Data Integrity and Compliance With Drug CGMP
Questions and Answers
Guidance for Industry

行业指南：数据完整性与药品 CGMP 合规问答

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行业指南：数据完整性与药品 CGMP 合规问答

I. INTRODUCTION 前言

The purpose of this guidance is to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs, as required in 21 CFR parts 210, 211, and 212. Unless otherwise noted, the term *CGMP* in this guidance refers to CGMPs for drugs (including biologics). FDA's authority for CGMP comes from section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Part 210 covers Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; part 211 covers Current Good Manufacturing Practice for Finished Pharmaceuticals; and part 212 covers Current Good Manufacturing Practice for Positron Emission Tomography (PET) Drugs. All citations to parts 211 and 212 in this document pertain to finished pharmaceuticals and PET drugs, but these requirements are also consistent with Agency guidance on CGMP for active pharmaceutical ingredients with respect to data integrity[2]. This guidance provides the Agency's current thinking on the creation and handling of data in accordance with CGMP requirements.

本指南的目的是澄清数据完整性在 21CFR 第 210、211 和 212 部分所要求的药品 CGMP 中的地位。除另有说明外，本指南中的术语 CGMP 指药品 CGMP（包括生物制品）。FDA 对 CGMP 的权力来自于 FDCA 第 501(a)(2)(B)条款。第 210 部分包括了药品生产、加工、包装和存贮中的 CGMP、通则；第 211 部分包括了制剂的 CGMP；第 212 部分则包括了 PET 药品的 CGMP。在本文件中所有对第 211 和 212 部分中的引用均针对制剂和 PET 药品，但这些要求在数据完整性方面与 FDA 对 API 的 CGMP 指南亦是一致的。本指南提供的是 FDA 当前对于根据 CGMP 要求创建和处理数据的观点。

FDA expects that all data be reliable and accurate (see the "Background" section). CGMP regulations and guidance allow for flexible and risk-based strategies to prevent and detect data integrity issues. Firms should implement meaningful and effective strategies to manage their data integrity risks based

[1] This guidance has been prepared by the Office of Pharmaceutical Quality and the Office of Compliance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, and the Office of Regulatory Affairs at the Food and Drug Administration. 本指南由 FDA 的 CDER 与 CBER 的药品质量办公室和 CVM 以及 ORA 一起制订。

[2] See the International Council for Harmonisation (ICH) guidance for industry *Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.* We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. 参见 ICH 行业指南 Q7 "原料药 GMP"。我们定期在官网更新指南，请检查最新版本。

on their process understanding and knowledge management of technologies and business models[3].

FDA 要求所有数据均是准确可靠的（参见“背景”部分）。CGMP 法规和指南允许使用基于风险的灵活策略来防止和发现数据完整性问题。公司应基于其对工艺的了解和对技术与业务模式的知识管理，实施有效的实质性策略来管理其数据完整性风险。

Meaningful and effective strategies should consider the design, operation, and monitoring of systems and controls based on risk to patient, process, and product. Management's involvement in and influence on these strategies is essential in preventing and correcting conditions that can lead to data integrity problems. It is the role of management with executive responsibility to create a quality culture where employees understand that data integrity is an organizational core value and employees are encouraged to identify and promptly report data integrity issues. In the absence of management support of a quality culture, quality systems can break down and lead to CGMP noncompliance.

有效的实质性策略应考虑系统设计、运行和监测，以及基于对患者、工艺和产品风险的控制。管理层有必要参与并对这些策略施加影响，以防止和纠正可能导致数据完整性问题的情形。管理层有义务履行其职责，创建一种质量文化，让员工了解数据完整性是组织的核心价值，鼓励员工发现并主动报告数据完整性问题。如果管理层不支持质量文化，质量体系有可能崩溃并导致 CGMP 不合规。

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

一般来说，FDA 的指南文件并不构成强制义务。相反，指南所描述的是 FDA 当前对某个主题的观点，应仅作为是建议，引用具体法律法规要求者除外。SHOULD 一词在 FDA 指南的使用表示建议或推荐做某事，但并非强制。

II. BACKGROUND 背景

In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The underlying premise in §§ 210.1 and 212.2 is that CGMP sets forth minimum requirements to assure that drugs meet the standards of the FD&C Act regarding safety, identity, strength, quality, and purity[4]. Requirements with respect to data integrity in parts 211 and 212 include, among other things:

近年，FDA 在 CGMP 现场检查中发现越来越多的 CGMP 违规涉及数据完整性问题。这种现象令人不安，因为数据完整性是药企确保药品安全性、有效性和质量的义务中的重要一环，亦是 FDA 保护公众健康的重要内容。这些与数据完整性有关的 CGMP 违规已导致大量强制措施，包

[3] See ICH guidance for industry *Q9 Quality Risk Management*. 参见 ICH 行业指南 Q9“质量风险管理”。

[4] According to section 501(a)(2)(B) of the FD&C Act, a drug shall be deemed adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."依据 FDCA 第 501(a)(2)(B)条款，如果“一种药品生产、加工、包装或保存所用方法或设施不符合 CGMP 要求，或不在 CGMP 合规状态下操作或管理，从而确保该药品满足法案关于安全的要求，不具备鉴别和剂要求，不符合其理应具备的质量和纯度属性”，则被认为是掺假药品。

括警告信、进口禁令和合意判决。§§210.1 和 212.2 的基本前提是 CGMP 设定了确保药品符合 FDCA 关于安全性、鉴别、剂量、质量和纯度方法标准的最低要求。在第 211 和 212 部分中关于数据完整性的要求包括：

- §211.68 (requiring that "backup data are exact and complete" and "secure from alteration, inadvertent erasures, or loss" and that "output from the computer … be checked for accuracy").
- §211.68（要求"备份数据应完整并准确"并且"受到保护不被修改、无意删除或丢失"以及"要检查计算机的输出信息的准确性"）
- §212.110(b) (requiring that data be "stored to prevent deterioration or loss").
- §212.110(b)（要求对数据进行"存贮以防止受损或丢失"）
- §§211.100 and 211.160 (requiring that certain activities be "documented at the time of performance" and that laboratory controls be "scientifically sound").
- §§211.100 和 211.160（要求特定活动"在执行时即进行记录"并且实验室控制应"科学合理"）
- §211.180 (requiring that records be retained as "original records," or "true copies," or other "accurate reproductions of the original records").
- §211.180（要求记录保存为"原始记录"或"真实副本"，或其它"原始记录的准确复制件"）
- §§ 211.188, 211.194, and 212.60(g) (requiring "complete information," "complete data derived from all tests," "complete record of all data," and "complete records of all tests performed").
- §§ 211.188, 211.194 和 212.60(g)（要求"完整信息"、"所有检测的完整数据"、"所有数据的完整记录"以及"执行的所有检测的完整记录"）
- §§ 211.22, 211.192, and 211.194(a) (requiring that production and control records be "reviewed" and that laboratory records be "reviewed for accuracy, completeness, and compliance with established standards").
- §§ 211.22, 211.192 和 211.194(a)（要求生产和检测记录经过"审核"，并且实验室记录应"检查其准确性、完整性和与既定标准的符合性"）
- §§211.182, 211.186(a), 211.188(b)(11), and 211.194(a)(8) (requiring that records be "checked," "verified," or "reviewed").
- §§ 211.182, 211.186(a), 211.188(b)(11)和 211.194(a)(8)（要求"检查"、"核对"或"审核"记录）

When considering how to meet many of these regulatory requirements, it may be useful to ask the following questions:

在考虑如何符合这些法规要求时，先提出以下问题可能会有所帮助：

- Are controls in place to ensure that data is complete?
- 是否有制订有控制措施确保数据是完整的？
- Are activities documented at the time of performance?

- 是否在执行活动时即进行了记录？
- Are activities attributable to a specific individual?
- 活动是否可追溯到具体人员？
- Can only authorized individuals make changes to records?
- 是否只有经过授权的人员方可修改记录？
- Is there a record of changes to data?
- 对数据的修改是否有记录？
- Are records reviewed for accuracy, completeness, and compliance with established standards?
- 是否审核记录的准确性、完整性以及与既定标准的符合性？
- Are data maintained securely from data creation through disposition after the record's retention period?
- 自创建开始直到记录达到保存时限后销毁期间，数据保存是否安全？

This guidance helps answer these questions and enables an understanding of key concepts behind the regulatory requirements.

本指南帮助回答这些问题，促进对法规要求背后的关键概念的理解。

While not in the scope of this guidance, data integrity-related CGMP violations can also impact or be directly linked to application filing, review, and regulatory actions.

虽然不在本指南范围内，但数据完整性有关的 CGMP 违规亦可能影响或直接关系到申报资料的提交、审核和强制措施。

Electronic signature and record-keeping requirements are laid out in 21 CFR part 11 and apply to certain records subject to records requirements set forth in Agency regulations, including parts 210, 211, and 212. For more information, see guidance for industry *Part 11, Electronic Records; Electronic Signatures—Scope and Application*, which outlines FDA's current thinking regarding the scope and application of part 11 pending FDA's reexamination of part 11 as it applies to all FDA-regulated products.

电子签名和记录保存要求在 21CFR 第 11 部分已有规定，适用于需要满足 FDA 法规（包括第 210、211 和 212 部分）中指定要求的特定记录。更多信息参见行业指南“第 11 部分—电子记录和电子签名—范围与应用”，其中说明了 FDA 当前对第 11 部分在重新检查其是否适用于所有 FDA 监管产品中对其范围和应用方面的观点。

III. QUESTIONS AND ANSWERS 问答

1. Please clarify the following terms as they relate to CGMP records: 请澄清以下术语在用于 CGMP 记录时的含义

a. What is "data integrity"? 什么是“数据完整性”？

For the purposes of this guidance, *data integrity* refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously

recorded, original or a true copy, and accurate (ALCOA)[5].

本指南中，数据完整性指南数据的完整性、一致性和准确性。完整、一致和准确的数据应可追溯、清晰、同步记录、为原件或真实副本并准确（ALCOA）。

Data integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record's retention period ends[6]. System design and controls should enable easy detection of errors, omissions, and aberrant results throughout the data's life cycle.

数据完整性在整个 CGMP 数据生命周期中都很关键，包括数据的创建、修改、处理、保存、归档、传输和超保存期后的处置。系统设计和控制应使其在整个数据生命周期中易于发现错误、遗漏和异常结果。

b. What is "metadata"? 什么是"元数据"？

Metadata is the contextual information required to understand data. A data value is by itself meaningless without additional information about the data. Metadata is often described as data about data. Metadata is structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data. For example, the number "23" is meaningless without metadata, such as an indication of the unit "mg." Among other things, metadata for a particular piece of data could include a date/time stamp documenting when the data were acquired, a user ID of the person who conducted the test or analysis that generated the data, the instrument ID used to acquire the data, material status data, the material identification number, and audit trails.

元数据是了解数据所需的环境信息。如果没有关于数据的其它信息，一个数据值自身是没有意义的。元数据通常被描述为数据的数据。元数据是结构式的信息，它描述、解释数据或使得数据易于检索、使用或管理。例如，数值"23"如果没有元数据例如显示单位"mg"是没有意义的。此外，元数据是一种特别的数据，可包括日期时间戳以记录数据是何时采集的、用户 ID 说明是谁执行了检测或分析从而生成该数据、用于采集数据的仪器 ID、原料状态数据、原料识别号和审计追踪。

Data should be maintained throughout the record's retention period with all associated metadata required to reconstruct the CGMP activity (e.g., §§211.188 and 211.194). The relationships between data and their metadata should be preserved in a secure and traceable manner.

在记录的整个保存期间，应将重建 CGMP 活动所需的相关元数据与数据一起保存（例如§§ 211.188 和 211.194）。数据与其元数据之间的关系应以安全和可追溯的方式保留。

c. What is an "audit trail"? 什么是"审计追踪"？

For purposes of this guidance, *audit trail* means a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record. For example, the audit trail for a high performance liquid

[5] These characteristics are important to ensuring data integrity and are addressed throughout the CGMP regulations for drugs. For *attributable*, see §§211.101(d), 211.122, 211.186, 211.188(b)(11), and 212.50(c)(10); for *legible*, see §§ 211.180(e) and 212.110(b); for *contemporaneously recorded* (at the time of performance), see §§211.100(b) and 211.160(a); for *original or a true copy*, see §§211.180 and 211.194(a); and for *accurate*, see §§211.22(a), 211.68, 211.188, and 212.60(g). 这些特性在确保数据完整性中是很重要的，在整个药品 CGMP 法规都有说明。对于可追溯性，参见§§ 211.101(d), 211.122, 211.186, 211.188(b)(11)和 212.50(c)(10)，清晰要求参见§§211.180(e) 和 212.110(b)，同步记录参见§§ 211.100(b) 和 211.160(a)，原始或真实副本参见§§211.180 和 211.194(a)，准确性参见§§211.22(a), 211.68, 211.188 和 212.60(g)。

[6] For examples of record retention periods, see §§211.180 and 212.110(c). 记录保存期例子参见§§211.180 和 212.110(c)。

chromatography (HPLC) run should include the user name, date/time of the run, the integration parameters used, and details of a reprocessing, if any. Documentation should include change justification for the reprocessing.

在本指南中，审计追踪意指一种安保用、由计算机生成带有时间戳的电子记录，它使得可以重构与一个电子记录创建、修改或删除有关的事件的过程。例如，HPLC 运行的审计追踪应包括有用户名、运行日期时间、所用积分参数以及重新处理的详细信息（如有）。文件记录应包括有重新处理的变更论证。

Audit trails include those that track creation, modification, or deletion of data (such as processing parameters and results) and those that track actions at the record or system level (such as attempts to access the system or rename or delete a file).

审计追踪包括追踪数据创建、修改或删除（如处理参数和结果）的信息，和追踪记录或系统层级动作的信息（如试图访问系统或重命名或删除一份文件）。

CGMP-compliant record-keeping practices prevent data from being lost or obscured and ensure that activities are documented at the time of performance (see §§211.68, 211.100, 211.160(a), 211.188, and 211.194). Electronic record-keeping systems, which include audit trails, can support these CGMP requirements.

符合 CGMP 要求的记录保存规范防止数据丢失或遮盖，确保活动在执行时即被记录（参见 §§ 211.68, 211.100, 211.160(a), 211.188 和 211.194）。含有审计追踪的电子记录保存系统可支持这些 CGMP 要求。

d. *How does FDA use the terms "static" and "dynamic" as they relate to record formats? FDA 在记录格式方面是如何使用术语"静态"和"动态"的?*

For the purposes of this guidance, *static* is used to indicate a fixed-data record such as a paper record or an electronic image, and *dynamic* means that the record format allows interaction between the user and the record content. For example, a dynamic chromatographic record may allow the user to change the baseline and reprocess chromatographic data so that the resulting peaks may appear smaller or larger. It also may allow the user to modify formulas or entries in a spreadsheet used to compute test results or other information such as calculated yield.

在本指南中，静态用于表示数据固化的记录，如纸质记录或电子图像，而动态则表示记录格式允许用户与记录内容进行互动，例如，动态色谱记录允许用户改变基线，重新处理色谱数据，这样得到的峰看起来会更小或更大。它亦可允许用户修改用于计算检测结果的数据表中的公式或录入数字，或其它信息如计算结果。

e. *How does FDA use the term "backup" in §211.68(b)? FDA 是如何使用§211.68(b)中的术语"备份"的?*

FDA uses the term *backup* in §211.68(b) to refer to a true copy of the original record that is maintained securely throughout the record retention period (e.g., §211.180). Backup data must be exact, complete, and secure from alteration, inadvertent erasures, or loss (§211.68(b)). The backup file should contain the data (which includes associated metadata) and should be in the original format or in a format compatible with the original format.

FDA 在§211.68(b)使用了术语备份用于借指在整个记录保存期内安全保存的原始记录的真实副本（例如§211.180）。备份数据必须准确、完整，安全不会被修改、无意擦除或丢失（§ 211.68(b)）。备份文件应含有数据（其中包括相关元数据），并应采用原始格式或与原始格式

兼容的格式。

FDA's use of the term *backup* is consistent with the term *archive* as used in guidance for industry and FDA staff *General Principles of Software Validation.*

FDA 对术语备份的使用与行业指南和 FDA 软件验证员工通则中所用的术语归档具有相同意思。

Temporary backup copies (e.g., in case of a computer crash or other interruption) would not satisfy the requirement in §211.68(b) to maintain a backup file of data.

临时备份副本（例如，如果计算机死机或其它中断）不能满足§211.68(b)的保存数据备份文件要求。

f. What are the "systems" in "computer or related systems" in §211.68? §211.68 里面"计算机或相关系统"中的"系统"是什么？

The American National Standards Institute (ANSI) defines systems as people, machines, and methods organized to accomplish a set of specific functions[7]. *Computer or related systems* can refer to computer hardware, software, peripheral devices, networks, cloud infrastructure, personnel, and associated documents (e.g., user manuals and standard operating procedures[8]).

美国国家标准研究所（ANSI）定义系统为组织起来完成一系列指定功能的人员、机器和方法。计算机或相关系统可代指计算机硬件、软件、外围设备、网络、云基础设施、人员和相关文件（例如用户手册和标准操作规程）。

2. When is it permissible to invalidate a CGMP result and exclude it from the determination of batch conformance? 什么时候允许宣布一个 CGMP 结果无效并在判定批合格时排除该结果？

Data created as part of a CGMP record must be evaluated by the quality unit as part of release criteria (see §§211.22 and 212.70) and maintained for CGMP purposes (e.g., §211.180[9]). Electronic data generated to fulfill CGMP requirements include relevant metadata required to reconstruct the CGMP activity captured in the record. Invalidating test results to exclude them from quality unit decisions about conformance to a specification requires a valid, documented, scientifically sound justification. See, for example, §§211.160(b), 211.188, 211.192, and 212.71(b) and the guidance for industry *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.* Even if test results are legitimately invalidated on the basis of a scientifically sound investigation, the full CGMP batch record provided to the quality unit would include the original (invalidated) data, along with the investigation report that justifies invalidating the result. The requirements for record retention and review do not differ depending on the data format; paper-based and electronic data record-keeping systems are subject to the same requirements.

作为 CGMP 记录一部分创建的数据必须由质量部分作为放行标准的一部分进行评估（参见§§211.22 和 212.70），并保存用于 CGMP 用途（例如§211.180）。为满足 CGMP 要求而生成的电子数据包括采集在记录中的重构 CGMP 活动所需的相关元数据。宣布检测结果无效并将其排除在质量部门关于是否符合质量标准的决定以外时，需要有效的书面科学合理论证。参见例如§§211.160(b), 211.188, 211.192 和 212.71(b)，以及行业指南"药品生产中 OOS 结果调

[7] American National Standard for Information Systems, *Dictionary for Information Systems*, American National Standards Institute, 1991. 美国国家信息系统标准，信息系统词典，美国国家标准研究所，1991

[8] See guidance for industry and FDA staff *General Principles of Software Validation*. 参见行业指南和 FDA 员工软件验证通则。

[9] For purposes of this guidance, the term *quality unit* is synonymous with the term *quality control unit*. For the definition of *quality control unit*, see §210.3(b)(15). 本指南中，质量部门与质量控制部门为同义词。质量控制部门的定义参见§210.3(b)(15).。

查”。即使检测结果根据科学合理的调查合法宣布无效，提交给质量部门的完整 CGMP 批记录仍要包括原始（宣布无效的）数据，以及论证该结果无效的调查报告。对记录保存和审核的要求不会因为数据格式不同而不同，纸质和电子数据记录保存系统要符合相同的要求。

3. Does each CGMP workflow on a computer system need to be validated? 是否需要对计算机系统中的每个 CGMP 工作流均进行验证？

Yes, a CGMP workflow, such as creation of an electronic master production and control record (MPCR), is an intended use of a computer system to be checked through validation (see §§211.63, 211.68(b), and 211.110(a)). The extent of validation studies should be commensurate with the risk posed by the automated system. When the same system is used to perform both CGMP and non-CGMP functions, the potential for non-CGMP functions to affect CGMP operations should be assessed and mitigated appropriately[10].

需要。一个 CGMP 工作流，如创建一份电子主生产和分析记录（MPCR），就是在验证中需要进行检查的一个计算机系统既定用途（参见§§211.63, 211.68(b)和 211.110(a)）。验证研究的范围应与自动化系统所带有的风险相称。如果同一系统用于同时执行 CGMP 和非 CGMP 功能，则应评估非 CGMP 功能影响 CGMP 操作的可能性，并适当降低风险。

If you validate the computer system but you do not validate it for its intended use, you cannot know if your workflow runs correctly[11]. For example, qualifying the Manufacturing Execution System (MES) platform, a computer system, ensures that it meets its relevant requirements and specifications; however, it does not demonstrate that a given MPCR generated by the MES contains the correct calculations. In this example, validating the workflow ensures that the intended steps, requirements, and calculations in the MPCR are accurate and perform properly. This is similar to reviewing a paper MPCR and ensuring all supporting procedures are in place before the MPCR is implemented in production (see §§211.100, 211.186, and 212.50(b) and the guidance for industry *PET Drugs—Current Good Manufacturing Practice (CGMP)*).

如果对计算机系统进行了验证，但没有针对其既定用途进行验证，则你并不知晓你的工作流是否运行正常。例如，确认生产执行系统（MES）平台，一个计算机系统，确保其符合相关要求和标准，但并未证明由 MES 生成的指定 MPCR 是否包括正确的计算。在此例中，对工作流进行验证就确保了 MPCR 中既定的步骤、要求和计算是准确的并能正常执行。这类似于在生产中执行 MPCR 之前对纸质 MPCR 的审核，以及确保所有支持性程序已制订（参见§§211.100, 211.186 和 212.50(b)，以及行业指南“PET 药品—CGMP”）。

FDA recommends you implement appropriate controls to manage risks associated with each element of the system. Controls that are appropriately designed to validate a system for its intended use address software, hardware, personnel, and documentation.

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[10] See note 8. 参见脚注 8.

[11] In computer science, *validation* refers to ensuring that software meets its requirements. However, this may not meet the definition of *process validation* as found in guidance for industry *Process Validation: General Principles and Practices:* “The collection and evaluation of data … which establishes scientific evidence that a process is capable of consistently delivering quality products.” See also ICH guidance for industry *Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients,* which defines *validation* as providing assurance that a specific process, method, or system will consistently produce a result meeting predetermined acceptance criteria. For purposes of this guidance, *validation* is being used in a manner consistent with the above guidance documents. 在计算机科学中，验证指南确保软件符合其需求。但是，这可能并不符合行业指南“工艺验证—通则与规范”中工艺验证的定义“数据的集合与评估……建立科学证据证明一个工艺有能力持续生产出具备指定质量产品”。亦参见 ICH 行业指南 Q7“原料药 GMP”，其中定义验证为提供保障确保特定工艺、方法或系统能持续生成一个结果满足既定的可接受标准。在本指南中，使用验证一词的含义与上述指南文件中相同。

FDA 建议实施适当的控制来管理与每个系统要素有关的风险。经过适当设计用于验证系统适合其既定用途的控制可解决硬件、软件、人员和文件问题。

4. How should access to CGMP computer systems be restricted? 应如何限制对 CGMP 计算机系统的访问？

You must exercise appropriate controls to assure that changes to computerized MPCRs or other CGMP records or input of laboratory data into computerized records can be made only by authorized personnel (§211.68(b)). Other examples of records for which control should be restricted to authorized personnel include automated visual inspection records, electronic materials management system records, and automated dispensing system weighing records. FDA recommends that you restrict the ability to alter specifications, process parameters, data, or manufacturing or testing methods by technical means where possible (e.g., by limiting permissions to change settings or data).

必须执行适当的控制来确保修改计算机化 MPCR 或其它 CGMP 记录或录入计算机化系统的实验室数据输入只能由经过授权的人员执行（§211.68(b)）。其它需要限制仅允许经授权人员操作的控制例子包括自动化目视检查记录、电子物料管理系统记录和自动化分料系统称量记录。FDA 建议尽可能采用技术手段限制修改标准、工艺参数、数据或生产或检测方法的能力（例如，限制修改设置或数据的许可）。

The system administrator role, including any rights to alter files and settings, should be assigned to personnel independent from those responsible for the record content. To assist in controlling access, it is important that manufacturers establish and implement a method for documenting authorized personnel's access privileges for each CGMP computer system in use (e.g., by maintaining a list of authorized individuals) (see §211.68(b)).

系统管理员身份，包括任何修改文件和设置的权力，均应指派给独立于负责这些记录内容的人员。为协助控制访问，生产商有必要建立和实施一种方法用于记录（例如，通过保存一张授权人员清单）经授权人员对每个在用 CGMP 计算机系统的访问权限（参见§211.68(b)）。

5. Why is FDA concerned with the use of shared login accounts for computer systems? 为什么 FDA 会担忧使用共用计算机系统登录账号？

When login credentials are shared, a unique individual cannot be identified through the login and the system would not conform to the CGMP requirements in parts 211 and 212. FDA requires that system controls, including documentation controls, be designed in accordance with CGMP to assure product quality (e.g., §§211.100 and 212.50). For example, you must implement documentation controls that ensure that the actions as described in question 4 are attributable to a specific individual (see §§ 211.68(b), 211.188(b)(11), 211.194(a)(7) and (8), and 212.50(c)(10)).

如果共用了登录凭证，则无法通过登录来识别人员的唯一身份，系统就不符合第 211 与 212 部分中的 CGMP 要求。FDA 要求系统控制（包括文件记录控制）的设计符合 CGMP 要求，确保产品质量（例如，§§211.100 和 212.50）。例如，你必须实施文件记录控制，确保问题 4 中所述的动作可以追溯到具体个人（参见§§211.68(b), 211.188(b)(11), 211.194(a)(7)和 (8)和 212.50(c)(10)）。

Shared, read-only user accounts that do not allow the user to modify data or settings are acceptable for viewing data, but they do not conform with the part 211 and 212 requirements for actions, such as second person review, to be attributable to a specific individual.

不允许用户修改数据或设置的共用、只读用户账号可用于浏览数据，但不符合第 211 和 212 部

分中关于动作（如第二人审核）要追溯到具体个人的要求。

6. How should blank forms be controlled? 空白表格要如何受控？

There must be document controls in place to assure product quality (see §§ 211.100, 211.160(a), 211.186, 212.20(d), and 212.60(g)). For example, bound paginated notebooks, stamped for official use by a document control group, provide good document control because they allow easy detection of unofficial notebooks as well as any gaps in notebook pages. If used, blank forms (e.g., electronic worksheets, laboratory notebooks, and MPCRs) should be controlled by the quality unit or by another document control method. As appropriate, numbered sets of blank forms may be issued and should be reconciled upon completion of all issued forms. Incomplete or erroneous forms should be kept as part of the permanent record along with written justification for their replacement (see, e.g., §§ 211.192, 211.194, 212.50(a), and 212.70(f)(1)(vi)). All data required to recreate a CGMP activity should be maintained as part of the complete record.

必须有文件控制用以确保产品质量（参见 §§ 211.100, 211.160(a), 211.186, 212.20(d)和 212.60(g)）。例如，标明页码装订好的笔记本，由文控组盖章用于正式用途就是一个很好的文件控制方式，因为这样很容易发现非正式的笔记本，以及笔记本页码遗漏。如果要使用空白记录（例如，电子数据表、实验室笔记本和 MPCR），则应由质量部门或采用另一种文件控制方式进行控制。适当时，可发放连续编号的空白表格，并对所有发放的表格在完成时进行数量衡算。不完整或填写错误的表格亦应保留，作为永久记录的一部分，同时对其替换有书面说明（参见例如 §§ 211.192, 211.194, 212.50(a)和 212.70(f)(1)(vi)）。重建 CGMP 活动所需的所有数据均应保存作为完整记录的一部分。

7. Who should review audit trails? 审计追踪应由谁审核？

Audit trail review is similar to assessing cross-outs on paper when reviewing data. Personnel responsible for record review under CGMP should review the audit trails that capture changes to data associated with the record as they review the rest of the record (e.g., §§ 211.22(a), 211.101(c) and (d), 211.103, 211.182, 211.186(a), 211.192, 211.194(a)(8), and 212.20(d)). For example, all production and control records, which includes audit trails, must be reviewed and approved by the quality unit (§ 211.192). The regulations provide flexibility to have some activities reviewed by a person directly supervising or checking information (e.g., § 211.188). FDA recommends a quality system approach to implementing oversight and review of CGMP records[12].

审计追踪审核类似于在纸上审核数据时对划掉的内容进行评估。负责 CGMP 记录审核的人员在审核记录中其余部分（例如 §§ 211.22(a), 211.101(c) 和 (d), 211.103, 211.182, 211.186(a), 211.192, 211.194(a)(8)和 212.20(d)）时应审核采集与记录有关数据的修改的审计追踪。例如，所有生产和检测记录，包括审计追踪，均必须由质量部门进行审核和批准（§ 211.192）。法规也给予了灵活性，允许有些活动由直接监管和检查信息的人员进行审核（例如 § 211.188）。FDA 建议采用质量体系的方式实施对 CGMP 记录的监管和审核。

8. How often should audit trails be reviewed? 审计追踪应多久审核一次？

If the review frequency for the data is specified in CGMP regulations, adhere to that frequency for the audit trail review. For example, § 211.188(b) requires review after each significant step in manufacture,

[12] See guidance for industry *Quality Systems Approach to Pharmaceutical CGMP Regulations.* See also guidance for industry *Contract Manufacturing Arrangements for Drugs: Quality Agreements* for information about auditing as it relates to contract facilities. 参见行业指南“药品 CGMP 法规的质量系统方法”。亦请参见行业指南“药品委托生产安排：质量协议”中关于审计的内容，因为它与合同场所有关。

processing, packing, or holding, and §211.22 requires data review before batch release. In these cases, you would apply the same review frequency for the audit trail.

如果对数据的审核频次已在 CGMP 法规里有规定，则审计追踪的审核频次应按该规定频次执行。例如，§211.188(b)要求生产、加工、包装或保存中的每个重大步骤均要进行审核，§211.22 要求在批放行之前进行数据审核。在这些情形下，审计追踪审核适用相同频次。

If the review frequency for the data is not specified in CGMP regulations, you should determine the review frequency for the audit trail using knowledge of your processes and risk assessment tools. The risk assessment should include evaluation of data criticality, control mechanisms, and impact on product quality[13].

如果数据的审核频次在 CGMP 法规中未规定，则应利用你们的流程和风险评估工具确定审计追踪的审核频次。风险评估应包括对数据关键程度、控制机制和对产品质量影响的评估。

Your approach to audit trail review and the frequency with which you conduct it should ensure that CGMP requirements are met, appropriate controls are implemented, and the reliability of the review is proven.

审计追踪审核的方式和频次应确保符合 CGMP 要求，实施了适当的控制，并且要证明审核的可靠性。

See the audit trail definition in 1.c. above for further information on audit trails.

审计追踪更多信息参见上述 1.C 中审计追踪定义。

9. Can electronic copies be used as accurate reproductions of paper or electronic records? 电子副本是否可用作电子或纸质记录的准确复制本？

Yes. Electronic copies can be used as true copies of paper or electronic records, provided the copies preserve the content and meaning of the original record, which includes all metadata required to reconstruct the CGMP activity and the static or dynamic nature of the original records.

可以。电子副本可用作纸质或电子记录的真实副本，前提是这些副本保存了原始记录的内容和含义，其中包括重建 CGMP 活动所需的所有元数据，以及原始记录的静态或动态属性。

True copies of dynamic electronic records may be made and maintained in the format of the original records or in a format that allows for the content and meaning of the original records to be preserved if a suitable reader and copying equipment (e.g., software and hardware, including media readers) are readily available (§§211.180(d) and 212.110).

动态电子记录的真实副本可以原始记录的格式制作和保存，或在具备适当的阅读器和复制设备（例如，软件和硬件，包括介质阅读器）时以能保存原始记录内容和含义的格式保存。

10. Is it acceptable to retain paper printouts or static records instead of original electronic records from stand-alone computerized laboratory instruments, such as an FT-IR instrument? 是否可以将单机版计算机化实验室仪器，如 FT-IR 仪器中的原始电子记录保存为纸质打印件或静态记录？

[13] Risks to data include, but are not limited to, the potential to be deleted, amended, or excluded without authorization or without detection. Examples of audit trails that may be appropriate to review on a risk-based frequency include audit trails that capture instrument operational status, instrument communication logs, and alert records. 数据风险包括但不仅限于可能被未经授权地或不被察觉地删除、修改或排除。可采用基于风险的频次对审计追踪进行恰当审核的例子包括采集仪器运行状态、仪器通信日志和修改记录的审计追踪。

A paper printout or static record may satisfy retention requirements if it is the original record or a true copy of the original record (see §§211.68(b), 211.188, 211.194, and 212.60). During data acquisition, for example, pH meters and balances may create a paper printout or static record as the original record. In this case, the paper printout or static record, or a true copy, must be retained (§211.180).

如果原始记录或原始记录的真实副本就是纸质打印件或静态记录的话，则该纸质打印件或静态记录就可满足保存要求（参见§§211.68(b), 211.188, 211.194 和 212.60）。在数据采集期间，例如，pH 计和天平可能会生成一张纸质打印件或静态记录作为原始记录。在此情形下，必须保存纸质打印件或静态记录，或真实副本（§211.180）。

However, electronic records from certain types of laboratory instruments—whether stand-alone or networked—are dynamic, and a printout or a static record does not preserve the dynamic record format that is part of the complete original record. For example, the spectral file created by FT-IR (Fourier transform infrared spectroscopy) is dynamic and can be reprocessed.

但是，来自某些类型的实验室仪器的电子记录（无论是单机版还是网络版）是动态的，并且打印件或静态记录无法保存作为完整原始记录一部分的动态记录格式。例如，由 FT-IR（傅里叶变换红外光谱仪）创建的光谱文件就是动态的，可以重新处理。

However, a static record or printout is fixed and would not satisfy CGMP requirements to retain original records or true copies (§211.180(d)). Also, if the full spectrum is not displayed in the printout, contaminants may be excluded.

但是，静态记录或打印件则是固化的，不满足保存原始记录或真实副本的 CGMP 要求（§211.180(d)）。同时，如果在打印件中未能显示全光谱，则可以排除污染。

You must ensure that original laboratory records, including paper and electronic records, are subject to second-person review (§211.194(a)(8)) to make certain that all test results and associated information are appropriately reported. Similarly, in microbiology, a contemporaneous written record is maintained of the colony counts of a petri dish, and the record is then subject to second-person review.

必须确保原始实验室记录，包括纸质和电子记录，均由第二人进行了审核（§211.194(a)(8)），确定所有检测结果和相关信息进行了恰当报告。类似的，在微生物检验中，同步写就的培养皿菌落计数保存后，由第二人进行审核。

Document control requirements in §211.180 pertain only to CGMP records.

§211.180 中的文件控制要求仅适用于 CGMP 记录。

For more information on static and dynamic records, see 1.d. in this guidance. For PET drugs, see the guidance for industry *PET Drugs—Current Good Manufacturing Practice (CGMP)* for discussion of equipment and laboratory controls, including regulatory requirements for records.

关于静态和动态记录的更多信息，参见本指南 1.d 部分。对于 PET 药品，参见行业指南“PET 药品—CGMP”中关于设备和实验室控制，包括对记录的法规要求。

11. Can electronic signatures be used instead of handwritten signatures for master production and control records? 主生产和检验记录中是否可使用电子签名替代手动签名？

Yes, electronic signatures with the appropriate controls can be used instead of handwritten signatures or initials in any CGMP required record. Although §211.186(a) specifies a “full signature, handwritten,” an electronic signature with the appropriate controls to securely link the signature with the associated record fulfills this requirement (21 CFR 11.2(a)). See part 11, which establishes criteria for when electronic signatures are considered the legally binding equivalent of handwritten signatures. Firms using

electronic signatures should document the controls used to ensure that they are able to identify the specific person who signed the records electronically.

可以，具备适当控制的电子签名可用于取代所有 CGMP 要求记录中的手动签名或首字母签名。尽管§211.186(a)说的是“全名手动签字”，但具备适当控制可保护签名与相关记录之间的安全链接的电子签名满足此要求（21 CFR 11.2(a)）。参见第 11 部分，其中制订了何时认为电子签名法定等同于手动签名的标准。使用电子签名的公司应记录下用于确保其可以识别具体电子签名人员的控制。

There is no requirement for a handwritten signature for the MPCR in the PET CGMP regulations (21 CFR part 212).

在 PET CGMP 法规（21 CFR part 212）中对于 MPCR 的手动签名没有要求。

12. When does electronic data become a CGMP record? 电子数据何时成为一份 CGMP 记录？

When generated to satisfy a CGMP requirement, all data become a CGMP record[14]. You must document, or save, the data at the time of performance to create a record in compliance with CGMP requirements, including, but not limited to, §§211.100(b) and 211.160(a).

当一个数据为满足 CGMP 要求而生成时，即成为 CGMP 记录。必须在执行时记录或保存数据，从而依据 CGMP 要求（包括但不仅限于§§211.100(b) and 211.160(a)）创建记录。

FDA expects processes to be designed so that data required to be created and maintained cannot be modified without a record of the modification. For example, chromatographic data should be saved to durable media upon completion of each step or injection (e.g., peak integration or processing steps; finished, incomplete, or aborted injections) instead of at the end of an injection set, and changes to the chromatographic data or injection sequence should be documented in an audit trail. Aborted or incomplete injections should be captured in audit trails and should be investigated and justified.

FDA 要求流程的设计使得数据在根据要求创建和保存之后，如需修改则必须有修改记录。例如，色谱数据在每步或每针（例如，峰积分或处理步骤，完成、不完成或中断进样）完成后应该保存在持久介质中，而不是在一个进样序列结束之后保存，对色谱数据或进样序列的修改应记录的审计追踪里。中断或未完进样在审计追踪里应采集，并进行调查和论证。

It is not acceptable to record data on pieces of paper that will be discarded after the data are transcribed to a permanent laboratory notebook (see §§211.100(b), 211.160(a), and 211.180(d)). Similarly, it is not acceptable to store electronic records in a manner that allows for manipulation without creating a permanent record.

将数据记录在纸片上，在数据转抄至永久实验室记录本上之后丢弃是不可接受的（参见§§211.100(b), 211.160(a)和 211.180(d)）。类似的，电子记录的存贮如果允许进行修改而不创建永久记录亦是不可接受的。

You may employ a combination of technical and procedural controls to meet CGMP documentation

[14] Under section 704(a) of the FD&C Act, FDA inspections of manufacturing facilities “shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs [and] nonprescription drugs intended for human use ... are adulterated or misbranded ... or otherwise bearing on violation of this chapter.” Accordingly, FDA routinely requests and reviews records not intended to satisfy a CGMP requirement but which nonetheless contain CGMP information (e.g., shipping or other records that may be used to reconstruct an activity). 依据 FDCA 第 704(a)条款，FDA 对生产现场的检查“应延伸至确定人用处方药品【和】非处方药品是否掺假或冒牌或存在本章中其它违规情形的所有相关事物（包括记录、文件、纸张、工艺、控制和设施）”。相应地，FDA 通常会索取并审核不是为了 CGMP 目的而存在但含有 CGMP 信息的记录（例如，发货或其它可能用于重构活动的记录）。

practices for electronic systems. For example, a computer system, such as a Laboratory Information Management System (LIMS) or an Electronic Batch Record (EBR) system, can be designed to automatically save after each entry. This would be similar to indelibly recording each entry contemporaneously on a paper batch record to satisfy CGMP requirements. The computer system described above could be combined with a procedure requiring data be keyed in or otherwise entered immediately when generated.

可联合使用技术方式和程序控制以符合电子系统的 CGMP 文件记录规范。例如，一个计算机系统，如实验室信息管理系统（LIMS）或电子批记录（EBR）系统可设计为在每次录入后自动保存。这类似于在纸质批记录上不会灭失地同步记录下每次录入，以满足 CGMP 要求。上述计算机系统可与键入数据时即刻采集或在数据生成时立即录入的程序相结合，。

For PET drugs, see the "Laboratory Controls" section of the guidance for industry *PET Drugs— Current Good Manufacturing Practice (CGMP).*

对于 PET 药品，参见行业指南"PET 药品—CGMP"的"实验室控制"部分。

13. Why has FDA cited use of actual samples during "system suitability" or test, prep, or equilibration runs in warning letters? 为什么 FDA 在警告信中将"系统适用性"或调试、准备或系统平衡运行中使用实际样品作为缺陷？

FDA prohibits sampling and testing with the goal of achieving a specific result or to overcome an unacceptable result (e.g., testing different samples until the desired passing result is obtained). This practice, also referred to as *testing into compliance*, is not consistent with CGMP (see the guidance for industry *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production*). In some situations, use of actual samples to perform system suitability testing has been used as a means of testing into compliance. FDA considers it a violative practice to use an actual sample in *test, prep,* or *equilibration* runs as a means of disguising testing into compliance.

FDA 禁止进样和检测直至获得想要的结果，或抹掉不可接受的结果（例如，检测不同样品直至获得想要的合格结果）。这种做法亦被称为"检测直至合格"，是不符合 CGMP 的（参见行业指南"药品生产中的 OOS 结果调查"。有时情形下，使用实际样品进行系统适用性测试被利用来作为检测直至合格的手段。FDA 认为在调试、准备或平衡运行过程中使用实际样品作为掩盖检测直至合格的手段是一种违规做法。

According to the United States Pharmacopeia (USP), system suitability tests must include replicate injections of a standard preparation or other standard solutions to determine if requirements for precision are satisfied (see USP General Chapter <621> *Chromatography*). System suitability tests should be performed according to the firm's established written procedures—which should include the identity of the preparation to be injected and the rationale for its selection—and the approved application or applicable compendial monograph (§§211.160 and 212.60).

根据 USP 要求，系统适用性测试必须包括重复进样对照品或其它标准溶液，以确定是否满足准确度要求（参见 USP 通则<621>色谱）。系统适用性测试应根据公司既定的书面程序—其中应包括有进样溶液的名称和选择原因—和批准的申报资料或适用的药典各论（§§211.160 和 212.60）执行。

If an actual sample is to be used for system suitability testing, it should be a properly characterized secondary standard, written procedures should be established and followed, and the sample should be from a different batch than the sample(s) being tested (§§211.160, 211.165, and 212.60). CGMP original records must be complete (e.g., §§211.68(b), 211.188, 211.194) and subjected to adequate

review (§§211.68(b), 211.186(a), 211.192, and 211.194(a)(8)).

如果在系统适用性测试中使用中了实际样品，则应对其进行恰当的性质鉴定作为工作对照品，应制订并遵守书面程序，而样品则应该是来自与待测样品不同的批次（§§211.160, 211.165, 和 212.60）。CGMP 原始记录必须完整（例如§§211.68(b), 211.188, 211.194），并经过充分的审核（§§211.68(b), 211.186(a), 211.192 和 211.194(a)(8)）。

Transparency is necessary. All data—including obvious errors and failing, passing, and suspect data—must be in the CGMP records that are retained and subject to review and oversight. An investigation with documented, scientifically sound justification is necessary for data to be invalidated and not used in determining conformance to specification for a batch (see §§211.160, 211.165, 211.188, and 211.192).

要保证透明度。所有数据—包括明显错误和失败、通过以及可疑数据---均应放在 CGMP 记录中进行保存，并接受审核和监管。要宣布无效的数据需有书面记录的调查、科学合理的论证，并且不能用于决定一个批次是否符合质量标准（参见§§ 211.160, 211.165, 211.188 和 211.192）。

For more information, see the ICH guidance for industry *Q2(R1) Validation of Analytical Procedures: Text and Methodology* and VICH guidances for industry *GL1 Validation of Analytical Procedures: Definition and Terminology* and *GL2 Validation of Analytical Procedures: Methodology*[15].

更多信息，参见 ICH 行业指南 Q2(R1)“分析方法验证：正文与方法学”和 VICH 行业指南“GL1 分析方法验证：定义与术语”和“GL2 分析方法验证：方法学”。

14. Is it acceptable to only save the final results from reprocessed laboratory chromatography?
是否可以只保存重新处理后的实验室色谱图得到的最终结果？

No. Analytical methods should be accurate and precise[16]. For most lab analyses, reprocessing data should not be regularly needed. If chromatography is reprocessed, written procedures must be established and followed and each result retained for review (see §§211.160, 211.165(c), 211.194(a)(4), and 212.60(a)). FDA requires complete data in laboratory records, which includes but is not limited to notebooks, worksheets, graphs, charts, spectra, and other types of data from laboratory instruments (§§211.194(a) and 212.60(g)(3)).

不可以。分析方法应准确精密。对于大多数实验室检测而言，不应该经常性需要重新处理数据。如果对色谱进行重新处理，则必须制订并遵守书面程序，并保存所有结果供审核（参见§§ 211.160, 211.165(c), 211.194(a)(4)和 212.60(a)）。FDA 要求化验室记录里包括完整数据，其中包括但不仅限于记录本、数据表、图表、图谱和来自实验室仪器的其它类型数据（§§ 211.194(a) 和 212.60(g)(3)）。

15. Can an internal tip or information regarding a quality issue, such as potential data falsification, be handled informally outside of the documented CGMP quality system?
是否可以在书面 CGMP 质量体系以外以非正式方式处理内部提醒或关于质量问题的信息，如潜在数据造假问题？

No. Regardless of intent or how or from whom the information was received, suspected or known falsification or alteration of records required under parts 210, 211, and 212 must be fully investigated under the CGMP quality system to determine the effect of the event on patient safety, product quality,

[15] VICH=Veterinary International Conference on Harmonisation.兽药国际协调委员会

[16] See ICH guidance for industry *Q2(R1) Validation of Analytical Procedures: Text and Methodology*.参见 ICH 行业指南 Q2(R1)“分析方法验证：正文与方法学”。

and data reliability; to determine the root cause; and to ensure the necessary corrective actions are taken (see §§211.22(a), 211.125(c), 211.192, 211.198, 211.204, and 212.100).

不可以。无论意图是什么、以何方式、何人收到信息，可疑或已知伪造或篡改 210、211 和 212 部分中所需记录的情形必须依据 CGMP 质量体系进行全面调查，确定事件对患者安全、产品质量和数据可靠性的影响，确定根本原因，并确保采取了必要的纠正措施（参见§§211.22(a), 211.125(c), 211.192, 211.198, 211.204 和 212.100）。

FDA invites individuals to report suspected data integrity issues that may affect the safety, identity, strength, quality, or purity of drug products at DrugInfo@fda.hhs.gov. "CGMP data integrity" should be included in the subject line of the email. This reporting method is not intended to supersede other FDA reports (e.g., field alert reports or biological product deviation reports that help identify drug products that pose potential safety threats).

FDA 请相关人员向 DrugInfo@fda.hhs.gov 报告可能影响药品安全、鉴别、剂量、质量或纯度的疑似数据完整性问题，提交时在邮件标题中注明"CGMP 数据完整性"字样。此报告方式不会取代其它的 FDA 报告（例如，有助于识别可能有潜在安全威胁的药品的工厂警示报告或生物产品偏差报告）。

16. Should personnel be trained in preventing and detecting data integrity issues as part of a routine CGMP training program? 是否要将防止和发现数据完整性问题培训作为常规 CGMP 培训计划的一部分？

Yes. Training personnel to prevent and detect data integrity issues is consistent with the personnel requirements under §§211.25 and 212.10, which state that personnel must have the education, training, and experience, or any combination thereof, to perform their assigned duties.

是的。对员工进行培训从而防止和发现数据完整性问题与§§211.25 和 212.10 中的人员要求是一致的，其中声明了员工必须具备履行其职责所需的教育、培训和经验。

17. Is FDA allowed to look at electronic records? 是否应允许 FDA 查看电子记录？

Yes. All records required under CGMP are subject to FDA inspection. This applies to records generated and maintained on computerized systems, including electronic communications that support CGMP activities. For example, an email to authorize batch release is a CGMP record that FDA may review.

是的。所有 CGMP 所要求的记录均要接受 FDA 检查。此原则适用于计算机化系统中生成和保存的记录，包括支持 CGMP 活动的电子通讯。例如，批准批次放行的邮件是一份 CGMP 记录，FDA 有可能会审核。

You must allow authorized inspection, review, and copying of records, which includes copying of electronic data (§§211.180(c) and 212.110(a) and (b)). See also the guidance for industry *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* and section 704 of the FD&C Act. Procedures governing the review of electronic records are described in chapter 5 of the *Investigations Operations Manual* (IOM) at https://www.fda.gov/iceci/inspections/iom/default.htm.

你必须允许对记录进行有授权的检查、审核和复制，其中包括复制电子数据（§§211.180(c) 和 212.110(a)和 (b)）。亦请参见行业指南"构成拖延、否定、限制或拒绝药品检查的情形"以及 FDCA 第 704 条款。管理电子记录审核的程序在"调查操作手册（IOM）"第 5 章中描述。

18. How does FDA recommend data integrity problems be addressed? FDA 建议如何解决数据完整性问题？

FDA encourages you to demonstrate that you have effectively remediated your problems by investigating to determine the problem's scope and root causes, conducting a scientifically sound risk assessment of its potential effects (including impact on data used to support submissions to FDA), and implementing a management strategy, including a global corrective action plan that addresses the root causes. This may include retaining a third-party auditor and removing individuals responsible for data integrity lapses from positions where they can influence CGMP- related or drug application data at your firm. It also may include improvements in quality oversight, enhanced computer systems, and creation of mechanisms to prevent recurrences and address data integrity breaches (e.g., anonymous reporting system, data governance officials and guidelines).

FDA 鼓励你们证明你们已通过调查确定了问题的范围和根本原因，对其潜在影响（包括对用于支持提交给 FDA 的申报资料中所用数据的影响）实施了科学合理的风险评估，实施了管理策略，包括解决根本原因的全球纠正措施计划，从而有效地弥补了问题。其中可能包括有聘请第三方审计员，解除对数据完整性问题负有责任的人员可能影响你公司 CGMP 有关数据或药品申报数据的职务。其中亦可包括对质量监管的提升、强化计算机系统，以及创建机制防止数据完整性问题的重复发生并解决数据完整性问题（例如，匿名报告体系、数据管理员和数据管理指南）。

These expectations mirror those developed for the Application Integrity Policy. For more detailed information, see *Points To Consider for Internal Reviews and Corrective Action Operating Plans* at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134744.htm.

这些期望反映了应用软件完整性方针的发展。更多细节参见“内审和纠正措施操作计划考虑要点”。