搬硬套。

赠书、购书或者反馈书本内的错误，请发邮件至 Leo3liu@163.com。

The book has not created any new knowledge, but writes this book after interpreting the requirements in the current relatively influential regulations and international guidelines. In the process of writing the book, the list of regulations and international guidelines referred to and cited by the author can be found in the appendix of this book. If you have to say that something new has been created, then the author has just created a path that he believes can meet the requirements of these regulations and international guidelines. Just as there is no single pair of shoes in the world that makes everyone fit their feet, there is no a common path that can be applied to every company to make this company meet the requirements of these regulations and international guidelines. Although the author has tried his best to write in detail regarding the executability of the contents, localization is still necessary. The contents in this book can only be regarded as a reminder and suggestion, and cannot be regarded as a substitute for the requirements of any regulations and international guidelines. When we read this book, we must be grateful for the contributions that these regulatory agencies and industry organizations have made to the pharmaceutical-related industries. Without them, the quality of the drugs and medical devices and other related products we use, would have been dependent on "advertising".

The content of the book is mostly in Chinese and English, but the mother language is Chinese. If the meanings expressed in Chinese and English are inconsistent, please believe the Chinese. The English in this

book can play a role in assisting understanding, because some industry terms in the book are translated from English regulations and international guidelines. In order to mitigate the differences in understanding, the author makes a comparison table of common English vocabulary translation conventions in the last chapter of this book, although only some of these translations are used in this book, not all of them. The examples in the templates of the book may not originate from a real system, and the contents inside may not be completely correct. Please don't copy and use them mechanically.

Applying for a free book, purchasing a book or feeding back the error in the book, please send email to Leo3liu@163.com.

目 录
Catalogue

第 1 章

计算机化系统风险管理规程
Cs Risk Management Procedure

版本信息 Version Information

版本号 Version	修订日期 Revision Date	修订原因 Revise Reason
01		新文件 New Document

1.1 目的 Purpose

本章用于描述基于风险的管理理念，确定验证范围和验证程度；当用户需求、法规要求或行业良好实践要求得不到满足的场景时，识别这些场景对业务运行、数据安全和数据可靠性方面带来的风险；以及如何缓解识别出的风险。

This document is to describe the risk based approach to determine scope and extent of the validation; when there are scenarios where user requirements, regulatory requirements or industry good practice requirements cannot be met, to identify the risks that these scenarios bring to business operation, data security and data integrity; and how to mitigate the identified risks.

1.2 适用范围 Scope

本文件适用于所有由公司部署的，或者由公司授权部署的，带有法规使用目的的计算机化系统。

This procedure applies all the systems that have regulated intended use, which are deployed by the company or that are authorized by the company.

尽管本文件不适用于 IT 基础架构的风险管理，但 IT 基础架构层面对风险的分级方法也可以参考本文的内容，IT 基础架构的风险管理见 SOP ×××-×××× “IT 基础架构风险管理”。

This procedure doesn't not apply to the risk management of IT infrastructure, although the risk leveling method at the IT infrastructure level can also refer to the content of this procedure, for that, please refer to SOP ×××-×××× "IT Infrastructure Risk Management".

1.3 定义和缩略语 Definitions and Abbreviations

术语/简称 Term / Abbreviation	定义 Definition
风险 Risk	风险是对意外影响的严重程度和可能性的度量。通常被认为是后果和可能性的乘积。 A measure of the probability and severity of undesired effects. Often taken as the simple product of probability and consequence.
风险评估 Risk Assessment	本文指对风险本身及与其关联影响的综合评估。 In this procedure, it means a comprehensive evaluation of a risk and its associated impact.
风险指数（RAI） Risk Annex Index（RAI）	反映一个计算机化系统 GxP 关键程度的定量或定性的指标。 A quantitative or qualitative index stands for GxP criticality of a computerized system.

1.4 角色和职责 Roles and Responsibilities

角色 Roles	职责 Responsibilities
流程所有者 Process Owner	从业务角度参与风险评估，确保业务方面的风险因素在风险评估过程中得到强调。 Participate in risk assessment from business perspective to ensure that business risk factors are addressed in the risk assessment process.
质量保证 Quality Assurance	从合规角度参与风险评估，确保合规方面的风险因素在风险评估过程中得到强调； Participate in risk assessment from compliance perspective to ensure that compliance risk factors are addressed in the risk assessment process; 审核并批准风险评估结果。 Review and approve risk assessment results.

角色 Roles	职责 Responsibilities
系统监护人 System Custodian	参与风险评估过程； Participate in the risk assessment process； 确保 QA 和其他相关利益群体的代表参与到风险评估过程； Ensure that representatives of QA and other relevant stakeholders participate in the risk assessment process； 确保高等级风险评估和详细的风险评估得到执行； Ensure that high-level risk assessment and detailed risk assessment are implemented； 确保风险评估的结果得到系统所有者和 QA 的批准。 Ensure that the results of the risk assessment are approved by the system owner and QA.
系统/数据所有者 System/ Data Owner	审核并批准风险评估结果； Review and approve risk assessment results； 需要时，为缓解措施提供必要的资源。 Allocate necessary resources for the mitigation measures, where required.

1.5 程序 Procedure

1.5.1 风险评估分类 Risk Assessment Classification

1.5.1.1 在本公司，风险评估分为两类：高等级风险评估和详细的风险评估。

In the company, Risk Assessment is divided into two categories: High Level Risk Assessment (HLRA) and detail Risk Assessment (RA).

1.5.1.2 基于对系统的 GAMP 类别、系统使用目的、系统关键程度和复杂程度的识别，高等级风险评估被用于决定系统验证范围和验证程度。

Based on the identification of the GAMP category, intended purpose, criticality and complexity of the system, a high-level risk assessment is used to determine the scope and extent of system validation.

1.5.1.3 基于用户需求、法规要求或行业良好实践要求得不到满足的场景，识别这些场景对应的风险优先级，详细的风险评估被用于决定测试严格程度和其他合适的风险缓解措施。

Based on scenarios when user requirements cannot be met, the risk priorities corresponding to these scenarios are identified, and a detailed risk assessment is used to determine test rigorousness and other proper risk mitigation measures.

1.5.2 高等级风险评估 High Level Risk Assessment

1.5.2.1 ISPE 将计算机化系统分为四类，即 GAMP5 类别 I、III、IV 和 V。其中类别 I 的系统，属于 IT 基础架构范畴，不在本文范围内。本公司使用下面描述的内容，来区分 GAMP5 类别 III、IV 和 V 的系统。

ISP edivides computerized systems into four categories, namely GAMP5 category I, III, IV and V. Among them, category I systems belong to the scope of IT infrastructure that is not within the scope of this procedure. Use the following description to distinguish GAMP5 III, IV and V systems.

（1）GAMP5 类别 III 的系统指业务流程不配置的系统，换句话说，也就是所有操作人员总是使用该系统做相同的事情。例如用于检测纯化水碳含量的手持式 TOC 检测仪，在首次配置完检测方法后，所有操作人员均使用该方法检测样品，而不需要修改检测方法或调用其他不同的检测方法。GAMP5 类别 III 的系统通常是开盒即用的。

A GAMP5 Category III system is a non-configured system, in other sentence, all the operators use it to conduct the same operation. For example, a portable TOC analyser used to test purified water, all operators use the same analytical method to test samples after the method was initially configured in the system, while they don't have to modify the method or to choose other different methods. usually, a category III system is Out-Of-Box (OOB).

(2) GAMP5 类别 IV 的系统指业务流程经过配置的系统，换句话说，也就是不同的操作人员使用该系统做的事情可能是不同的。例如用于物质含量检测的 HPLC，不同的用户可以在系统内创建不同的分析方法，用于检测不同的物质。针对这类系统，用户不需要通过修改已有代码或创建新代码实现业务流程。GAMP5 类别 IV 的系统一定是商业市售的。

A GAMP5 category IV system is a configured system, in other sentence, different operators may use it to conductdifferent operations. For example, a HPLC used to test substance content, different users can create different analytical methods in the system to test different substances. For a Category IV system, a user doesn't have to realize their business process (es) by modifying existing program codes or creating new program codes. A GAMP5 Category IV system must be Commercial Off The Shelf (COTS).

(3) GAMP5 类别 V 的系统是指业务流程定制化的系统。这类系统不是商业市售的，可能是在商业市售系统的基础上定制化了某些模块，这些定制化的模块是通过修改已有代码或创建新代码实现的；或者整体上都是通过创建新代码实现的。通常，一个 GAMP5 类别 V 的系统，对一个组织来说是唯一的，在其他的地方一般不可能出现完全相同的第二个。

A GAMP5 category V system is a customized system. It can't be a COTS, maybe, its some modules are customized based on a COTS, these modules are made by modifying the existing program codes or by creating new program codes; or the system is wholly made by creating new program codes. Usually, a GAMP5 category V system is unique for an organization, it is of very low probability that the second same one will be used somewhere else.

1.5.2.2 基于系统用途，使用下表内描述的内容，判断系统是否带有法规使用目的：

Use the contents describedin the table below to determine whether the system has a regulated intended use based on the purpose of the system:

序号 No.	在适用时，用“是”或“否”回答每个问题 Answer each question with a "yes" or "no" when it is applicable	
1	用于质量体系管理流程的管理信息系统 (MIS) A Managerial Information System that used for the process (es) of a Quality System	
1.1	计算机化系统是否用于创建、审核、批准和维护带有法规要求的文件? Is the computerized system used to create, review, approve and maintain documents with regulatory requirements?	□Yes □No
1.2	计算机化系统是否用于管理偏差、变更和 CAPA? Is the computerized system used to manage deviations, changes, and CAPA?	□Yes □No
1.3	计算机化系统是否用于管理投诉或召回? Is the computerized system used to manage customer complaint and product recall?	□Yes □No
1.4	计算机化系统是否用于管理 OOS/ OOT? Is the computerized system used to manage OOS/ OOT?	□Yes □No
1.5	系统是否用于管理人员培训或用于支持其他带有法规要求的质量体系管理流程 (例如年度产品质量回顾)? Is the system used to manage personnel training or to support other quality system management processes with regulatory requirements (such as annual product quality reviews)?	□Yes □No

序号 No.	在适用时，用“是”或“否”回答每个问题 Answer each question with a "yes" or "no" when it is applicable	
1.6	计算机化系统是否用于支持向法规主管机构递交注册文件或数据？ Is the computerized system used to support the submission of registration documents or data to regulatory authorities?	□Yes □No
2	用于环境监视的管理信息系统（MIS） A Managerial Information System（MIS）that used for environment monitoring	
2.1	计算机化系统是否用于监视、采集或储存环境参数（例如温度、湿度或压力）？ Is the computerized system used to monitor, collect, or store environmental parameter data (such as temperature, humidity, or pressure)?	□Yes □No
2.2	计算机化系统是否用于统计计算、算法拟合或生成所监视的环境参数数据的趋势？ Is the computerized system used for statistical calculations, algorithm fitting or generating trends of monitored environmental parameter data?	□Yes □No
2.3	计算机化系统是否用于处理环境参数数据报警？ Is the computerized system used to process environmental parameter data alarms?	□Yes □No
3	用于实验室控制的管理信息系统（MIS） A Managerial Information System（MIS）that used for laboratory control	
3.1	计算机化系统是否用于维护 QC 仪器设备的信息，例如仪器设备 ID，仪器设备计量或验证有效期等？ Is the computerized system used to maintain the information of QC instruments, such as instrument ID, instrument calibration or validation expiry date, etc.?	□Yes □No
3.2	计算机化系统是否用于维护试剂或溶液的信息，例如试剂或溶液的名称，试剂或溶液的有效期等？ Is the computerized system used to maintain reagent or solution information, such as the name and expiry date of the reagent or solution, etc.?	□Yes □No
3.3	计算机化系统是否用于管理、执行或记录 QC 业务流程，例如样品称量和溶液配制等？ Is the computerized system used to manage, execute or record QC business processes, such as sample weighing and solution preparation?	□Yes □No
3.4	计算机化系统是否用于控制分析仪器的运行？ Is the computerized system used to control the operation of analytical instruments?	□Yes □No
3.5	计算机化系统是否用于决定取样计划？ Is the computerized system used to determine the sampling plan?	□Yes □No
3.6	计算机化系统是否用于支持/实施工艺或分析方法验证？ Is the computerized system used to support/ implement process or analytical method validation?	□Yes □No
3.7	计算机化系统是否用于对检测数据进行统计计算、算法拟合或评估检测数据的可接受性？ Is the computerized system used to perform statistical calculations, algorithm fitting, or assess the acceptability of the test data?	□Yes □No
3.8	计算机化系统是否用于管理稳定性分析以及相关稳定性取样方案？ Is the computerized system used to manage stability analysis and related stability sampling plans?	□Yes □No
3.9	计算机化系统是否用于管理中控和最终放行测试？ Is the computerized system used to manage in-process control and final release testing?	□Yes □No
4	用于仓储的管理信息系统（MIS） A Managerial Information System（MIS）that used for warehousing	
4.1	计算机化系统是否用于创建或维护物料或产品状态（如待验、放行、拒绝），包括有效期？ Is the computerized system used to create or maintain the material or product status (such as quarantined, released, rejected), including expiry date?	□Yes □No

序号 No.	在适用时，用“是”或“否”回答每个问题 Answer each question with a "yes" or "no" when it is applicable	
4.2	计算机化系统是否用于创建产品追溯码或追溯产品？ Is the computerized system used to create product traceability codes or to trace products?	□Yes □No
4.3	计算机化系统是否用于支持/控制原辅料、中间体和成品运输和交货？ Is the computerized system used to support/control the transportation and delivery of raw materials, intermediates and finished products?	□Yes □No
4.4	计算机化系统是否用于支持供应商评估？ Is the computerized system used to support supplier evaluation?	□Yes □No
4.5	计算机化系统是否用于维护合格供应商名录？ Is the computerized system used to maintain a list of qualified suppliers?	□Yes □No
4.6	计算机化系统是否用于支持/控制产品储存，或维护库存量？ Is the computerized system used to support/control product storage or maintain material inventory?	□Yes □No
4.7	计算机化系统是否用于支持/控制不合格物料或产品的隔离或销毁？ Is the computerized system used to support/control the isolation or destruction of rejected materials or products?	□Yes □No
4.8	计算机化系统是否用于创建和维护销售记录？ Is the computerized system used to create and maintain distribution records?	□Yes □No
5	用于制造流程的管理信息系统（MIS） A Managerial Information System（MIS）that used for manufacturing process	
5.1	计算机化系统是否用于维护生产设备的信息，例如设备 ID，设备计量有效期、验证有效期和清洁有效期等？ Is the computerized system used to maintain the information of production equipment, such as equipment ID, equipment calibration expiry date, validation expiry date, and cleaning validation expiry date, etc.?	□Yes □No
5.2	计算机化系统是否用于控制或执行可能影响产品 SISPQ 的制造操作？ Is the computerized system used to control or execute manufacturing operations that may affect the product SISPQ?	□Yes □No
5.3	计算机化系统是否会创建或保存涉及产品接受或拒绝的数据？例如系统产生的数据会被包含在批报告中或用于批次放行？ Does the computerized system create or store data related to product acceptance or rejection? For example, will the data generated by the system be included in the batch report or used for batch release?	□Yes □No
5.4	计算机化系统是否用于管理产品主处方（物料清单和/或工艺路线）？ Is the computerized system used to manage product master formula（bill of materials and/or process routes）?	□Yes □No
5.5	计算机化系统是否用于创建或维护主控批记录？ Is the computerized system used to create or maintain Master Batch Records（MBR）?	□Yes □No
5.6	计算机化系统是否直接影响产品标签或标识？如系统控制和支持贴标签活动？ Does the computerized system directly affect product labeling or marking? Such as system control and support for labeling activities?	□Yes □No
5.7	计算机化系统是否用于创建产品追溯码或追溯产品？ Is the computerized system used to create product traceability codes or to trace products?	□Yes □No
6	用于物料或样本检验的实验室应用系统（LAS） A Laboratory Application System（LAS）that used for material and sample testing	

序号 No.	在适用时，用“是”或“否”回答每个问题 Answer each question with a "yes" or "no" when it is applicable	
6.1	计算机化系统是否用于创建 QC 数据，或者 QC 支持性数据？ Is the computerized system used to create QC data，or QC supporting data?	□Yes □No
6.2	计算机化系统是否用于对 QC 数据进行统计计算、算法拟合或评估数据的可接受性？ Is the computerized system used to perform statistical calculations，algorithm fitting，or assess the acceptability of QC data?	□Yes □No
6.3	计算机化系统是否用于控制分析仪器的运行？ Is the computerized system used to control the operation of analytical instruments?	□Yes □No
6.4	计算机化系统是否用于支持/实施工艺或分析方法验证？ Is the computerized system used to support/ implement process or analytical method validation?	□Yes □No
6.5	计算机化系统是否用于管理中控和最终放行测试？ Is the computerized system used to manage in-process control and final release testing?	□Yes □No
6.6	计算机化系统是否用于提供 QC 数据以支持 OOS 或生产失败调查？ Is the computerized system used to provide QC data to support OOS or Manufacturing Failure Investigation（MFI）?	□Yes □No
6.7	计算机化系统创建的、处理的或储存的 QC 数据，是否会用于法规申报？ Will the QC data created，processed or stored in the computerized system be used for regulatory submission?	□Yes □No
7	用于制造流程控制的流程控制系统（PCS） A Process Control System（PCS）that used for manufacturing process control	
7.1	计算机化系统是否用于控制工艺设备？ Is the computerized system used to control the process equipment?	□Yes □No
7.2	计算机化系统是否用于控制工艺支持性设备？ Is the computerized system used to control process supporting equipment?	□Yes □No
7.3	计算机化系统是否用于控制会影响环境参数的设备/装置，在这些环境内会执行 GxP 相关操作？ Is the computerized system used to control equipment/devices that will affect the environmental parameters，in which GxP related operations will be performed?	□Yes □No
7.4	计算机化系统是否用于控制或执行可能影响产品 SISPQ 的制造流程？ Is the computerized system used to control or execute the manufacturing process that may affect the product SISPQ?	□Yes □No
7.5	计算机化系统是否会创建涉及产品接受或拒绝的数据，例如系统产生的数据包含在批报告中或用于批次放行？ Does the computerized system create or store data related to product acceptance or rejection? For example，will the data generated by the system be included in the batch report or used for batch release?	□Yes □No
7.6	计算机化系统是否用于管理产品主处方（物料清单和/或工艺路线）？ Is the computerized system used to manage product master formula（bill of materials and/or process routes）?	□Yes □No
7.7	计算机化系统是否用于创建或维护主控批记录？ Is the computerized system used to create or maintain Master Batch Records（MBR）?	□Yes □No
7.8	计算机化系统是否直接影响产品标签或标识？如系统控制和支持贴标签活动？ Does the computerized system directly affect product labeling or marking? Such as system control and support for labeling activities?	□Yes □No