2021

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H - MEDICAL DEVICES

PART 820 QUALITY SYSTEM REGULATION

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Subpart A - General Provisions 总则

Sec. 820.1 Scope 范围

(a) Applicability. (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of blood and blood components used for transfusion or for further manufacturing are not subject to this part, but are subject to subchapter F of this chapter. ~~Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable current good tissue practice procedures in part 1271 subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general.~~

a) 适用性（1）此质量体系法案中包含了有关现行cGMP的要求。此法案中所提到的要求是来控制所有用于人体的成品器械的设计、生产、包装、标记、储存、装配、维修服务以及用于上述环节的设备和控制方法。此法案旨在确保成品器械的安全性和有效性，同时要符合联邦食品，药品和化妆品法案（简称法案）。此法案规定了适用于医疗器械产品生产商的基本要求。如果制造商仅涉及本法案要求中的部分环节，而非其它，那么此生产商只需符合本法案要求中所指的其涉及领域的要求即可。就I级器械而言，其设计只适用于820 .30(a)(2) 节中所列的那些器械。此法案不适用于成品零部件的生产商，但鼓励此类生产商使用此法案中适合的规定作为指导。用于输血或进一步制造的血液和血液成分的制造商不受本部分的约束，但受本章第F分章的约束。

(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

（2）本部分的规定应适用于在美国、哥伦比亚特区或波多黎各联邦的任何州或地区制造、进口或提供进口的本部分所定义的供人使用的任何成品装置。

(3) In this regulation the term "where appropriate" is used several times. When a requirement is qualified by "where appropriate," it is deemed to be "appropriate" unless the manufacturer can document justification otherwise. A requirement is "appropriate" if non-implementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

（3）在本法规中，“适当情况下”一词被多次使用。当一项要求被“在适当的地方”限定时，它被认为是“适当的”，除非制造商能以其他方式证明理由。如果不执行可能导致产品不符合其规定的要求或制造商无法执行任何必要的纠正措施，则要求是“适当的”。

(b) The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

（b）此部分的质量体系法案是对本章节中其他部分法案的补充。如果本部分适用法规与本章其他部分之间发生冲突，特指

适用于所述装置的法规应取代任何其他普遍适用的要求。

(c) Authority. Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

（c）权威性。本 820 部分根据法案第 501、502、510、513、514、515、518、519、520、522、701、704、801、803 节（《美国法典》第 21 卷第 351、352、360、360c、360d、360e、360h、360i、360j、360l、371、374、381、383 节）的授权制定和发布。未遵守本部分任何适用规定的，视为根据法案第 501（h）节表述的掺假装置。此装置及对未能遵守该规定的负责人，将承受到监管行动的约束。

(d) Foreign manufacturers. If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

（d）海外制造商。如果向美国提供进口设备的制造商拒绝 FDA 对其海外设施的检查以确保符合本部分的要求，则会被判定其设计、制造、包装、贴标签、储存、安装或维修在该设施生产并提供进口到美国的装置所用的方法、设施和控制不符合本部分及法案 520（f）节的要求，并根据本法案第 501（h）节的规定，判定该工厂制造的产品被掺假。

(e) Exemptions or variances. (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. ~~For guidance on how to proceed for a request for a variance, contact Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1438, Silver Spring, MD 20993-0002.~~

（e） 豁免或差异。(1) 任何人如欲申请豁免或变更任何设备质量体系要求，均须符合《联邦食品、药品和化妆品法》第 520（f）（2）条的要求。豁免或变更申请应按照本章§10.30 中规定的程序，即 FDA 的行政提交程序。

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

（2）当 FDA 确定任何器械质量体系要求的差异符合公众健康的最佳利益时，FDA 可以发起并批准该差异。只有当公共卫生需要该设备并且该设备在没有此差异的情况下不能满足需求的情况下，此差异才会继续有效。

Sec. 820.3 Definitions 定义

(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.

（a）法案是指经修订的《联邦食品、药品和化妆品法案》(第 201-903，52 Stat.1040 等，修订版（21 U.S.C.321-394)）。法案第 201 节中的所有定义应适用于本部分的规定。

(b) Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

（b）投诉是指任何书面的、电子的或口头的形式宣称，已放行销售的医疗器械存在与设备的特性、质量、耐久性、可靠性、

安全性、有效性或性能相关的缺陷。

(c) Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
（c）组件是指任何原材料、物质、零件、部件、软件、固件、标签或组件，这些原材料、物质、零件、部件拟作为成品、包装和标记设备的一部分。

(d) Control number means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.
（d）控制编号是指任何有意义或者独特的符号，例如由数字或字母或两者共同组成的有特点的组合，用于确定单个产品或批次产品的生产、包装、标签及分销的历史。

(e) Design history file (DHF) means a compilation of records which describes the design history of a finished device.
（e）设计历史文件（DHF）是指描述成品设备设计历史的记录汇编。

(f) Design input means the physical and performance requirements of a device that are used as a basis for device design.
（f）设计输入是指作为设备设计基础的设备的物理和性能要求。

(g) Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.
（g）设计输出是指设计工作在每个设计阶段和总设计工作结束时的结果。完成的设计输出是设备主记录的基础。总的完成设计输出包括设备、其包装和标签以及设备主记录。

(h) Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.
（h）设计评审是指对设计进行文件化的、全面的、系统的检查，以评估设计要求的充分性，评估设计满足这些要求的能力，并识别问题。

(i) Device history record (DHR) means a compilation of records containing the production history of a finished device.
（i）设备历史记录（DHR）指包含成品设备生产历史的记录汇编。

(j) Device master record (DMR) means a compilation of records containing the procedures and specifications for a finished device.
（j）设备主记录（DMR）指包含成品设备程序和规范的记录汇编。

(k) Establish means define, document (in writing or electronically), and implement.
（k）建立指定义、记录（书面或电子）和实施。

(l) Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
（l）成品设备是指适合使用或能够运行的任何设备或任何设备的附件，无论其是否包装、标记或灭菌。

(m) Lot or batch means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
（m）批次是指由单一类型、型号、类别、尺寸、成分或软件版本组成的一个或多个部件或成品装置，这些部件或成品装置

在基本相同的条件下制造，并在规定的范围内具有统一的特性和质量。

(n) Management with executive responsibility means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.
（n）具有行政责任的管理层是指制造商的高级雇员，他们有权建立或更改制造商的质量方针和质量体系。

(o) Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.
（o）制造商是指设计、制造、组装、装配或加工成品装置的任何人。制造商包括但不限于履行合同灭菌、安装、重新贴标、再制造、重新包装或规范制定职能的人员，以及履行这些职能的外国实体的初始分销商。

(p) Manufacturing material means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.
（p）制造材料是指用于或用于促进制造过程的任何材料或物质，制造过程中产生的伴随成分或副产品成分，其作为残留物或杂质存在于成品装置中或其上，而不是由制造商设计或意图造成的。

(q) Nonconformity means the nonfulfillment of a specified requirement.
（q）不合格是指不满足规定要求。

(r) Product means components, manufacturing materials, in- process devices, finished devices, and returned devices.
（r）产品是指部件、制造材料、半成品、成品和被退回的设备。

(s) Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
（s）质量是指影响设备满足适用性（包括安全性和性能）能力的所有特征和特性。

(t) Quality audit means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
（t）质量审核是指对制造商质量体系进行系统、独立的检查，该检查应在规定的间隔和足够的频率下进行，以确定质量体系活动和此类活动的结果是否符合质量体系程序，这些程序是否有效实施，以及这些程序适用于实现质量体系目标。

(u) Quality policy means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
（u）质量方针是指一个组织在质量方面的总体意图和方向，由负有行政责任的管理层制定。

(v) Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
（v）质量体系是指实施质量管理的组织结构、职责、程序、过程和资源。

(w) Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.
（w）再制造商是指对成品设备进行加工、处理、翻新、重新包装、恢复或采取任何其他行动，显著改变成品设备性能或安

全规范或预期用途的任何人。

(x) Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.
（x）返工是指对不合格品采取的措施，以便在放行前满足规定的 DMR 要求。

(y) Specification means any requirement with which a product, process, service, or other activity must conform.
（y）规范是指产品、过程、服务或其他活动必须符合的任何要求。

(z) Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
（z）验证是指通过检查和提供客观证据来确认特定预期用途的特定要求能够得到充分满足。

(1) Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
（1）过程验证是指通过客观证据确定一个过程始终产生符合其预定规范的结果或产品。
(2) Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).
（2）设计验证是指通过客观证据确定产品特性符合用户需求和预期用途。

(aa) Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
（aa）验证是指通过检查和提供客观证据确认已满足规定的要求。

~~(bb) Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.~~
~~(cc) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:~~
~~(1) A device identifier – a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and~~
~~(2) A production identifier – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:~~
~~(i) The lot or batch within which a device was manufactured;~~
~~(ii) The serial number of a specific device;~~
~~(iii) The expiration date of a specific device;~~
~~(iv) The date a specific device was manufactured.~~
~~(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.~~
~~(dd) Universal product code (UPC) means the product identifier used to identify an item sold at retail in the United States.~~

Sec. 820.5 Quality system 质量体系

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.
各制造商应建立并保持适用于设计或制造的特定医疗器械的质量体系，并满足本部分的要求。

Subpart B - Quality System Requirements 质量体系要求

Sec. 820.20 Management responsibility 管理职责

(a) Quality policy. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

（a）质量方针。具有执行责任的管理层应制定质量方针、目标和承诺。具有行政责任的管理者应确保质量方针在组织的各个层次上得到理解、实施和保持。

(b) Organization. Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

（b）组织。各制造商应建立并维持适当的组织结构，以确保装置的设计和生产符合本法规的要求。

(1) Responsibility and authority. Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

（1）责任和权力。各制造商应确定管理、执行和评估影响质量工作的所有人员的适当职责、权限和相互关系，并提供执行这些任务所需的独立性和权限。

(2) Resources. Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

（2）资源。每个制造商应提供足够的资源，包括指派训练有素的人员，用于管理、执行工作和评估活动，包括内部质量审核以满足本法规的要求。

(3) Management representative. Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

（3）管理者代表。管理层应任命并记录管理层成员的任命，该成员无论其他责任如何，均应确立以下职责的权力和责任：

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

（i）确保质量体系要求按照本法规有效建立并保持；以及

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

（ii）向负有行政责任的管理层报告质量体系的执行情况，以供审查。

(c) Management review. Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

（c）管理评审。具有行政责任的管理层应按照既定程序，以规定的时间间隔和足够的频率对质量体系的适宜性和有效性进行评审，以确保质量体系满足本法规的要求和制造商既定的质量方针和目标。质量体系评审的日期和结果应形成文件。

(d) Quality planning. Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

（d）质量计划。每个制造商应制定一个质量计划，其中规定了与设计和制造的设备相关的质量实践、资源和活动。制造商应确定如何满足质量要求。

(e) Quality system procedures. Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.
（e）质量体系程序。各制造商应建立质量体系程序和说明。在适当的情况下，应建立质量体系所用文件结构的大纲。

Sec. 820.22 Quality audit 质量审核

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.
各制造商应制定质量审核程序，并进行此类审核，以确保质量体系符合既定的质量体系要求，并确定质量体系的有效性。质量审核应由对审核事项无直接责任的人员进行。必要时，应采取纠正措施，包括重新审核缺陷事项。每次质量审核的结果报告和重新审核（如进行）应由负责审核事项的管理层进行审核。应记录质量审核和再审核的日期和结果。

Sec. 820.25 Personnel 人员

(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.
（a）总则。每个制造商应配备足够的人员，具备必要的教育、背景、培训和经验，以确保正确执行本部分所需的所有活动。

(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.
（b）培训。各制造商应建立识别培训需求的程序，并确保所有人员都经过培训，以充分履行其分配的职责。培训应形成文件。

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
（1）作为培训的一部分，应使人员了解产品疵点，这些疵点可能是由于其特定工作的不当执行造成的。
(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.
（2）执行验证和确认活动的人员应了解其工作职能中可能遇到的缺陷和错误。

Subpart C - Design Controls 设计控制

Sec. 820.30 Design controls 设计控制

(a) General. (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

（a）总则。(1) 任何 III 类或 II 类装置以及下列表格中列出的 I 类装置的每个制造商应建立并保持程序以控制产品的设计，用于确保规定的设计要求得到满足。

(2) The following class I devices are subject to design controls:

（2） 以下 I 类设备应进行设计控制：

(i) Devices automated with computer software; and

（i） 使用计算机软件自动操作的装置；以及

(ii) The devices listed in the following chart.

（ii）下表所列装置。

章节 Section	装置 Device
868.6810	Catheter, Tracheobronchial Suction. 气管、支气管抽吸导管。
878.4460	Glove, Surgeon's. 外科手套。
880.6760	Restraint, Protective. 约束，保护装置。
892.5650	System, Applicator, Radionuclide, Manual. 系统，治疗探头，放射性核素，手动。
892.5740	Source, Radionuclide Teletherapy. 放射源，放射性核素远程治疗。

(b) Design and development planning. Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

（b）设计和开发策划。各制造商应建立和保持设计和开发活动的计划并确定实施责任。策划应识别和描述与不同部门或活动的接口，这些部门或活动为设计和开发过程提供输入。随着设计和开发的发展，应对计划进行评审、更新和批准。

(c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

（c）设计输入。各制造商应制定和维护程序，以确保与设备相关的设计要求适当，并满足设备的预期用途，包括用户和患者的需要。程序应包括处理不完整、含糊或冲突要求的机制。设计输入要求应记录在案，并应由指定个人审核和批准。批准，包括批准要求的个人的日期和签字，应记录在案。

(d) Design output. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

（d）设计输出。各制造商应建立和保持程序以定义和记录设计输出，以便对设计输入要求的符合性进行充分评估。设计输出程序应包含或引用验收标准，确保识别出对装置正常运行至关重要的设计输出。设计输出在发布前应形成文件，进行评审和批准。应记录批准，包括批准输出的日期和个人签名。

(e) Design review. Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

（e）设计评审。各制造商应制定和维护程序，以确保在设备设计开发的适当阶段计划并进行设计结果的正式文件审查。程序应确保每次设计审查的参与者包括与被审查设计阶段相关的所有职能部门的代表和对正在审查的设计阶段不负有直接责任的个人以及所需的任何专家。设计评审的结果，包括设计评审的识别、日期和执行评审的个人，应记录在设计历史文件（DHF）中。

(f) Design verification. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

（f）设计验证。各制造商应建立并保持验证装置设计的程序。设计验证应确认设计输出满足设计输入要求。设计验证的结果，包括设计验证的识别、方法、日期和执行验证的人员，应记录在 DHF 中。

(g) Design validation. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

（g）设计验证。各制造商应建立并维护验证装置设计的程序。设计验证应在规定的操作条件下对初始生产装置、批次或批次或其等效物进行。设计验证应确保装置符合规定的用户需求和预期用途，并应包括在实际或模拟使用条件下对生产装置进行测试。设计验证应包括软件验证和风险分析（如适用）。设计验证的结果，包括设计、方法、日期和执行验证的人员的标识，应记录在 DHF 中。

(h) Design transfer. Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

（h）设计转换。每个制造商应建立和维护程序，以确保装置设计正确地转化为生产规范。

(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

（i）设计更改。各制造商应在实施设计变更之前，建立和维护识别、文件、验证或适当的验证、审查和批准程序。

(j) Design history file. Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

（j）设计历史文件。每个制造商应为每种类型的装置建立并维护一个 DHF。DHF 应包含或引用必要的记录，以证明设计是按照批准的设计计划和本部分的要求开发的。

Subpart D - Document Controls 文件控制

Sec. 820.40 Document controls 文件控制

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:
各制造商应建立并保持控制本法规要求的所有文件的程序。程序应包含以下内容：

(a) Document approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.
（a）文件批准和分发。各制造商应指定一名人员，在发布满足本法规要求的所有文件之前，对其适当性进行审查和批准。文件的批准，应包括批准日期及签名并形成文件。为满足本法规要求而建立的文件应在使用现场方便获得，或必要时获得。所有作废文件应立即从所有使用点移除，或以其他方式防止非预期使用。

(b) Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.
（b）文件变更。除非另有特别规定，文件的变更应由原审批部门进行审查和批准。批准的变更应及时传达给相关人员。各制造商应保存文件更改记录。变更记录应包括变更说明、受影响文件的标识、批准人的签字、批准日期以及变更生效的时间。

Subpart E - Purchasing Controls 采购控制

Sec. 820.50 Purchasing controls 采购控制

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.
各制造商应制定和维护程序，以确保所有采购或其他接收的产品和服务符合规定要求。

(a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements that must be met by suppliers, contractors, and consultants. Each manufacturer shall:
（a）供应商、承包商和顾问的评估。各制造商应制定并保持（包括质量要求）的一定的要求，供应商、承包商和顾问应满足该要求。其中包括：

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
（1）评估潜在供应商、承包商和顾问满足规定要求（包括质量要求）的能力，并进行选择。评价应形成文件。
(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
（2）根据评估结果，确定对产品、服务、供应商、承包商和顾问确定控制类型和程度。
(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.
（3）建立并维护合格供应商、承包商和顾问的记录。

(b) Purchasing data. Each manufacturer shall establish and maintain data that clearly describe or reference the specified

requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.

（b）采购数据。各制造商应建立和维护数据，明确采购或以其他方式接收的产品和服务的规定要求，包括质量要求。在可能的情况下，采购文件应包括供应商、承包商和顾问同意将产品或服务的变更通知制造商的协议，以便制造商确定变更是否会影响成品设备的质量。采购数据应根据§820.40 进行批准。

Subpart F - Identification and Traceability 标识和可追溯性

Sec. 820.60 Identification 标识

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

各制造商应建立和维护在接收、生产、分销和安装的所有阶段识别产品的程序，以防止混淆。

Sec. 820.65 Traceability 可追溯性

~~Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.~~

~~拟用于外科植入体内或支持或维持生命的器械，以及如果未能按照标签中提供的使用说明正确使用可能会对使用者造成重大伤害的产品制造商应制定并维护以下程序：用控制编号标识每个单元、批次或批次成品装置上的适当的部件。这些程序应有助于采取纠正措施。此类标识应记录在 DHR 中。~~

Subpart G - Production and Process Controls 生产和过程控制

Sec. 820.70 Production and process controls 生产和过程控制

(a) General. Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

（a）总则：各制造商应建立、实施、控制和监控生产过程，以确保设备符合其规范。如果制造过程可能导致与设备规范的偏差，制造商应建立并保持过程控制程序，说明确保符合规范所需的任何过程控制。如果需要过程控制，应包括：

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

（1）形成文件的作业指导书，标准的操作程序（SOP's），规定和控制生产方式的方法；

(2) Monitoring and control of process parameters and component and device characteristics during production;

（2） 生产过程中过程参数、组件和器械特性的监控；

(3) Compliance with specified reference standards or codes;

（3）符合规定的参考标准或代码；

(4) The approval of processes and process equipment; and

（4）过程和过程设备的批准；和

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and

approved representative samples.
（5） 工艺标准应以文件形式或经确定和批准的代表性样品表示。

(b) Production and process changes. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to § 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 820.40.
（b）生产和工艺变更。各制造商应建立和保持规范、方法、工艺或程序变更的程序。此类变更应在实施前根据§820.75 进行验证或在适当情况下进行验证，并且这些活动应记录在案。应根据§820.40 批准变更。

(c) Environmental control. Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.
（c）环境控制。如果可以合理预期环境条件会对产品质量产生不利影响，制造商应建立并保持适当控制这些环境条件的程序。应定期检查环境控制系统，以验证该系统（包括必要的设备）是否足够且运行正常。这些活动应记录和评审。

(d) Personnel. Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.
（d）人员。如果人员与产品或环境的接触可能会对产品质量产生不利影响，则各制造商应制定并保持对人员的健康、清洁、个人行为和服装的要求。制造商应确保需要在特殊环境条件下临时工作的维护人员和其他人员由经过培训的人员进行适当培训或监督。

(e) Contamination control. Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.
（e）污染控制。各制造商应制定和维护程序，防止设备或产品受到可能对产品质量产生不利影响的物质污染。

(f) Buildings. Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.
（f）建筑物。建筑物应具有适当的设计，并有足够的空间进行必要的操作，防止混淆，并确保有序处理。

(g) Equipment. Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.
（g）设备。各制造商应确保制造过程中使用的所有设备符合规定要求，并进行适当的设计、布局、放置和安装，以便于维护、调整、清洁和使用。

(1) Maintenance schedule. Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.
（1）维护计划。各制造商应制定并维护设备的调整、清洁和其他维护计划，以确保符合生产规范。应记录维护活动，包括执行维护活动的日期和人员。
(2) Inspection. Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.

（2）检查。各制造商应按照既定程序定期检查，以确保遵守适用的设备维护计划。检查应包括进行检查的日期和个人并形成文件。

(3) Adjustment. Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

（3）调整。各制造商应确保在需要定期调整的设备上或设备附近明显张贴任何固有限制或容许公差，或执行这些调整的人员可随时获得这些限制或公差。

(h) Manufacturing material. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

（h）制造材料。如果可以合理预期制造材料会对产品质量产生不利影响，制造商应建立并保持使用和移除此类制造材料的程序，以确保移除或限制其数量不会对设备质量产生不利影响。应记录此类制造材料的移除或减少。

(i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

（i）自动化流程。当计算机或自动数据处理系统作为生产或质量体系的一部分使用时，制造商应根据既定协议验证计算机软件的预期用途。所有软件更改应在批准和发布前进行验证。这些验证活动和结果应记录在案。

Sec. 820.72 Inspection, measuring, and test equipment 检验、测量和实验设备

(a) Control of inspection, measuring, and test equipment. Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

（a）检验、测量和试验设备的控制。各制造商应确保所有检验、测量和试验设备，包括机械、自动化或电子检验和试验设备，适用于其预期用途，并能够产生有效结果。每个制造商应建立和维护程序，以确保设备定期校准、检查、检查和维护。程序应包括设备的搬运、保存和储存规定，以保持其准确性和适用性。这些活动应记录在案。

(b) Calibration. Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

（b）校准。校准程序应包括特定目的的准确度和精确度的极限。当不满足精度和精度限制时，应规定补救措施，以重新建立限值，并评估是否对设备质量产生任何不利影响。这些活动应记录在案。

(1) Calibration standards. Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

（1）校准标准。用于检验、测量和试验设备的校准标准应可追溯至国家或国际标准。如果没有国家或国际标准或不适用时，制造商应使用独立的可复验的标准。如果没有适用的标准，制造商应建立并保持内部标准。

(2) Calibration records. The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of

equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

（2）校准记录。应记录设备标识、校准日期、执行每次校准的人员以及下一次校准日期。这些记录应显示在每件设备上或附近，或应随时提供给使用此类设备的人员和负责校准设备的人员。

Sec. 820.75 Process validation 过程确认

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

（a）如果一个过程的结果不能通过随后的检验和试验得到充分验证，则应按照确信度较高的程序对该过程进行验证，并按照既定的程序进行批准。应记录验证活动和结果，包括批准验证的日期和签名，以及在适当情况下验证的主要设备，应形成文件。

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

（b）各制造商应建立并保持对已验证工艺的工艺参数进行监测和控制的程序，以确保继续满足规定的要求。

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

（1）各制造商应确保经验证过程由有资质的个人执行。

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

（2）对于已验证的过程，应记录监测和控制方法和数据、执行日期，以及在适当情况下，执行过程的个人或使用的主要设备。

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

（c）当发生变更或工艺偏差时，制造商应审查和评估工艺，并在适当情况下进行再验证。这些活动应记录在案。

Subpart H - Acceptance Activities 接收活动

Sec. 820.80 Receiving, in-process, and finished device acceptance 进货产品、过程产品和最终产品的接收

(a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

（a）总则。各制造商应制定并维护验收活动程序。验收活动包括检查、测试或其他验证活动。

(b) Receiving acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

（b）接收验收活动。各制造商应建立并保持进货验收程序。进货产品应经检验、试验或其它验证符合规定的要求。验收或拒收应记录在案。

(c) In-process acceptance activities. Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

（c）过程产品接收活动。各制造商应建立并保持适当的验收程序，以确保满足规定的过程产品的要求。这些程序应确保过程产品处于受控状态，直到所需的检验和试验或其他验证活动完成，或收到必要的批准，并形成文件。

(d) Final acceptance activities. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

（d）最终产品的接收活动。各制造商应制定并维护成品设备验收程序，以确保每一个批次的成品设备符合验收标准。成品设备在放行前应隔离或以其他方式充分控制。成品设备在放行前应完成下列活动：

(1) The activities required in the DMR are completed;

（1）完成 DMR 中要求的活动；

(2) the associated data and documentation is reviewed;

（2）相关数据和文件经过检查；

(3) the release is authorized by the signature of a designated individual(s); and

（3）经指定人员签字批准放行；以及

(4) the authorization is dated.

（4）批准日期。

(e) Acceptance records. Each manufacturer shall document acceptance activities required by this part. These records shall include:

（e）接收记录。各制造商应记录本部分要求的验收活动。这些记录应包括：

(1) The acceptance activities performed;

（1）完成的接收活动；

(2) the dates acceptance activities are performed;

（2）完成的接受活动的日期

(3) the results;

（3）结果；

(4) the signature of the individual(s) conducting the acceptance activities; and

（4）执行接收活动的个人的签名；以及

(5) where appropriate the equipment used. These records shall be part of the DHR.

（5）在适当的情况下使用设备。这些记录应为 DHR 的一部分。

Sec. 820.86 Acceptance status 接收状态

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

各制造商应通过适当的方式识别产品的验收状态，以表明产品符合或不符合验收标准。在产品的制造、包装、贴标签、安装和维修过程中，应保持验收状态的标识，以确保只有通过所需验收活动的产品才能被销售、使用或安装。

Subpart I - Nonconforming Product 不合格品

Sec. 820.90 Nonconforming product 不合格品

(a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

（a）不合格品的控制。各制造商应建立并保持程序，以控制不符合规定要求的产品。程序应规定不合格产品的标识、文件、评估、隔离和处置。对不合格品的评估应包括确定是否需要对不符合项负责的人员或组织进行调查和通知。评估和调查应记录在案。

(b) Nonconformity review and disposition. (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

（b）不合格评审和处置。（1）各制造商应建立并保持程序，规定不合格品的评审责任和处置权限。程序应规定审查和处置过程。不合格品的处置应形成文件。文件应包括使用不合格产品的理由和授权使用人员的签名。

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

（2）各制造商应建立并保持返工程序，包括返工后不合格产品的重新试验和重新评估，以确保产品符合其当前批准的规范。返工和重新评估活动，包括确定返工对产品的任何不利影响，应记录在 DHR 中。

Subpart J - Corrective and Preventive Action 纠正和预防措施

Sec. 820.100 Corrective and preventive action 纠正和预防措施

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

（a）各制造商应制定并维护实施纠正和预防措施的程序。程序应包括以下方面的要求：

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

（1）分析过程、工作操作、让步、质量审核报告、质量记录、服务记录、投诉、退货和其他质量数据来源，以确定不合格产品或其他质量问题的现有和潜在原因。必要时，应采用适当的统计方法来检测重复出现的质量问题；

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

（2）调查与产品、过程和质量体系有关的不合格原因；

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

（3）识别需要采取纠正的措施，以防止不合格品和其他质量问题再次发生；

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

（4）验证或确认纠正和预防措施，以确保此类措施有效且不会对成品产生不利影响；

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
（5）实施并记录纠正和预防已识别质量问题所需的方法和程序的变更；
(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
（6）确保与质量问题或不合格产品有关的信息传播给直接负责确保该产品质量或预防该问题的人员；以及
(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
（7）对发现的质量问题，以及纠正和预防措施的有关资料提交管理评审。

(b) All activities required under this section, and their results, shall be documented.
（b）本节要求的所有活动及其结果应记录在案。

Subpart K - Labeling and Packaging Control 标记和包装控制

Sec. 820.120 Device labeling 器械标记

Each manufacturer shall establish and maintain procedures to control labeling activities.
各制造商应建立并保持控制标签活动的程序。

(a) Label integrity. Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.
（a）标签完整性。标签应打印和使用，并在常规的加工、储存、搬运、分发和其他适当条件下保持清晰和附着。

(b) Labeling inspection. Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.
（b）标签检查。在指定个人检查标签是否准确之前，不得发布标签以供储存或使用，包括正确的唯一设备标识符（UDI）或通用产品代码（UPC）、到期日期、控制号、存储说明、处理说明和任何附加处理说明。发布，包括执行检查的个人的日期和签名，应在 DHR 中记录。

(c) Labeling storage. Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.
（c）标签储存。每个制造商应以提供适当标识的方式储存标签，并设计为防止混淆。

(d) Labeling operations. Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.
（d）标签操作。各制造商应控制标签和包装操作，以防止标签混淆。DHR 中应记录每个生产单元、批次或批次使用的标签和标签。

(e) Control number. Where a control number is required by § 820.65, that control number shall be on or shall accompany the device through distribution.
（e）控制编号。如果§820.65 要求提供控制编号，则该控制编号应在装置上，或应随装置一起分发。

Sec. 820.130 Device packaging 器械包装

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.
各制造商应确保设备包装和装运集装箱的设计和构造，能够保护设备在处理、储存、搬运和分销的常规条件下不产生变化或损坏。

Subpart L - Handling, Storage, Distribution, and Installation 搬运、储存、配送和安装

Sec. 820.140 Handling 搬运

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.
各制造商应建立并保持程序，以确保在搬运过程中不会出现混淆、损坏、变质、污染或其他对产品的不利影响。

Sec. 820.150 Storage 储存

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.
（a）各制造商应建立并保持产品储存区和储存室的控制程序，以防止在使用或分销期间出现混淆、损坏、变质、污染或其他不利影响，并确保不使用或分销过时、拒收或变质的产品。当产品质量随着时间的推移而恶化时，应以便于适当库存周转的方式储存，并应视情况对其状况进行评估。

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.
（b）各制造商应建立并保持程序，说明授权接收和发送至储存区和储存室的方法。

Sec. 820.160 Distribution 配送

~~(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.~~
~~（a）各制造商应建立和维护成品装置的控制和配送程序，以确保仅配送批准发布的装置，并审查采购订单，以确保在装置配送前解决含糊不清和错误。如果器械的适用性或质量随着时间的推移而恶化，程序应确保不配送过期器械或劣化超过可接受适用性的器械。~~
~~(b) Each manufacturer shall maintain distribution records which include or refer to the location of:~~
~~（b）各制造商应保存配送记录，包括或提及以下内容：~~
~~(1) The name and address of the initial consignee;~~
~~（1）初始收货人的名称和地址；~~
~~(2) The identification and quantity of devices shipped;~~
~~（2）装载设备的标识和数量；~~
~~(3) The date shipped; and~~
~~（3）装运日期；以及~~

~~(4) Any control number(s) used.~~
~~（4）使用的任何控制编号。~~

Sec. 820.170 Installation 安装

~~(a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.~~
~~（a）需要安装的装置的每个制造商应制定并保持适当的安装和检查说明，以及适当的试验程序。说明和程序应包括确保正确安装的说明，以便装置在安装后按预期运行。制造商应将说明书和程序与装置一起分发或以其他方式提供给装置安装人员。~~
~~(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.~~
~~（b）安装设备的人员应确保按照制造商的说明和程序进行安装、检查和任何必要的测试，并记录检查和任何试验结果，以证明正确安装。~~

Subpart M – Records 记录

Sec. 820.180 General requirements 总要求

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.
本部分要求的所有记录应保存在制造商负责官员和 FDA 指定执行检查的员工可合理访问的制造厂或其他地点。此类记录，包括未储存在被检查机构的记录，应随时可供 FDA 员工审查和复制。此类记录应清晰易读，并应尽量减少变质和防止丢失。应备份存储在自动数据处理系统中的记录。

(a) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.
（a）保密。制造商视为机密的记录可作标记，以帮助 FDA 确定是否可根据本章第 20 部分的《公共信息条例》披露信息。

(b) Record retention period. All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.
（b）记录保存期。本部分要求的所有记录应保留不低于装置设计和预期寿命的时间，但在任何情况下，不得少于制造商发布用于商业分销之日起 2 年。

(c) Exceptions. This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.
（c）例外情况。本节不适用于§820.20（c）管理评审、§820.22 质量审计要求的报告，以及用于满足§820.50（a）供应商、

承包商和顾问评估要求的供应商审计报告，但适用于根据这些规定制定的程序。应食品和药品管理局指定员工的要求，负有行政责任的管理层员工应以书面形式证明本部分所要求的管理评审和质量审核以及供应商审核（如适用）已经执行并记录了执行日期，已采取任何必要的纠正措施。

Sec. 820.181 Device master record 器械主记录

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:
各制造商应保存设备主记录（DMR）。各制造商应确保按照§820.40 的规定编制和批准各 DMR。每种装置的 DMR 应包括或参考以下信息的位置：

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;
（a）设备规范，包括适当的图纸、组成、配方、组件规范和软件规范；

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;
（b）生产工艺规范，包括适当的设备规范、生产方法、生产程序和生产环境规范；

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;
（c）质量保证程序和规范，包括验收标准和所使用的质量保证设备；

(d) Packaging and labeling specifications, including methods and processes used; and
（d）包装和标签规范，包括使用的方法和过程；以及

(e) Installation, maintenance, and servicing procedures and methods.
（e）安装、维护和维修程序和方法。

Sec. 820.184 Device history record 器械的历史记录

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:
各制造商应保存设备历史记录（DHR）。各制造商应建立并保持程序，以确保各批次或单元的 DHR 得到记录，以证明装置是按照 DMR 和本部分的要求制造的。DHR 应包括或提及以下信息的位置：

(a) The dates of manufacture;
（a）制造日期；

(b) The quantity manufactured;
（b）制造数量；

(c) The quantity released for distribution;
（c）发出数量；

(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;

（d）证明设备按照 DMR 制造的验收记录；

(e) The primary identification label and labeling used for each production unit; and
（e）主要识别标签和用于每个生产单元的标签；以及

(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.
（f）任何唯一设备标识符（UDI）或通用产品代码（UPC），以及使用的任何其他设备标识和控制编号。

Sec. 820.186 Quality system record 质量体系记录

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.
各制造商应保持质量体系记录（QSR）。QSR 应包括本部分所要求的活动的程序和文件，这些文件不是针对特殊类型的器械，包括但不局限于§820.20 所要求的记录。各制造商应确保 QSR 按照§820.40 的规定编制和批准。

Sec. 820.198 Complaint files 抱怨文件

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:
（a）各制造商应保存投诉文件。各制造商应建立并维持由正式指定部门接收、审查和评估投诉的程序。此类程序应确保：

(1) All complaints are processed in a uniform and timely manner;
（1）所有投诉均得到统一及时的处理；
(2) Oral complaints are documented upon receipt; and
（2）口头投诉一经收到即记录在案；以及
(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.
（3）对投诉进行评估，以确定投诉是需要按照本章第 803 部分"医疗器械报告"要求向 FDA 报告。

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.
（b）各制造商应审查和评估所有投诉，以确定是否有必要进行调查。如果未进行调查，制造商应保存一份记录，包括未进行调查的原因和不调查决定的责任人姓名。

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.
（c）任何涉及设备、标签或包装可能不符合其任何规范的投诉应进行审查、评估和调查，除非此类调查已针对类似投诉进行，且无需进行另一次调查。

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:

（d）根据本章第 803 部分的规定，必须向食品和药品管理局报告的代表事件的投诉应由指定的个人立即审查、评估和调查，并应保存在投诉文件的单独部分或以其他方式明确标识。除§820.198（e）所要求的信息外，本段规定的调查记录还应包括以下决定：

(1) Whether the device failed to meet specifications;
（1）设备是否不符合规范要求；
(2) Whether the device was being used for treatment or diagnosis; and
（2）设备是否用于治疗或诊断；以及
(3) The relationship, if any, of the device to the reported incident or adverse event.
（3）设备与报告事件或不良事件的关系（如有）。

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:
（e）根据本节进行调查时，本节第（a）条规定的正式指定单位应保存调查记录。调查记录应包括：

(1) The name of the device;
（1）设备名称；
(2) The date the complaint was received;
（2）收到投诉的日期；
(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
（3）任何唯一设备标识符（UDI）或通用产品代码（UPC），以及使用的任何其他设备标识和控制编号；
(4) The name, address, and phone number of the complainant;
（4）投诉人的姓名、地址和电话号码；
(5) The nature and details of the complaint;
（5）投诉的性质和细节；
(6) The dates and results of the investigation;
（6）调查的日期和结果；
(7) Any corrective action taken; and
（7）采取的任何纠正措施；以及
(8) Any reply to the complainant.
（8）对投诉人的任何答复。

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.
（f）当制造商正式指定的负责处理投诉的部门与制造场地不在一起时，被调查的投诉和调查记录应便于制造厂合理查阅。

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:
（g）如果制造商正式指定的处理投诉单位位于美国境外，则本节要求的记录应在美国合理查阅，具体情况如下：

(1) A location in the United States where the manufacturer's records are regularly kept; or
（1）美国境内定期保存制造商记录的机构地点；或
(2) The location of the initial distributor.
（2）初始分销商的位置。

Subpart N – Servicing 服务

Sec. 820.200 Servicing 服务

~~(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.~~
~~(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.~~
~~(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.~~
~~(d) Service reports shall be documented and shall include:~~
~~(1) The name of the device serviced;~~
~~(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;~~
~~(3) The date of service;~~
~~(4) The individual(s) servicing the device;~~
~~(5) The service performed; and~~
~~(6) The test and inspection data.~~
~~[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 78 FR 58822, Sept. 24, 2013]~~

Subpart O - Statistical Techniques 统计技术

Sec. 820.250 Statistical techniques 统计技术

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.
（a）在适当的情况下，每个制造商应建立和保持程序，以识别建立、控制和验证过程能力和产品特性的可接受性所需的有效统计技术。

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.
（b）使用抽样计划时，应以有效的统计原理为基础编写抽样计划。各制造商应建立并保持程序，以确保取样方法适合其预期用途，并确保在发生变化时，对取样计划进行审查。这些活动应记录在案。