医疗器械注册
医疗器械培训
FDA 510(k)代理
CE认证
QSR820验厂
巴西验厂

卓远天成

美国医疗器械质量体系法规

21CFR820 (QSR820)
中文译稿

(修改截止于2014年4月1日)

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2014年06月

卓远天成

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INTRODUCTION

Shenzhen Joyantech Consulting Co., Ltd is a professional consulting company engaged in Medical Device International Consultant, able to provide for you with many consulting services on Medical Device Marketing Registration Consultant in various countries or regions (such as FDA510k, CE certification, CMDCAS, TGA and the like), Medical Device Quality System Audit Consultant(such as QSR820, GMP for CFDA, Japan GMP, Brazil GMP, ISO 13485 and the like); and also able to provide for you with various Special Subjects Trainings such as Medical Device Risk Management, Software Validation, Sterilization Validation, Clinical Evaluation, Usability Validation and so on.

The consultants and experts of Joyantech boast the working experience in senior management positions of large-sized medical device companies, and professional background of engaging in medical device certification and audit, who is familiar with operation mode and characteristics of medical device industry, proficient in the Acts, Regulations, Standards, Technical Specifications, and has a strong advantage In aspects of Regulatory Guidance, the Standard Understanding, Product Testing, Files Compilation, Product Improvement, etc.

Joyantech have good relations of cooperation with the well-known international certification bodies from Britain, Germany, Switzerland and other countries as well as national authoritative certification and test institutes. The company's service has been widely recognized by clients.

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【 子部分 A ––– 总则 】

§ 820 . 1 范围

(a) 适用性

(1) 在这个质量体系规范中描述了现行生产管理规范 (CGMP) 的要求。本规范中的要求规定了所有医疗器械成品在设计、制造、包装、标签、存贮、安装和服务中使用的方法及为其所用的条件和控制。这些要求是为确保医疗器械成品的安全和有效，并遵从美国食品、药品和化妆品法 (法案)。本规范提出了适用于医疗器械成品制造商的基本要求。如果某制造商只进行本规范的一部分操作，而不进行其它操作，则该制造商仅需执行适用于他所进行操作的那些要求。有关 I 类器械，设计控制仅按 § 820 . 30 (a) (2) 中列出的要求进行。本规范不适用于成品组件和零件的制造商，但鼓励这样的制造商使用本规范中的适当规定作为指导。人类血液制品及血液成分的制造商不属于本规范管理范围，而属于 606 部分管理范围。如同本章 1271 . 3 (d) 所定义的那样，人类细胞、组织、细胞组成的和基于人体组织的产品 (HcT / PS)，属于医疗器械产品 (遵循上市前评审或通知，或豁免通知，基于一种据法案之器械规定所提交的申请或基于一种符合公卫生服务法案第 351 节的生物产品许可申请)，这些产品遵循本规范且也遵循本章的第 1271 部分 C 子部分阐明的捐赠者 –– 合格性程序以及第 1271 部分 D 子部分之适用的现行优良组织规范程序。若发生第 1271 部分的适用规章与本章的其他部分相矛盾的情况，专门适用于所讨论器械的规章将取代较为一般的规章。

(2) 本规范的规定适用于本规范定义的医疗器械成品 , 即使用对象是人的，其在美国各州或联邦领土、哥伦比亚特区或波多黎哥联邦共和国制造、进口或为进口而提供的器械成品。

(3) 在本规范中，几次使用了短语“适当时”。当要求以“适当时”

来限定时，如果制造商没有合理的理由来证明不适宜，就认为此要求是“适当的”。如果不贯彻“适当的”要求，就会导致产品达不到要求或制造商不能采取某些必要的纠正措施。

(b) 范围

除另有陈述外，本质量体系规范补充了本章其他部分的规范。在不可能执行全部适用条文的情况下，包括本规范和本章其他部分，专门适用于所讨论器械的规章将取代其他一般的规章。

(c) 权威性

第 820 部分由法案 (21 USC. 351，352，360，360c，360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383)501，502，510，513，514, 515, 518, 519, 520,522, 701, 704, 801, 803节授权建立并提出。不执行适用规范，根据法案 501 (h) 节，将导致伪劣器械。这样的器械和未能执行规范的人都将受到处罚。

(d) 外国制造商

若某提供给美国进口器械的制造商，拒绝接受 FDA 对外来设备进行检查以判定是否符合本规范，就会出现法规的 801(a)节中的后果。即，用于其中的方法及为其所用的条件和控制——设计、制造、包装、标签、存贮、安装或这种条件下生产进口给美国的设备之服务——都未遵从法案 520 (f) 节和本规范的要求。根据法案 501 (h) 节，这种条件下制造出来的器械都属于伪劣产品。

(e) 豁免或偏离

(1) 任何希望豁免或偏离器械质量体系要求的申请，都要遵从法案 520 (f) (2) 的要求。豁免或偏离申请将依据本章 § 10 . 30 的程序提交，即 FDA 的管理程序。以下地址可提供参考：器械放射卫生中心，小制造商处 (HFZ — 2 20) , 1 3 50 PICCa rd Dr . , ROCkVille , MD 20850 , U . S . A . , 电话 l — 800 — 638 — 2041 或 l — 301 — 443 — 6597 , FAX 301 — 443 — 8818。

(2) 当某种偏离有益于公众健康时，FDA 就会提出并认可这项偏离。这种偏离仅能在一段时间内维持有效，即当器械仍能满足公众健康需要，并且如果没有偏离，器械不可能制造得非常有效这一段时间内。

§ 820 . 3 定义

(a) 法案指的是：美国食品、药品、及化妆品法修正案，(secs201 — 903 节，52 Stat. 1040et seq., 修正版 21 U . S . C . 321 — 394) 。法案的 201 节中的全部定义都适用于本规范。

(b) 抱怨指的是任何以书面、口头、电讯的形式宣称，已经投放市场的医疗器械在其特性、质量、耐用性、可靠性、安全性及性能等方面存在不足的行为。

(c) 组份指的是原材料、物资、小件、零件、软件、固件、标签或有包装和标签的成品器械的零配件。

(d) 控制编号指的是有区别的符号，如字母或数字的不同组合，或以原制造、包装、标签和分发的单个或批量成品的区别符号来分辨。

(e) 设计历史文件 (DHF) 指的是描述某医疗器械成品设计过程的有关记录。

(f) 设计输入指的是作为器械设计基础对器械的物理和特性要求。

(g) 设计输出指的是各设计阶段的设计成果和最终的总设计成果。已完成的设计输出包括器械、其包装和标签、器械主记录。

(h) 设计评审是指依照文件进行广泛、系统的设计评审，以评价设计要求的适当性，并评价设计达到这些要求的能力，查明问题所在。

(i) 器械历史纪录 (DHR) 是指包括医疗器械成品制造过程的记录。

(j) 器械主记录 (DMR) 是指包括医疗器械成品的程序和规范的完整记录。

(k) 建立是指定义、文件化 (书写的或电子的) 和执行。

(l) 器械成品是指适用于使用或具有功能的器械或器械附件，不论是否经过包装、贴标签或灭菌。

(m) 次或批是指一种或几种组成或成品器械具有单一类型、型号、类别、尺寸、成分或软件版本，必须在相同条件下制造，并在规定的限度内具有相同的特征和质量。

(n) 负有执行职责的管理者是指制造商的高级雇员，其有权建立或改变制造商的质量方针和质量体系。

(o) 制造商是指设计、制造、构造、装配或加工成品器械的人。制造

商包括但不局限于那些从事灭菌、安装、再贴标签、再制造、再包装、或规范开发的人以及从事这些工作的外国实体的一级经销商。

(p) 制造材料是指实现生产过程所用的材料或物质，制造加工过程中的伴随组分或副产品，以残余物或混杂物的形式存在。

(q) 不合格是指未达到特定的要求。

(r) 产品是指组成、制造过程材料、加工过程中的器械、成品器械及返回器械。

(s) 质量是指使器械安全适用的总性质和特征，包括安全性和性能。

(t) 质量审核是指在规定的时间间隔，以足够的次数，对制造商质量体系进行有组织的自主检查、检验质量体系行为和结果是否执行质量体系程序，以保证有效地执行程序，达到质量体系目标。

(u) 质量方针是指组织关于质量的总体目的和方向，由具有执行职责的管理人员建立。

(v) 质量体系是指检查质量管理的组织机构、职责、程序、处理和资源。

(w) 再制造是指对成品器械进行加工、调节、更新、再包装、再贮存，大大改变了成品器械的性能、安全性规范或用途。

(x) 返工指的是对不合格产品采取某些措施，以使其在获准配发之前达到指定的 DMR 要求。

(y) 规范是指生产、加工、服务、或其他行为必须遵守的一些需求。

(Z) 确认是指通过检查和提供客观证据证明能始终达到预定的规范。

(1) 过程确认是指通过客观的证据证明加工生产出的产物或产品始终达到预定的规范。

(2) 设计确认是指通过客观的证据证明器械规范与使用者的需要和设计的用途相一致。

(aa) 验证是指通过检查和提供客观的证据来证明已经满足指定要求。

(bb) 作为器械管理的人类细胞、组织，或细胞产品或组织基产品(HCT/P) 是指本章 1271.3(d) 中定义的，不符合 1271.10(a) 的标准但也作为器械管理的 HCT/P。

(cc) 唯一器械标识符 (UDI) 是指通过本章 830.20 的要求，来识别销售和使用之器械的一种标识符。唯一器械标识符由下列要素组成:

(1) 器械标识符 ---UDI 的强制的、固定的部分，其用以识别

器械的具体版本或型号，以及器械的标记者，和

(2) 生产标识符 ---UDI 的条件性的、可变化的部分，其用以识别包含在器械标签上的下列一项或多项：

(i) 器械制造的次或批；

(ii) 具体器械的序号；

(iii) 具体器械的有效期；

(iv) 具体器械的制造日期；

(v) 对于作为器械管理的 HCT/P，本章 1271.290(c) 所要求的清晰的识别码。

(dd) 通用产品代码是指用于识别在美国零售物品的标识符。

§ 820 . 5 质量体系

各制造商应建立并保持一个质量体系，适合于他们设计或制造的医疗器械，并且达到本规范的要求。

【子部分 B--- 质量体系要求】

§ 820 . 20 管理职责

(a)质量方针 负有执行职责的管理者应建立质量方针目标和质量承诺，并保证质量方针在企业各级人员中的理解、贯彻和持续执行 .

(b) 组织 各制造商都应建立并维持一个适当的组织结构，以保证器械依造本规范进行设计和生产。

(1) 职责和权限 各制造商都应任命有相应职责、权限和能独立行使职权的人员负责管理、执行和评价质量体系。

(2) 资源 各制造商应提供足够的资源，包括分派训练有素的人员从事管理、执行和评价活动，包括内部质量审核，以达到本规范的要求。

(3) 管理者代表 负有执行职责的管理者应任命其中一员为管理者代表，并且文件化。管理者代表不论其他职责如何，必须履行下列职责和权力：

(i) 确保按本规范要求有效建立和保持。

(ii) 向管理机构汇报质量体系进行情况，供其讨论。

(c) 管理评审 具有执行职责的管理者应按照已建立的程序，以足够的次数定期评审质量体系的适宜性和有效性，以保证质量体系符合本规范及制造商建立的质量方针和目标的要求。质量体系评审的结果应形成文件。

(d) 质量策划 各制造商应编制质量计划，确定与设计和制造的器械相关的质量实践、资源与活动，制造商应确定如何达到质量体系要求的措施。

(e) 质量体系程序 各制造商应建立质量体系的各种程序和实施指南，并形成文件。

§ 820 . 22 质量审核

制造商应建立质量审核和进行这种审核的程序，以保证质量体系符合已建立的质量体系要求，并判定该质量体系的有效性。质量审核应由对被审核事项无直接责任的人执行。若有必要时，应采取纠正措施，包括对有缺陷的事项进行再审核。被审核事项的责任者应对审核的结果及再审核的情况进行复核 . 审核与再审核的日期和结果应形成文件。

§ 820 . 25 人员

(a) 一般要求 制造商应具有足够的工作人员，具备必要的教育、背景、培训和经验，以保证本规范所要求的活动正确实施。

(b) 培训 制造商应该建立程序，识别培训需求并保证全部工作人员在经过培训后能胜任他们各自的职责，并提供与培训有关的文件。

(1) 作为培训的一部分，应使工作人员懂得由于错误执行指定工作可能会导致器械产生缺陷。

(2) 使从事验证和确认工作的工作人员能预见可能会发生的缺陷和错误。

【子部分 C--- 设计控制】

§ 820 . 30 设计控制

(a) 总则

(1) II、III 类器械的制造商，以及 (a) (2) 段列出的 I 类器械的制造商，应建立并保持控制器械设计的程序，以保证达到特定的要求。

(2) 下列 I 类器械也需设计控制。

(i) 有计算机软件的自动化器械。

(ii) 下面列出的器械：

节	设 备
868. 6810	导管、气管支气管抽气器
878. 4460	外科手术手套
880. 6760	保护性限制物
892. 5650	手动放射性核素敷贴系统
892. 5740	远距离放射性核素治疗源

(b) 设计和开发策划 各制造商应建立并保持设计和开发计划，描述或指明设计开发活动，并规定执行者的职责。计划应规定和描述提供或导致设计开发过程输入的不同小组或活动间的接口。随着设计开发活动的展开，计划应得到评审、更新和批准。

(c) 设计输入 各制造商应建立并保持程序，保证器械的设计要求是适当的，阐明器械的预期用途，包括使用者和病人的需要。该程序应包括指出不完善的、含糊不清的或矛盾要求的机制。设计输入要求应形成文件，由指定的人员评审和批准。批准，包括批准人的签字和日期应文件化。

(d) 设计输出 各制造商应建立并保持设计输出的程序，该程序应从能够对设计输入要求进行充分评价的角度来规定并文件化设计输出。设计输出程序应包含或引用接收准则，并确保正确实现器械功能必需的设计输出得到识别。设计输出形成文件，在发布前得到评审和批准。

批准，包括批准设计输出者的签字和日期应形成文件。

(e) 设计评审 各制造商应建立并保持一套程序，确保在器械设计开发的适当阶段，设计结果的正式文件化评审得到策划和实施。程序应确保每次设计评审的参加者包括：与被评审的设计阶段相关的所有职能的代表、与被评审的设计阶段无直接责任关系的人以及必需的专家。设计评审的结果包括设计评审对象、评审人员和日期，都应记录在设计历史文件 (DHF) 中。

(f) 设计验证 各制造商应建立并保持验证器械设计的程序。设计验证应证明设计输出达到设计输入要求。设计验证的结果，包括设计验证对象、方法、验证人员和日期，都应当记录在设计历史文件中。

(g) 设计确认 各制造商应建立并保持设计确认的程序。应在规定的操作条件下，对最初生产的若干产品、若干批次产品或相应量的产品进行设计确认。设计确认应保证器械满足规定的用户需要和预期用途，还应包括产品在实际或模拟使用条件下的试验。设计确认应包括软件确认及适当时候的风险分析。设计确认的结果，包括设计确认对象、确认方法、执行人员和日期都应记录在设计历史文件中。

(h) 设计转换 各制造商应建立并保持一套程序以确保器械设计正确地转换成生产规范。

(i) 设计更改 各制造商应建立并保持一套程序，确保设计更改得到识别、形成文件、确认或适当时验证、评审，并在实施前得到批准。

(j) 设计历史文件 各制造商应为每个类型的器械建立并保持设计历史文件。设计历史文件应包含或引用必要的记录，以证实设计符合批准的设计计划和本规范的要求。

【 子部分 D--- 文件控制 】

§ 820 . 40 文件控制

各制造商应建立并保持一套程序以控制本规范所要求的全部文件。程序应提供下列内容：

(a) 文件批准和发布　各制造商应委派专人检查所有文件的适用性，并在文件发布之前予以批准，以满足本规范的要求。批准，包括批准人的签字和日期应形成文件。对于所有指定的、使用的或其他必需的场合，为满足本规范的要求而建立的文件应是有效的。所有作废的文件应从所有使用场所及时撤走，或者用其他手段防止其非预期的使用。

(b) 文件更改　文件的更改应由进行原文件审查和批准相同职能的人或部门进行审查和批准，除非另外专门指定人选。批准的更改应及时地传达给有关人员。各制造商应保留更改文件的记录。更改记录应包括修改内容、受影响文件的识别、批准人的签名、批准日期及更改生效的时间。

【 子部分 E--- 采购控制 】

§ 820 . 50 采购控制

各制造商应建立并保持一套程序，确保所有采购的或收到的产品和服务符合规定要求。

(a) 对供应商、承包商及咨询机构的评价　各制造商应建立供应商、承包商和咨询机构必须满足的要求，包括质量要求。各制造商应：

(1) 根据满足规定要求——包括质量要求——的能力，评价和选择潜在的供应商、承包商及咨询机构。评价应形成文件。

(2) 根据评价结果，确定对产品、服务、供应商、承包商和咨询机构实施控制的类型和程度。

(3) 建立和保持可接受的供应商、承包商及咨询机构的纪录。

(b) 采购资料　针对采购或收到的产品和服务，各制造商应建立并保留清晰地描述或引用规定要求，包括质量要求的资料。可能的话，应包括一份供应商、承包商和咨询机构同意告知制造商其产品或服务发生更改的协议，以便制造商可以判断这些改变是否影响其成品器械的质量。采购资料应依照 §820.40 得到批准。

【子部分 F--- 标识和可追溯性】

§820 . 60 标识

各制造商应建立并保持在接收、制造、交付和安装各阶段标识产品的程序，以防止混淆。

§820 . 65 可追溯性

预期经外科植入人体，支持或维持生命器械的制造商，和依照制造商提供的使用说明书正确使用时，器械失效预期会对使用者造成严重伤害的制造商，应建立并保持用控制编号来识别每个或每批成品，适当时包括部件的程序。程序应便于实施纠正措施。这种标识应记录在器械历史记录中。

【子部分 G--- 生产和过程控制】

820 . 70 生产与过程控制

(a) 总则 各制造商应制定、实施、控制并监测生产过程，确保器械符合其技术规范。制造加工过程中可能发生偏离技术规范的地方，制造商应建立并保持过程控制的程序，来描述任何必要的控制以确保符合技术规范。过程控制应包括：

(1) 形成文件的指导书，标准操作程序 (SOPs) ，规定和控制生产方式的方法；

(2) 生产中过程参数、组分和产品特性的监测和控制；

(3) 遵循规定的参考标准或编号；

(4) 过程和过程设备的批准；

(5) 以文件化标准来阐述或以经确认和批准的代表性样品来表现的工艺要求。

(b) 生产和过程变更 各制造商应建立并保持变更技术参数、方法、过程或程序的程序。这些变更在执行之前应被验证或在适当时依照 §820 . 75 予以确认，这些活动均应形成文件。改变应依照 §820 . 40 得到批准。

(c) 环境控制 在有理由认为周围环境条件对产品质量有不利影响时，制造商建立并保持适当控制环境条件的程序。应定期检查环境控制系统，以证实该系统，包括必需设备的适应性，并发挥良好作用。这些活动应形成文件并评审。

(d) 人员 如果有理由认为工作人员和产品或环境的接触对产品质量有不利影响时，各制造商应建立并保持对工作人员的健康、卫生、个人行为和服装的要求。各制造商应保证在指定的环境下临时工作的维护和其他人员接受适当的训练或由接受过训练的人监督。

(e) 污染控制 各制造商应建立并保持一套程序，防止对产品质量有

不良影响的物质污染设备或产品。

(f) 厂房　厂房应设计适当，具有足够的空间以进行必需的操作，防止混乱，并保持有序的搬运。

(g) 设备　各制造商应确保在制造加工过程中使用的全部设备都符合指定要求，并经过适当设计、架构、放置和安装以便于保养、调试、清洁和使用。

(1) 维护计划　各制造商应建立并保持调试、清洁和其他的设备维护计划，确保符合制造规范。维护活动，包括实施维护活动的人员和日期应形成文件。

(2) 检查　各制造商应按照已建立的程序进行定期检查，确保遵守设备维护计划。检查，包括检查人和日期应形成文件。

(3) 调试　各制造商应将设备固有的极限和允许公差的说明放在需要定期调试的设备上或其附近，或者从事这些调试的工作人员随时可取。

(h) 制造材料　在有理由认为某制造过程材料对产品质量具有不利影响的情况下，各制造商应建立并保持使用和去除这种制造过程材料的程序，以保证其被去除或限定在不会对产品质量有不利影响的数量内。去除或减少制造过程材料应形成文件。

(i) 自动化过程　当计算机或自动化数据处理系统作为生产和质量体系的一部分来使用时，制造商应依照已建立的方案确认计算机软件是否具有预期的用途。所有的软件更改应在批准和发布之前被确认。确认活动和结果应形成文件。

820 . 72 检验、测量及试验设备

(a) 检验、测量及实验设备的控制 各制造商应确保所有的检验、测量及实验设备，包括机械的、自动的、或电子的检验和试验设备，适合其预期目的，并能产生有效结果。各制造商应建立并保持关于设备常规校准、检验、检查和维护的程序。该程序应包括设备操作、防护和存贮的规定，以保持其精度和适用性。这些活动应形成文件。

(b) 校准 校准程序应包括特定的方法和准确度、精密度的极限范围。当准确度和精密度的极限范围不能满足时，应采取有效措施重建极限，并评价是否对器械质量产生不利影响。这些活动应文件化。

(1) 校准标准 用于检验、测量及试验设备的校准标准应追溯到国家或国际标准。如果国家或国际的标准不现实或无法找到，制造商应使用一个独立的可再现标准。如果没有合适的标准存在，制造商应建立和保持一个内部标准。

(2) 校准记录 设备标识、校准日期、每次校准的执行人及下次校正日期均应形成文件。这些记录应放在每台设备上或其附近，或者使用设备和负责校准设备的人随时可取。

820 . 75 过程确认

(a) 当过程的结果不能由后续的检验和试验充分验证时，这样的过程应得到高度保证的确认并按已建立的程序批准。确认活动和结果，包括批准确认人员的签字和日期，适当时确认的主要设备，均应形成文件。

(b) 各制造商应建立并保持已确认过程的过程参数之监视和控制的程序，以确保持续地满足规定需求。

(1) 各制造商应确保由具有资格的人员来实施已确认的过程。

(2) 对于已确认的过程，其监视与控制方法、数据、实施日期，适当时完成过程确认的操作者或使用的主要设备均应形成文件。

(c) 发生更改或过程偏离时，制造商应复核和评价过程，必要时再确认。这些活动应形成文件。

【子部分 H––– 验收活动】

§ 820 . 80 进货、中间产品和成品的验收

(a) 总则　各制造商应建立并保持验收活动的程序。验收活动包括检验 . 试验或其他的验证活动。

(b) 进货验收活动　各制造商应建立并保持进货验收的程序。进货产品应进行检验、试验或用其他手段证实其符合规定要求。接受或拒收应形成文件。

(c) 中间产品的验收活动　适当时，各制造商应建立并保持验收程序，确保中间产品符合规定要求。这种程序应确保中间产品得到控制，直到要求的检验、试验或其他验证活动已经完成，或者收到必需的文件化的批准。

(d) 最终验收活动　各制造商应建立并保持成品验收的程序，确保每次生产量、批或批次成品符合验收标准。成品应隔离放置或其他方式适当控制直至放行。成品不能放行销售直至：

（1）　完成 DMR 要求的活动；

（2）　相关数据和文件已评审；

（3）　指定的人员签字批准放行；

（4）　已注明批准日期。

(e) 验收记录　各制造商应将本规范要求的验收活动形成文件。这些记录应包括：

（1）　实施的验收活动；

（2）　实施验收的日期；

（3）　结果；

（4）　执行验收活动的人员签字；

（5）　适用时，使用的设备。

这些记录是器械历史记录的一部分。

§ 820 . 86 验收状态

各制造商应以适当的方式识别产品的验收状态，指明这些条款是否符合验收标准。在产品制造、包装、标签、安装和服务的全过程中，应保持验收状态的标识，以确保只有通过验收的产品才能销售、使用或安装。

【 子部分 I--- 不合格品 】

§ 820 . 90 不合格品

(a) 不合格品的控制 各制造商应建立并保持控制不符合规定的要求的产品的程序。程序中应写明不合格产品的标识、证明文件、评价、隔离和处置。不合格评价应包括确定是否需要调查或通知对不合格品负有责任的个人或组织。评价和调查应形成文件。

(b) 不合格的评审和处置

(1) 各制造商应建立并保持规定不合格品评审职责和处置不合格品权限的程序。程序应阐明评审和处置过程。不合格品的处置应形成文件。文件应包括使用不合格品的理由和批准使用者的签名。

(2) 各制造商应建立并保持返工的程序，包括不合格品返工后的再测试和再评价，以保证产品符合批准的现行规范。返工和再评价活动，包括确定返工对产品的不利影响，均应记录在器械历史记录中。

【 子部分 J--- 纠正和预防措施 】

§ 820 . 100 纠正和预防措施

(a) 各制造商应建立和保持实施纠正和预防措施的程序，程序应包括对下列方面的要求：

(1) 分析过程、操作、让步、质量审核报告、质量记录、服务记录、抱怨、退货或其他来源的质量数据，以识别导致不合格品或其他质量问题的已存在的和潜在的原因。必要时，使用必要的统计技术发现重复发生的质量问题。

(2) 调查与产品、过程和质量体系有关的不合格原因。

(3) 确定纠正和预防不合格品和其他质量问题再发生的必要措施。

(4) 验证或确认纠正和预防措施，确保这些措施是有效的并对成品器械无不利影响。

(5) 实施和纪录纠正和预防已识别的质量问题所必需的方法和程序更改。

(6) 保证与质量问题或不合格品有关的信息能传达给那些直接负责保证该产品质量或预防此类问题的有关人员。

(7) 把已识别的质量问题的相关信息以及纠正和预防措施提交管理评审。

(b) 本节所要求的全部活动和结果应形成文件。

【子部分 K--- 标记和包装的控制】

820 . 120 器械标记

各制造商应建立和保持控制标记活动的程序。

(a)标签的完整性 标签应印刷和粘贴，以便在通常的加工、贮存、搬运、发放、适当时使用条件下，标签是清晰的、贴牢的。

(b) 标记的审查 标记不得放行存储或使用，直至指定专人检查标记的正确性，适当时包括正确的有效期、控制编号、存贮说明、搬运指导及任何附加的处理说明。放行，包括执行检查人员的签字和日期，应记录在器械历史记录中。

(c) 标记的存贮 各制造商应以能够正确识别并可防止混淆的方式来贮存标记。

(d) 标记的操作 各制造商应控制标记和包装的操作以防止标记混淆。每个生产单位、批或批次使用的标签和标记应记录在器械历史文件中。

(e) 控制编号 按 §820 . 65 的要求需要控制编号之处，在整个发放过程中控制编号应置于器械上或随附于器械。

820 . 130 器械包装

各制造商应确保器械包装和装运容器经过设计和制造，能保护器械在通常的加工、储存、搬运和销售情况下不致变样或损坏。

【子部分 L--- 搬运、存贮、销售和安装】

§ 820 . 140 搬运

各制造商应建立并保持一套程序，确保在搬运过程中不会发生混淆、损坏、变质、污染或其他对产品的不利影响。

§ 820 . 150 存贮

(a) 各制造商应建立并保持控制产品存贮区和储藏室的程序，以防止混淆、损坏、变质、污染或其他在使用或分销售以前的不利影响，以确保不使用或销售过期的、质次的或变质的产品。产品质量随时间推移而下降时，应以便于适当的存货周转的方式来存放，且存放条件经评估是适当的。

(b) 各制造商应建立并保持一套程序，描述接收来自于或送往存贮区和储藏室的授权方法。

§ 820 . 160 销售

(a) 各制造商应该建立并保持成品器械控制和销售的程序，确保只销售已批准放行的器械，且定购单得到评审，确保模糊不清之处和错误在放行销售之前得到解决。器械的适用性和质量随时间推移而下降时，程序应确保过期的器械或变质不能使用的器械不会销售。

(b) 各制造商应保持销售记录，包括或指明其位置：

(1) 第一经销商的名称和地址；

(2) 装运器械的名称和数量；

(3) 装运日期；和

(4) 使用的任何控制编号。

§ 820 . 170 安装

(a) 需要安装的器械的制造商，应建立并保持适当的安装、检查指导

书以及适当时试验的程序。指导书和程序应包括确保正确安装的指导方法，使安装后器械能正常使用。制造商应随器械一起发送这些指导书和程序，或以其他方式使安装器械的人员可以获得。

(b) 安装器械的人应确保按照制造商的指导书和程序来进行安装、检查和试验，并应将检查和试验结果形成文件，以证明正确安装。

【 子部分 M––– 记录 】

§ 820 . 180 一般要求

本规范所要求的所有记录应保存在制造商处或制造商负责此事的领导人和 FDA 指定执行检查的雇员容易得到的其他地方。这些记录，包括那些没有保存在被检查机构的，应备好，以便 FDA 雇员评审和复制。这些记录应字迹清楚，小心保存以防变质，并防止丢失。保存在自动数据处理系统中的数据应备份。

(a) 保密 制造商认为是机密的记录可以进行标记，以便 FDA 确定是否可以依照本章第 20 部分的公共信息条例公开这些信息。

(b) 记录保存期 本规范所要求的全部记录应保留至与器械设计和预期寿命相当的时间，但自制造商进行商业销售之日起，不能少于 2 年。

(c) 例外 本节不适用于 820 . 20 (c) 管理评审、820 . 22 质量审核所要求的报告以及用于满足 820 . 50 (a) 供应商、承包商和咨询机构的评价要求的供应商审核报告，但适用于按照这些条款所建立的程序。根据 FDA 指定雇员的要求，具有执行职责的管理者中的一名雇员应以书面形式证实本规范所要求的管理评审、质量审核、适用时供应商审核，已得到实施并形成文件；还应证实实施这些活动的日期，且已采取了要求的纠正措施。

§ 820 . 181 器械主记录

各制造商应保留器械主记录 (DMRs) ，并保证每个器械主记录都依照 820 . 40 进行准备和批准。每类器械的 DMR 应包括下列信息或指明所在位置 :

(a) 器械规范包括相应的图纸、组成、配方、组件规范和软件规范；

(b) 生产加工规范包括相应的设备规范、生产方法、生产程序、生产环境规范；

(c) 品质保证程序和规范，包括接收标准和使用的质量保证设备；

(d) 包装和标记规范，包括使用和处理方法；和

(e) 安装、维护和服务的程序及方法。

820 . 184 器械历史纪录

各制造商应保存器械历史纪录 (DHRs) 。各制造商应建立并保持一套程序，确保各批次、批或单个产品的 DHR 得到保持，以证明器械依照 DMR 和本规范要求来制造。DHR 应包括下列信息或指明所在位置 :

(a) 制造日期；

(b) 制造数量；

(c) 放行销售数量；

(d) 证明器械依照 DMR 制造的验收记录；

(e) 用于各生产单位标识的最初标签和标记；

(f) 任何唯一器械标识符或通用产品代码，和任何其他的器械标识和使用的控制编号。

§ 820 . 186 质量体系记录

各制造商应保存质量体系记录 (QSR) 。QSR 应包括本规范所要求的活动的程序和文件，或指明其位置，不是针对特定的器械，包括但不限于 820 . 20 所要求的纪录。各制造商应确保 QSR 按照 820 . 40 进行准备和批准 。

§ 820 . 198 抱怨档案

(a) 各制造商应该保留抱怨档案。各制造商应建立并保持由正式指定单位接收、评审和评价抱怨的程序。该程序应确保：

(1) 用统一的、及时的方式处理抱怨。

(2) 口头的抱怨应记录在相应的记录单上。

(3) 评价抱怨以确定这种抱怨所代表的事件是否需要依照本章 803 部分 –– 医疗器械报告，向 FDA 报告。

(b) 各制造商应评审和评价所有的抱怨以确定是否需要进行调查。如果不进行调查，制造商应保存一份记录，包括没有调查的理由和决定不进行调查的负责人的姓名。

(c) 涉及器械、标签或包装可能不符合规范的任何抱怨，都应评审、评价和调查，除非已为类似的抱怨进行过调查，并且再作调查没有必要。

(d) 任何抱怨 –– 其所代表的事件需要依照本章 803 或 804 部分 –– 医疗器械报告 –– 向 FDA 报告，应立即由指定的人员进行评审、评价和调查，且应以抱怨档案的一个独立部分进行保存或能清晰的识别。作为 820 . 198 (e) 所要求信息的补充，这一段落的调查记录应包括如下的判定：

(1) 器械是否未达到规范要求；

(2) 器械是否正在用于处理或诊断；以及

(3) 器械与已报告的事故或不良事件关系，如果有任何一点的话。

(e) 进行本节所述的调查时，应由本节 198 (a) 段中正式指定的单位保存调查的书面记录。调查记录应包括：

(1) 器械名称；

(2) 接到抱怨的日期；

(3) 任何唯一器械标识符或通用产品代码，和任何其他的器械标识和使用的控制编号；

(4) 抱怨人的姓名、地址及电话号码；

(5) 抱怨的性质与细节

(6) 调查日期与结果

(7) 所有已采取的纠正措施；

(8) 对抱怨的所有回复。

(f)当制造商正式指定的抱怨处理单位设立在与制造机构分开的地方，已调查的抱怨和调查记录应便于制造商获取。

(g) 如果制造商正式指定的抱怨处理单位设在美国以外，本节所要求的记录理应在美国或下列之一的地方方便获得：

(1) 制造商的记录完整保存的美国某地；或

(2) 第一经销商处。

【 子部分 N--- 服务 】

§ 820 . 200 服务

(a) 在规定有服务要求的情况下，各制造商应建立并保持实施和验证服务是否达到规定要求的指导书和程序。

(b) 各制造商应使用与 §820 . 100 相适应的适当统计技术来分析服务报告。

(c) 收到服务报告的制造商 --- 报告所代表的事件必须按本章 803 或 804 部分向 FDA 报告，应自动地将该报告视为抱怨，并按 820 . 198 的要求进行处理。

(d) 服务报告应形成文件，并应包括：

(1) 服务的器械名称；

(2) 任何唯一器械标识符或通用产品代码，和任何其他的器械标识和使用的控制编号；

(3) 服务日期；

(4) 服务人员；

(5) 已实施的服务；

(6) 试验和检查数据。

【 子部分 O--- 统计技术 】

§ 820 . 250 统计技术

(a) 适用时，各制造商应建立并保持识别‘建立、控制及验证过程能力和产品特征必需的’有效的统计技术的程序。

(b) 用到的抽样方案应书面化，并基于一种有效的统计学原理。各制造商应建立并保持一套程序以确保抽样方法对于其预期用途来讲是合适的，并确保发生变化时评审抽样方案。这些活动应形成文件。

【Subpart A--General Provisions】

Sec. 820.1 Scope.

(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 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) 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) 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 nonimplementation 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) 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) 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) 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) 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 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 Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002, 1–800–638–2041 or 301–796–7100, FAX: 301–847–8149.

(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.

[61 FR 52654, Oct. 7, 1996, as amended at 65 FR 17136, Mar. 31, 2000; 65 FR 66636, Nov. 7, 2000; 69 FR 29829, May 25, 2005; 72 FR 17399, Apr. 9, 2007; 75 FR 20915, Apr. 22, 2010]

Sec. 820.3 Definitions.

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

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

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

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

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

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

(r) Product means components, manufacturing materials, in– process devices, finished devices, and returned devices.
(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) 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) Quality policy means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
(v) Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
(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) Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.
(y) Specification means any requirement with which a product, process, service, or other activity must conform.
(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) Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
(2) Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).
(aa) Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
(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.
[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 55822, Sept. 24, 2013]

Sec. 820.5 Quality system.

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--Quality System Requirements】

Sec. 820.20 Management responsibility.

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

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

(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) 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) 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 Quality audit.

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 Personnel.

(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) 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) 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) 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--Design Controls】

Sec. 820.30 Design controls.

(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.

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

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

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

(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) 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––Document Controls】

Sec. 820.40 Document controls.

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) 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) 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--Purchasing Controls 】

Sec. 820.50 Purchasing controls.

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

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

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

(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--Identification and Traceability 】

Sec. 820.60 Identification.

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 Traceability.

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--Production and Process Controls】

Sec. 820.70 Production and process controls.

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

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

(3) Compliance with specified reference standards or codes;

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

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

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

(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) 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) 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) 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. 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) 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 Inspection, measuring, and test equipment.

(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) 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) 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) 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 Process validation.

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

(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) 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——Acceptance Activities】

Sec. 820.80 Receiving, in-process, and finished device acceptance.

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

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

(2) the associated data and documentation is reviewed;

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

(4) the authorization is dated.

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

(1) The acceptance activities performed;

(2) the dates acceptance activities are performed;

(3) the results;

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

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

Sec. 820.86 Acceptance status.

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--Nonconforming Product】

Sec. 820.90 Nonconforming product.

(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) 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.

(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--Corrective and Preventive Action】

Sec. 820.100 Corrective and preventive action.

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

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

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

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

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

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

【Subpart K––Labeling and Packaging Control】

Sec. 820.120 Device labeling.

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

(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) 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.

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

(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) Control number. Where a control number is required by 820.65, that control number shall be on or shall accompany the device through distribution.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 55822, Sept. 24, 2013]

Sec. 820.130 Device packaging.

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––Handling, Storage, Distribution, and Installation】

Sec. 820.140 Handling.

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 Storage.

(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) 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 Distribution.

(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) Each manufacturer shall maintain distribution records which include

or refer to the location of:
(1) The name and address of the initial consignee;
(2) The identification and quantity of devices shipped;
(3) The date shipped; and
(4) Any control number(s) used.

Sec. 820.170 Installation.

(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) 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––Records】

Sec. 820.180 General requirements.

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) 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) 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) 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.

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

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

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

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

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

Sec. 820.184 Device history record.

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) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

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

(e) The primary identification label and labeling used for each production unit; and

(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 55822, Sept. 24, 2013]

Sec. 820.186 Quality system record.

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 Complaint files.

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

(2) Oral complaints are documented upon receipt; and

(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.

(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) 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) 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) Whether the device failed to meet specifications;

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

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

(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) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(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.

(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:

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

(2) The location of the initial distributor.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006; 78 FR 55822, Sept. 24, 2013]

【Subpart N––Servicing】

Sec. 820.200 Servicing.

(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 55822, Sept. 24, 2013]

【Subpart O--Statistical Techniques】

Sec. 820.250 Statistical techniques.

(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) 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.

Revised as of April 1, 2014