美国 FDA 医疗器械体系法规 QSR820 中文版

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Sec.820.1 范围

Sec. 820.1 Scope.
（a） 适用性 *Applicability*。
（1） 本质量体系法规阐明了当前良好制造法规 Current good manufacturing practice（CGMP）的要求。本标准适用于所有预期用于人类的成品器械的设计、制造、包装、标识、储存、安装和服务中所使用的管理方法、设施和控制。本标准的目的是保证成品器械的安全性和有效性，并符合联邦食品、药品和化妆品法案 Federal Food, Drag and Cosmetic Act（the act）。本法规适用于所有的医疗器械成品制造商。如果制造商仅从事本部分有要求服从的某些过程而未从事其它过程，则只需符合其实施的过程的要求。对于Ⅰ类设备，设计控制仅适用于 Sec.820.30（a）（2）中列出的设备。本法规不适用于成品器械的部件或零件制造商，但鼓励这类制造商把本法规的适当规定作为指南来使用。人血和血液成分制造商不受本部分法规的限制，但应遵循本章 606 部分法规的要求。

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) 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 human blood and blood components are not subject to this part, but are subject to part 606 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.

（2） 本部分的规定适用于本部分定义的预期用于人体的所有成品器械，不论其在美国(包含:美国任何州或领土,哥伦比亚特区,波多黎各联邦)本土制造还是进口,提供进口的产品。

(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.

（3）在本法规中“适用时”（where appropriate）出现过多次。当要求根据“where appropriate”被认为是合格时，其要求应被认为是“适用的”（appropriate），除非组织能提供文件证明其理由。如果不执行预期结果会导致产品不符合其特定的要求，或组织不需要执行任何必要的纠正措施，那么要求就是适用的（appropriate）。

(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.

（b） 限制。除非特别规定，则本部分质量体系法规是本章其它部分法规的补充要求。在不能符合所有适用的法规，包括本章此部分和其它部分的情况，特别是对讨论中的设备，此法规应取代其它通用要求。

(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.

（c） 权限。PART820 是在（21U.S.C.法令 351、352、360、360c、360d、360e、360h、360i、360j、360l、370、374、381、383 中）501、502、510、513、514、515、518、519、520、522、701、704、801、803 下建立并发布的。不符合本部分（Part 820）的任何适用的规定，依据法令 section 501（h）条款，可判定该产品为伪劣产品。这类产品及对此不符合负责的任何个人，将依法被起诉。

(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.

（d） 外国制造商。如果把器械进口到美国的制造商拒绝允许或同意 FDA 对其外国工厂履行为确定器械是否符合本法规（Part 820）所进行的检查，可按 section 801（a）条款对其提出诉讼。即准备出口到美国的设备，其设计、生产、包装、标签、贮存或服务中使用的方法和设备控制不符合本法令 section 520（f）和本部分（Part 820）的要求，可按本法令 section 501（h）条款判定在此条件下制造的产品为伪劣产品。

(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.

（e） 豁免或特别许可/ *Exemptions or variances*

（1） 任何人希望得到任何医疗器械质量体系要求的豁免或特别许可，应符合法令 section 520（f）（2）的要求。根据本章 Sec.10.30 即 FDA 行政程序，来提交豁免或特别许可的申请。可以从器械和辐射健康中心和小型制造商援助处获得指导，地址（HFZ-220），1350 Piccard Dr.，Rockville，MD20850，U.S.A.，电话 1-800-638-2041 或 1-301-443-6597，传真 301-443-8818。

(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 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. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 240-276-3150, FAX 240-276-3151.

（2） 在有关部门确定此种改变符合美国公众健康的最佳利益时，FDA 可能发起并同意器械质量体系的特别许可。公在美国公众健康确实需要该设备，且如无此特别许可，则器械就不可能充分有效的生产的情况下，特别许可才有效。

(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.

（f） 本部分不适用于本章 897 部分定义的烟草销售商。

Sec.820.3 定义 / Definitions

（a） 法案 Act。指明 Federal Food, Drug and Cosmetic Act，如修正的（secs.201-903，52 Stat. 1040 et sep.，21 U.S.C. 321-394）。所有法案 section 201 中的定义在本部分法规中均适用。

(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.

（b） 投诉 Complaint。在设备交付后所有的书面的、电子的或口头的，对设备的标识、质量、耐用性、可靠性、安全性、有效性和性能方面缺陷的信息。

(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.

（c） 部件 Component。所有意图用来包含成为已完成的、包装、标识的器械的一部分的原材料、物资、构件、零件、软件、固件、连接件、标签或它们的集合。

(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.

（d） 控制号 Control number。任何鉴别性符号，如由字母、数字或它们的组合形成的唯一性组合，由控制号可以确定一批或一个器械的制造、包装、标识和交付的历史。

(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.

（e） 设计历史文件 Design history file（DHF）。成品器械的设计历史记录的汇总。

(e)*Design history file* (*DHF*) means a compilation of records which describes the design history of a finished device.

（f） 设计输入 Design input。器械实体和性能要求，是产品设计的基础。

(f)*Design input* means the physical and performance requirements of a device that are used as a basis for device design.

（g） 设计输出 Design output。是指每个设计阶段和最后所有的设计成果的结果。已完成的设计输出是器械主记录的基础。全部最终完成的设计输出，由器械及其包装和标识和设备主记录组成。

(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.

（h） 设计评审 Design review。是指对设计的一个文件化的、全面的、系统的检查，评价其满足设计要求，评价其有能力满足要求，并识别任何问题。

(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.

（i） 设备历史记录 Device history record（DHR）。成品器械历史记录的汇总。

(i)*Device history record* (*DHR*) means a compilation of records containing the production history of a finished device.

（j） Device master record（DMR）。成品器械的程序和规范的汇总。

(j)*Device master record* (*DMR*) means a compilation of records containing the procedures and specifications for a finished device.

（k） 建立 Establish。定义文件（书面或电子的）并执行。

(k)*Establish* means define, document (in writing or electronically), and implement.

（l） 成品器械 Finished device。设备或其附件，无论其是否包装、标识或灭菌，能够满足使用要求或者说能够实现其功能。

(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.

（m） Lot 或 batch。一个或多个元件或成品器械，均为同一种规格、型号、尺寸、成分或软件版本，在相同条件下生产，满足相同的特性和质量要求。

(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.

（n） 执行职责的管理者 Management with executive responsibility。是组织的高级员工，他们负有建立或更改组织的质量方针和质量体系的职权。

(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.

（o） 制造商/组织 Manufacturer。是指设计、制造、制作（fabricate）、装配或加工成品器械的任何人。制造商包括但不仅限于根据合同执行灭菌、安装、重新标识、重新制造、重新包装或特定的开发职责的制造商，和执行这些职责的国外组织的国内分销商。

(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.

（p） Manufacturing material。指任何用于或用于催化制造过程的任何原料或物质，在制造过程中产生的伴随的成分或副产品，其在成品器械中/上呈现为残留物或杂质，它不是制造商的设计或意图。

(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.

（q） 不合格 Nonconformity。未满足规定的要求。

(q)*Nonconformity* means the nonfulfillment of a specified requirement.

（r） 产品 Product。部件、原材料、在制品、成品和返回品。

(r)*Product* means components, manufacturing materials, in- process devices, finished devices, and returned devices.

（s） 质量 Quality。一组固有特性满足要求的程序，包括安全和性能。

(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.

（t） 质量审核 Quality Audit。按规定的时间间隙和频率，对制造商的质量体系进行系统、客观的检查，以确定质量体系活动及其结果符合质量体系程序，这些程序得到有效执行，程序适应质量目标的需求。

(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.

（u） 质量方针 Quality policy。由制造商的最高管理者发布的组织总的质量宗旨和方向。

(u)*Quality policy* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

（v） 质量体系 Quality system。质量管理的组织结构、职责、程序、过程和资源。

(v)*Quality system* means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

（w） Remanufacturer。指对成品器械进行处理、修整、修复、重新包装、恢复或其它活动的人，使成品器械的性能、安全规范或预期用途产生重大更改。

(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.

（x） 返工 Rework。为使不合格品在其交付前符合 DMR 的要求而采取的措施。

(x)*Rework* means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

（y） 规范 Specification。产品、过程、服务或其它活动应符合的要求。

(y)*Specification* means any requirement with which a product, process, service, or other activity must conform.

（z） 确认 Validation。通过检查和提供客观证据证明满足预期用途的要求。

(z)*Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

（1） 过程确认 Process validation。根据客观证据确定过程可持续产生满足预先确定规范的结果或产品。

(1)*Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

（2） 设计确认 Design validation。根据客观证据确定设备规范符合使用者的需求和预期用途。

(2)*Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).

（aa） 验证 Verification。通过检查和提供客观证据证明满足规定的要求。

(aa)*Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Sec.820.5 质量体系/ Quality system.

制造商应建立并实施适应特定的医疗器械设计或制造，并符合本部分要求的质量体系。

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.

Subpart B——质量体系要求/ **Quality System Requirements**

Sec.820.20 管理职责/ Management responsibility

（a） 质量方针：负有执行职责的管理者应建立质量方针和目标以及在质量方面的承诺，应保证组织内所有级别都能正确理解并执行质量方针。

(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.

（b） 组织：建立并保持适宜的组织结构，确保产品的设计和生产符合本部分（Part 820）的要求。

(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.

（1） 职责和权限。制造商应明确影响质量的管理、操作和评价人员的职责、权限及相互关系，为其提供执行这些工作必需的自主权和权限。

(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.

（2） 资源。制造商应提供适当的资源，包括由经过培训的人员，执行管理、操作和包括内部质量审核在内的活动，以符合本部分（Part 820）的要求。

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.

（3） 管理者代表。最高管理者应在管理层中以书面方式指定一名管理者代表，无论其在其它方面的职责如何，应具有以下方面的职责和权限：

(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:

（i） 确保根据本部分（Part 820）的要求有效地建立、实施和保持质量管理体系；

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

（ii） 向负有执行职责的管理者报告质量体系运行情况，以供评审。

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

（c） 管理评审。负有执行职责的管理者，应按程序规定的时间间隔对质量体系进行审核。确保质量体系的持续适宜性和有效性，以满足本标准的要求和组织规定的质量方针和目标。评审的日期和结果应形成文件并记录。

(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.

（d） 质量策划。制造商应建立质量策划，确定设计和制造设备所需的质量准则、资源和活动，形成质量计划。组织应确定如何满足质量要求。

(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.

（e） 质量体系程序。制造商应建立质量体系程序和规范，适用时应建立质量体系的文件化的结构描述。

(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.

Sec.820.22 质量审核 Quality audit.

制造商应建立并实施质量审核程序和活动，以确保质量体系符合既定的质量体系要求，确定质量体系的有效性。质量审核应由与所审核的活动无直接责任的人员进行。纠正措施，必要时包括对不符合项的重新审核。每次质量审核和重新审核的结果应形成报告，报告要经对审核负有责任的管理者评审。审核和重新审核的日期和结果应予记录。

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.

Sec.820.25 人员/ Personnel

（a） 概述。制造商应有足够的人员，经过必要的教育、工作背景、专业培训和相关的经验，以保证所有法规要求的活动能够得到正确的执行。

(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.

（b） 培训。制造商应建立培训的文件，明确培训需求，保证所有人员都能得充分的培训，以保证满足工作的要求。培训应形成记录。

(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.

（1） 作为培训的一部分，应使员工意识到他们的特殊工作中的不正确的操作可造成设备的缺陷。

(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.

（2） 负有验证和确认职责的人员应意识到，在其工作中会遇到缺陷和错误。

(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.

Subpart C——设计控制 Design controls
Sec.820.30 设计控制 Design controls
（a） 概述/ *General.*

（1）在本段（a）（2）列表中的 class Ⅰ、Ⅱ、Ⅲ类设备制造商应建立和保持产品设计控制的程序，以确保满足特定的设计要求。

(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.

（2）下列 class Ⅰ的设备应遵循设计控制：

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

（i） 由计算机软件自动操作的设备；

(i) Devices automated with computer software; and

（ii） 下列表格中所列设备
(ii) The devices listed in the following chart.

Section
Device
868.6810 导管、呼吸机
878.4460 手套、外科医生用手套
880.6760 阻止、保护用品
892.5650 生化、涂药器、放射性、手工制造（Manual）
892.5740 源、放射治疗

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.

880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

（b） 设计和开发策划。组织应建立并实施设计和开发计划，其内容描述或包括了设计和开发的相关活动并定义了执行的职责。计划应明确并描述不同部门/组间的接口及活动，其结果是设计输入和开发过程。计划应随着设计和开发的推进进行评审、更新，并经批准。

(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.

（c） 设计输入。组织应建立并保持程序，以保证与产品相关的设计要求是适宜的，并满足设备的预期用途，包括使用者和患者的需要。这个程序应包括解决任何不完全、不明确和相互矛盾的要求的机制。设计输入要求应经审核，并经指定的人员审核和批准。审批应包括审批人员的签名和日期，审批应予记录。

(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.

（d） 设计输出。组织应建立并保持文件化的设计输出程序，使经过评审的设计输出文件满足设计输入的要求。设计输出程序应包括或涉及接收标准，确保实现设备基本的、适用的功能。设计输出应是文件化的，在发布前应经评审和批准。审批应文件化，包括批准人的签名及日期。

(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.

（e） 设计评审。组织应建立并实施程序，确保在产品设计开发的适当阶段，有计划地对设计结果进行正式的评审。程序应确保每次设计评审的参与者，应包括与被评审的设计阶段有关的所有职能部门的代表，和一名或多名与被评审设计阶段无直接责任的人员，需要时也可包括其它专家。评审结果，包括设计标识（identification of design）、日期、评审的人员，应在设计历史文件中予以记录。

(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).

（f） 设计验证。组织应建立并实施设计验证的程序。确保设计输出满足设计输入的要求。设计验证的结果，包括设计标识（identification of design）、方法、日期、验证的人员，应在设计历史文件中予以记录。

(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.

（g） 设计确认。组织应建立并实施设计确认程序。设计确认应在规定的操作条件下，对最初的产品、批次或其等价物上进行。设计确认应确保产品满足规定的用户需求和预期的使用要求，也包括在实际或模拟的使用条件下对产品单元进行试验。适用时，设计确认应包括软件确认和风险分析。设计确认的结果，包括设计标识（identification of design）、方法、日期、确认的人员，应在设计历史文件中予以记录。

(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.

（h） 设计转换。组织应建立并保持文件化的程序，以保证产品的设计能够正确的转换成产品的规范。

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

（i） 设计更改。组织应建立并保持程序，在执行前设计更改应被识别、文件化、确认或适用时经验证、评审和批准。

(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.

（j） 设计历史文件。组织应建立并保持每个型号的产品的 DHF。DHF 应包括或涉及必要

的记录，以证明设计的进程符合被批准的设计计划和本部分的要求。
(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.

Subpart D——文件控制 **Document Controls**
Sec.820.40 文件控制 **Document Controls**
组织应建立并实施程序，以控制所有本部分要求的文件。程序应包括：

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

（a） 文件的批准和发布。所有文件在发布前应由授权人员评审、批准其适宜性，以满足本部分的要求。文件的批准，包括批准发布人员的签名及日期应形成记录。确保在文件适用的场所能够获得相关文件，从所有发放或使用场所及时撤出作废文件，以防止作废文件的非预期使用。

(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.

（b） 文件更改。除非有专门指定，文件的更改应由文件的原审批部门/组织进行审批。经批准的更改应及时通知相关人员。组织应保持文件更改的记录。更改记录应包括对更改的描述，受影响的文件的标识，批准人的签名、批准日期及更改生效的时间。
(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.

Subpart E——采购控制 **Purchasing Controls**

Sec.820.50 采购控制 **Purchasing Controls**

组织应建立并保持程序，确保所有采购或其它委托生产和服务的活动满足规定的要求。

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

（a） 评价供应商。组织应建立并保持对供应商的要求，要求应包括对质量体系的要求。组织应：

(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:

（1） 根据其满足要求，包括质量要求的能力，评价和选择潜在的供应商。评价应予记录。

(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.

（2） 根据评价的结果，确定对产品、服务、供应商进行控制的方式和程度。

(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

（3） 建立并保持合格供应商的记录。

(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

（b） 采购文件。组织应建立并实施明确描述/表述采购产品的采购文件。文件应包括对质量的要求。可行时，采购文件应包括供应商同意，当其产品发生更改时，及时通知组织的协议，使组织确定其更改是否对成品器械的质量产生影响。采购文件应按 Sec.820.40 的要求被批准。

(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.

Subpart F——标识和可追溯性 **Identification and Traceability**

Sec.820.60 标识 Identification.

组织应建立并保持程序，在接收、生产、交付和安装的各个过程识别产品，防止混用。

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

Sec.820.65 可追溯性

外科植入性或用于支持或维持生命的设备，根据其标签提供的使用指南正确使用，执行失败将不可避免地导致使用者的严重伤害，生产这些设备的组织应建立并实施程序，对每个/批成品器械标识以控制号。此程序有助于采取纠正措施，这些标识应在设备历史记录（DHR）中予以记录。

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.

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

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

（a） 概述。组织应形成、管理、控制并监视生产过程，以确保产品符合其规范的要求。任何与产品规范的偏离将会对生产过程产生影响。组织应建立并保持过程控制程序，描述任何必要的程序，以确保符合标准要求。过程控制应包括：

(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:

（1） 文件化的指导书，标准的操作程序（SOP'S），定义并控制生产的方式；

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

（2） 监视和控制过程参数、元件和设备特性；

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

（3） 符合相关的标准或法规；

(3) Compliance with specified reference standards or codes;

（4） 过程及过程设备的确认；

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

（5） 标准的工艺，应在文件化的标准中加以明确或通过标识和批准标准样件的方式进行。

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

（b） 生产和过程更改。组织应建立并保持技术规范、方法、过程或程序的更改程序。执行前，类似的更改依据 Sec.820.75，应经验证，适当时经确认，这些活动应予记录。根据 Sec.820.40，更改应被批准。

(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.

（c） 环境控制。环境条件可以对产品质量产生不利的影响，组织应建立并保持程序，对环境条件给予充分的控制。应定期对环境控制体系进行检查，以确定体系，包括必要的设备是适宜的，功能是完全的。这些活动应被文件化并经评审。

(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.

（d） 人员。组织应建立并实施要求，包括健康、清洁、人员技能和人员的服装要求，如果类似的人员与产品或环境的接触，能够对产品质量产生预期的影响。组织应确保维护和其它需要在特定环境条件下工作的临时人员受到充分的培训或得到一个专业人员的监督指导。

(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.

（e） 污染控制。组织应建立并实施程序，防止设备的污染或生产过程产生的物质对产品质量造成的不利影响。

(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.

（f） 建筑物。建筑物应经过适当的设计，有足够的空间，以执行必要的操作，防止混淆，确保有序操作。

(f)*Buildings.* Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.

（g） 设备。组织应确保所有在生产过程中使用的设备符合特定的要求，并经过适当的设计、构造、摆放和安装，以便于维护、校准、清洁和使用。

(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.

（1） 保养计划。组织应建立并实施设备校准、清洁和其它保养的计划，以确保设备符合其制造特性的要求。保养活动，包括日期的实施保养活动的人员应予记录。

(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.

（2） 检查。组织应对已建立的程序进行定期检查，以确保设备保养计划能够得到持续的执行。检查，包括日期和执行检查的人员应予记录。

(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.

（3） 校准。组织应确保将规定的限制或允许的误差粘贴在应定期校准的设备上，或放在其附近，或张贴到实施校准工作的人员容易看到的地方。

(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.

（h） Manufacturing material。当某种 manufacturing material 可能对产品质量产生不利影响，组织应建立并实施使用或 removal 这类 Manufacturing material 的程序，确保 removal 或限制其总量不会对产品质量产生不利影响。

(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.

（i） 自动过程。当计算机或自动数据处理系统成为产品或质量体系的组成部分，组织应依据规定的方法，针对其要实现的功能对计算机软件进行验证。所有软件的更改应在其批准和发布前进行确认。确认的活动和结果应予记录。

(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.

Sec.820.72 检验、测量和试验设备/ Inspection, measuring, and test equipment.

（a） 检验、测量和试验设备的控制。组织应确保所有的检验、测量和试验设备，包括机械的、自动的或电子的检验和试验设备，符合其预期的要求，并能得到有效的结果。组织应建立并实施程序，确保仪器得到周期的校准、检验、检查和保养。程序应包括仪器的搬运、保管和贮存的规定，使其能够保持精确度和可用。这些活动应予记录。

(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.

（b） 校准。校准程序应包括对精确度和精度的特定的说明和限制。当其精确度和精度不符合要求时，应采取补救措施和重新建立限制，并评价是否已对产品质量产生不利的影响。这些活动应予记录。

(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.

（1） 校准标准。检验、测量和试验设备的校准标准应可追溯到国家或国际标准。如果国家或国际标准不适用或不可用，组织可采用一个独*立的、可重复实现的标准。如果没有适用的标准，组织应建立并实施一个内部标准。

(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.

（2） 校准记录。设备标识、校准数据、校准日期、每个校准的执行者及下次校准的日期应予记录。应在每个设备上或其附近位置予以标识，或者应使仪器的使用者和设备校准人员方便地获得这些记录。
(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.

Sec.820.75　过程确认 Process validation

（a） 当过程的结果不能通过其后的检验和试验完全验证时，过程应依据已建立的程序，进行高等级的保证来确认和批准。确认的活动及其结果，包括确认批准人的签名、日期，适用时经确认的主要设备，应予以记录。

(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.

（b） 组织应建立并保持程序，监视和控制过程参数，确保持续满足过程规定的要求。

(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.

（1） 组织应确保过程确认由合格的人员执行；

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

（2） 用于已确认的过程，其监视和控制的方法和数据、操作的日期，适用时，过程的操作者或使用的主要设备，应予记录。

(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.

（c） 若发生变化或过程的偏离，适用时，组织应评审和评价过程，并重新确认。这些活动应予记录。

(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.

Subpart H——检验活动 **Acceptance Activities**

Sec.820.80 进货、过程和成品器械检验 Receiving, in-process, and finished device acceptance

（a） 概述。组织应建立并实施检验活动的程序。检验包括检验、试验或其它确认的活动。

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

（b） 进货检验活动。组织应建立并实施进货验收的程序。进货的产品应经检验、试验或其它验证活动，确定其符合规定的要求。接收或拒收都应予记录。

(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.

（c） 过程检验活动。适用时，组织应建立并实施检验程序，确保生产过程中规定的要求得到满足。程序应确保过程生产的受控，直到要求的检验、试验或其它的验证活动已经完成，或得到必需的批准。所有活动应予记录。

(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.

（d） 最终检验活动。组织应建立并实施成品器械检验的程序，确保每个产品的运作，或每批成品器械符合接收标准。成品器械应隔离存放，或以其它适当的方式进行控制，直到交付。成品器械不应被交付，除非

(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:

（1） DMR 要求的活动全部完成；

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

（2） 相关数据和文档经过评审；

(2) the associated data and documentation is reviewed;

（3） 由负有权限的人员签名认可/批准出厂，并

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

（4） 确定日期。

(4) the authorization is dated.

（e） 检验记录。在本部分，组织应按要求记录检验活动。这些记录应包括：

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

（1） 实施的检验活动；

(1) The acceptance activities performed;

（2） 实施检验活动的日期；

(2) the dates acceptance activities are performed;

（3） 结果；

(3) the results;

（4） 执行检验活动的人员的签名；

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

（5） 适用时，包括使用的仪器。这些记录应作为 DHR 的一部分。

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

Sec.820.86　检验状态 Acceptance status.

组织应通过适当的方式，识别产品的检验状态，以明确表明产品符合或不符合检验标准。应在产品的制造、包装、标识、安装和服务的全过程中对其检验状态进行标识，以保证产品只有在经过规定的检验活动后才能被交付、使用或安装。

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.

Subpart I——不合格品 **Nonconforming Product**

Sec.820.90　不合格品 Nonconforming Product

（a） 不合格品的控制。组织应建立并保持不合格品的控制程序。程序应对不合格品的标识、记录、评价、隔离和处置做出规定。对不合格品的评价应包括确定是否要调整和通知对不合格品承担责任的人员或组织。评价和任何调查都应予记录。

(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.

（b） 不合格品的评审和处置 *Nonconformity review and disposition.*
（1） 组织应建立并实施程序，规定对不合格品进行评审和处置的人员的职责和权限，阐明评审和处置的过程。不合格品的处置应予记录。记录应包括使用不合格品的理由及批准其使用者的签名。

(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.

（2） 组织应建立并实施返工程序，包括在返工后重新测试和评价不合格品，确保产品符合其规定的要求。返工和重新评价的活动，包括确定返工是否给产品带来不利影响，应记入DHR。

(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.

Subpart J——纠正和预防措施 **Corrective and Preventive Action**
Sec.820.100 纠正和预防措施 Corrective and preventive action

（a） 组织应建立并实施纠正和预防措施程序。程序应包括以下要求：

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

（1） 分析过程、操作、让步接收、质量审核报告、质量记录、服务记录、顾客投诉、返回品及其它质量数据来源，以识别现存的和潜在的不合格品发生的原因或其它质量问题。应采用适当的统计技术以发现重复出现的质量问题。

(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;

（2） 调查不合格品产生的原因，如相关的产品、过程和质量体系。

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

（3） 识别针对不合格品和其它质量问题需采取的纠正和预防措施。

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

（4） 检验或验证纠正和预防措施，以确保其活动的有效性，且不会对成品器械产生不利影响。

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

（5） 实施并记录为纠正和预防已识别的质量问题而进行的方法和程序的更改。

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

（6） 确保将质量问题或不合格品的有关信息，传递到对保证产品质量或预防出现质量问题负有直接责任的人员。

(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

（7） 已识别的质量问题及其纠正和预防措施应提交管理评审。

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

（b） 本部分要求的所有活动及其结果应予记录。

(b) All activities required under this section, and their results, shall be documented.

Subpart K——标签和包装控制 **Labeling and Packaging Control**

Sec.820.120 设备标签 Device labeling.

组织应建立并实施程序，对标签活动进行控制。

Each manufacturer shall establish and maintain procedures to control labeling activities.

（a） 标签的完整性。标签应是打印/印刷的，在常规的加工、贮存、搬运、交付及使用条件下应是清楚和粘贴牢固的。

(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.

（b） 标签的检验。标签在未经指定人员检验前不能放行或贮存，应检验其正确性，包括适用的场合、正确的有效期、控制号、贮存要求、搬运要求，及其它附加的处置要求。放行，包括实施检查的人员的签名和日期，应在 DHR 中予以记录。

(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 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.

（c） 标签的贮存。组织应通过适当的标识和设计，以防止标签贮存时的混淆。

(c)*Labeling storage.* Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.

（d） 标签的操作。组织应控制标识和包装操作，以防止标签的混用。用于每个产品单元、组、批的标签和标识，应在 DHR 中给予记录。

(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.

（e） 控制号。在 Sec.820.65 要求控制号的情况下，在整个交付过程中控制号应始终附着在或伴随着产品。

(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.

Sec.820.130　设备包装 Device packaging

组织应确保设备的包装和搬运箱经过设计和构造，以保护产品在常规的加工、贮存、搬运和交付的过程中发生改变或损伤。

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.

Subpart L——搬运、贮存、交付和安装 **Handling, Storage, Distribution, and Installation**

Sec.820.140　搬运 Handling

组织应建立并实施程序，以确保在搬运过程中不会发生混淆、损坏、质量下降、污染或其它对产品质量的不利影响。

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.

Sec.820.150　贮存 Storage

（a） 组织应建立并实施程序，对贮存区域和库房进行控制，防止在使用或交付前出现混淆、损坏、质量下降、污染或其它不利的影响，确保废品、拒收的产品或质量不好的产品未被使用或交付。

(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.

（b） 组织应建立并实施程序，说明出入库的方法权限。
(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

Sec.820.160　交付 Distribution

（a） 组织应对已完成的设备建立和实施控制和交付程序，确保只有经过批准的产品才能被放行。在产品交付前应进行合同评审，确保所有不清楚或错误的事项均得到解决。当设备有适用或保质期时，程序应确保超期或超过适用期质量下降的设备不被交付。

(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.

（b） 组织应建立并保持产品交付的记录，其内容应包括或涉及到

(b) Each manufacturer shall maintain distribution records which include or refer to the location of:

（1） 最初销售者的名称和地址；

(1) The name and address of the initial consignee;

（2） 发运设备的标识及数量；

(2) The identification and quantity of devices shipped;

（3） 发运的日期；

(3) The date shipped; and

（4） 使用的控制号。

(4) Any control number(s) used.

Sec.820.170 安装 Installation

（a） 对有安装要求的设备，组织应建立并实施适当的安装和检验规程，适用时包括测试程序。安装和程序应包括能够确保设备正确安装的指导，使设备在安装后能够按照预期的要求工作。组织应确保规程和程序随设备同时交付，或者让设备安装人员掌握规程或程序。

(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.

（b） 设备安装人员应按规程和程序实施安装、检验和其它要求的测试，应记录检验和试验的结果，以证明安装的正确。
(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.

Subpart M——记录 **Records**
Sec.820.180 一般要求 General requirements.
本部分要求的记录应保存在制造单位或其它地点，便于组织相关权限的人员获得，FDA 人

员可以检查。类似的记录，包括未存放在被检查组织的记录应便于 FDA 人员评审或复制。记录应是清楚的且妥善保存、防止丢失。保存在自动数据处理系统中的记录应进行备份。

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.

（a） 保密性。组织应标识认为是保密的记录，以帮助 FDA 按照本章 part 20 公众信息法规的要求确定其信息是否公开。

(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.

（b） 记录的保存期。本部分要求的记录的保存期应不少于设备的设计和预期寿命。在任何情况下，记录的保存期自产品售出之日起不少于 2 年。

(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.

（c） 例外。本部分不适用于 Sec.820.20（c）管理评审、Sec.820.22 质量审核和用于满足 Sec.820.50（a）供应商评价的供应商审核报告，但其适用于依据这些规定建立的程序。根据 FDA 职责人员的要求，组织负有执行职责的人员，应以书面形式证明，本部分（Part 820）所要求的管理评审、质量审核、适用的供应商审核的活动已执行并保存记录，记录应包括执行的日期和任何按要求已采取的纠正措施。

(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.

Sec.820.181 Device master record

组织应保持 device master record（DMR's）。组织应按照 Sec.820.40 的要求提供并批准每个 DMR。每个类型产品的 DMR 应包括或应涉及的内容，包括以下信息：

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:

（a） 设备规范，应包括适用的图样、成分/结构（composition）、配方（formulation）、

部件规范和软件规范。

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

（b） 生产过程规范，包括适用的设备规范、生产方法、生产程序和生产环境规范。

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

（c） 质量保证程序和规范，包括接收标准和使用的质量保证设备。

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;

（d） 包装和标签规范，包括使用的方式和过程。

(d) Packaging and labeling specifications, including methods and processes used; and

（e） 安装、维护及服务的程序和方法。

(e) Installation, maintenance, and servicing procedures and methods.

Sec.820.184 设备历史记录 Device history record

组织应保持设备历史记录（DHR's）。组织应建立并实施程序，以确保每批产品的 DHR's 得到保存，以证明设备的制造符合 DMR 和本部分（Part 820）的要求。DHR 应包括以下内容：

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:

（a） 生产日期；(a) The dates of manufacture;

（b） 数量；(b) The quantity manufactured;

（c） 交付的数量；(c) The quantity released for distribution;
（d）证明设备的制造符合 DMR 的检验记录；(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;
（e） 主要的标签和对应每个产品的标签；(e) The primary identification label and labeling used for each production unit; and
（f） 使用的设备标识和控制号。(f) Any device identification(s) and control number(s) used.

Sec.820.186 质量体系记录 Quality system record
组织应保持质量体系记录（QSR）。QSR 应包括本部分要求的活动的程序和文件的记录，

但不是指某个特定产品的记录。QSR 包括，但不限于 Sec.820.20 要求的记录。组织应确保按照 Sec.820.40 的要求提供并批准 QSR。

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.

Sec.820.198　投诉文件 Complaint files.

（a） 组织应保持投诉文件。组织应建立并实施程序，由规定的部门负责接受、评审和评估投诉。程序应确保：

(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:

（1） 所有的投诉都按照规定的方式及时处理；

(1) All complaints are processed in a uniform and timely manner;

（2） 口头投诉应予记录；

(2) Oral complaints are documented upon receipt; and

（3） 投诉应经评估，以确定是否是一起事故，应按照本章 803 或 804 医疗器械报告的要求向 FDA 报告。

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

（b） 组织应对所有的投诉进行评审和评估，以确定是否要进行调查。若未进行调查，组织应保存记录，包括不需调查的原因和做出不需调查的负责人员的名字。

(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.

（c） 任何可能是设备失效力、标签或包装未满足其规范的投诉，应经评审、评价和调查，除非已因一个类似的投诉进行了调查。

(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.

（d） 所有表现为事故、应按本章 803 或 804 部分的要求向 FDA 报告的投诉，应立即由授

权的人员对其进行评审、评估和调查，应作为投诉文件中独*立的一部分，或通过其它方式进行标识。另外，根据 Sec.820.198（e）的要求，本部分中的调查记录应包括以下的决定：

(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:

（1） 设备是否不符合规范的要求；

(1) Whether the device failed to meet specifications;

（2） 设备是否用于治疗和诊断；

(2) Whether the device was being used for treatment or diagnosis; and

（3） 如果有，说明设备与所报告的事故或不利影响的关系。

(3) The relationship, if any, of the device to the reported incident or adverse event.

（e） 当按照本节的要求进行调查时，应由本节（a）提及的规定的部门保存调查记录。调查记录应包括：

(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:

（1） 设备名称； The name of the device;

（2） 接到投诉的日期；The date the complaint was received;

（3） 设备标识和控制号；Any device identification(s) and control number(s) used;

（4） 投诉者的姓名、地址、电话；The name, address, and phone number of the complainant;

（5） 投诉的性质（nature）和细节；The nature and details of the complaint;

（6） 调查的日期和结果；The dates and results of the investigation;

（7） 所采取的纠正措施；Any corrective action taken; and

（8） 投诉的回复。Any reply to the complainant.

（f） 当组织规定的接待投诉的部门远离制造单位时，应使制造单位容易的获得经调查的投诉和调查记录。

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.

（g） 当组织规定的接待投诉的部门在美国本土这外，本节所要求的记录应容易地在美国本土获得：

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:

（1） 定期地将制造商的记录存放到美国本土某地。

(1) A location in the United States where the manufacturer's records are regularly kept; or

（2） 最初分销商所在地。(2) The location of the initial distributor.

Subpart N——服务 **Servicing**

Sec.820.200 服务 Servicing

（a） 当服务作为一种特定的要求时，组织应建立并实施规范和程序，以执行并验证其服务满足特定的要求。

(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） 组织应按照 Sec.820.100 的要求，通过适当的统计方法分析服务报告。

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100.

（c）当组织收到的服务报告表现为事故时，应立即按照本章 803 或 804 部分的要求向 FDA 报告，并自动将报告看成是一个投诉，按照 Sec.820.198 的要求处理。

(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） 服务报告应文件化，包括：

(d) Service reports shall be documented and shall include:

（1） 设备名称；The name of the device serviced;

（2） 设备标识和控制号；Any device identification(s) and control number(s) used;

（3） 服务日期；The date of service;

（4） 服务人员；The individual(s) servicing the device;

（5） 服务的内容；The service performed; and

（6） 试验和检验数据。The test and inspection data

Subpart O——统计技术 **Statistical techniques**

Sec.820.250 统计技术 Statistical techniques

（a） 适用时，组织应建立并实施程序，识别适当的统计技术要求，以建立、控制和验证过程能力和产品特性的可接受性。

(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.

（b） 抽样计划。适用时，基于某个适用的统计原理建立抽样计划。组织应建立并实施程序，以确保抽样的方法满足其预期的用途，并确保抽样计划更改时经评审，这些活动应形成文件。

(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.

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