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龙德医疗器械工具丛书

医疗器械法规中英文对照系列

供内部学习使用

美国医疗器械质量体系检查指南QSIT 中英对照版

Quality Systems Inspection Technique

（法规原文版本为1999年8月）

第1版

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内容提要

质量体系检查指南（QSIT）为美国医疗器械质量体系/GMP 检查的执行提供了使用说明，由食品和药品管理局（FDA）法规事务办公室（ORA）和设备与辐射健康中心（CDRH）制定。

本指南制定的目的是为了帮助FDA检查员实施医疗器械820审核的指南性文件，详细描述了审核的7大子系统模块，以及各子系统的检查方法，以及关注重点；是FDA检查员的必修课程，也是FDA专门编制的检查员手册。同时，也是企业准备820审厂时非常重要一份资料，企业可依据本指南，了解FDA的审核方式及审核重点，也可在质量体系管理过程中，运用QSTI的方法和技术进行内部质量体系审核或质量体系的模拟审核，为FDA的正式厂审做准备。

本书中英对照内容仅代表编者自己的观点，如读者发现有任何纰漏或不当之处，欢迎指正。

本书仅供行业内部学习参考使用，法规权威解释以原文为准，所引用原法规版本为1999年8月，为避免引起误导，建议读者以本法规正规发布官网的最新法规为准。

Preface

This document was developed by the Quality System Inspections Reengineering Team Members

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This reference is intended to be used in conjunction with the:

- Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845).
- Investigations Operations Manual (IOM).
- Code of Federal Regulations, Title 21 (21 CFR) Part 820 Quality System Regulation; Part 803 Medical Device Reporting; Part 806 Medical Device Corrections and Removals; Part 821 Medical Device Tracking.
- Compliance Policy Guides (CPG) for devices (Sub Chapter 300).
- Guideline on General Principles of Process Validation, FDA, May 1987.

Other references include:

- The Federal Food, Drug, and Cosmetic Act; The Safe Medical Devices Act (SMDA) of 1990 and the Medical Device Amendments of 1992.
- Medical Device Quality Systems Manual: A Small Entity Compliance Guide.
- The FDA Worldwide Quality System Requirements Guidebook for Medical Devices.
- Other device specific guidance documents prepared by CDRH for the medical device industry.
- FDA Recognized Standards.

These additional guidances are posted to the CDRH Internet World Wide Web Home Page at http://www.fda.gov/cdrh. See IOM Chapter 10, References, for additional information.

前言

本文件是由质量体系检查小组成员开发的

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此文件预期与以下参考资料配合使用：

- 医疗器械制造商检查用的符合程序指南手册(CP 7382.845)
- 调查操作手册(IOM)
- 联邦法规代码(CFR),第 21 章 820 部分质量体系法规，803 部分医疗器械报告；806 部分医疗器械的纠正和移除；821 部分医疗器械追溯
- 器械符合性政策指南(CPG)(第 300 子章节)
- 过程确认总则指南，FDA，1987.5

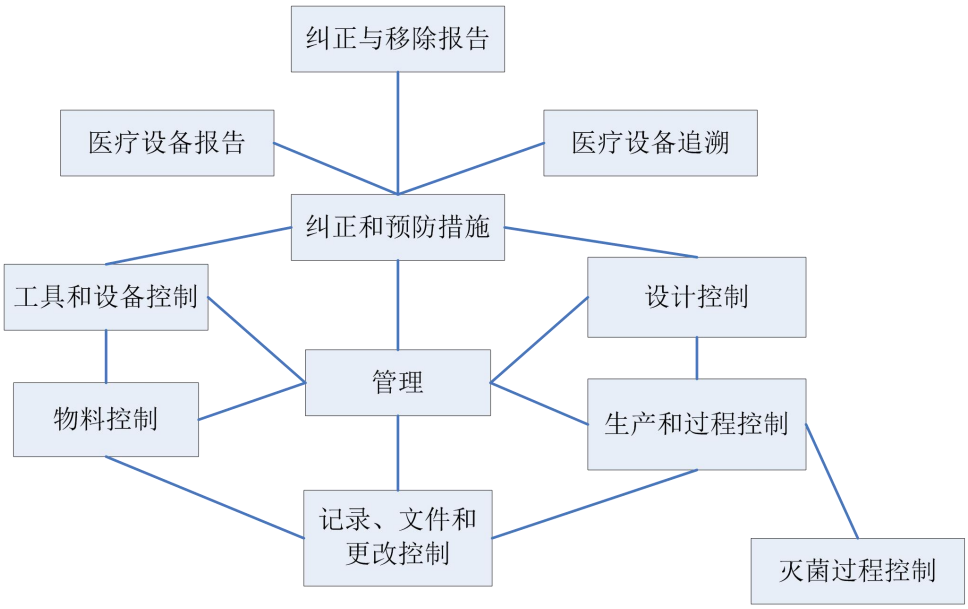
其他可参考包括：

- 联邦食品，药品以及化妆品法案；1990 年的医疗器械安全法案以及 1992 年的医疗器械修正案
- 医疗器械质量体系手册：小型实体符合性指南
- FDA 全球医疗器械质量体系要求指南
- 由 CDRH 为医疗器械行业编写的其他器械的具体指南文件
- FDA 认可的标准

更多的指南发布在 CDRH 网络主页 http://www.fda.gov/cdrh.

更多的信息见 IOM 第 10 章


Reports of Corrections and Removals
Medical Device Reporting
Medical Device Tracking
Corrective & Preventive Actions
Facility & Equipment Controls
Design Controls
MANAGEMENT
Material Controls
Production & Process Controls
Records/ Documents/ Change Controls
Sterilization Process Controls


纠正与移除报告
医疗设备报告
医疗设备追溯
纠正和预防措施
工具和设备控制
设计控制
管理
物料控制
生产和过程控制
记录、文件和更改控制
灭菌过程控制

目录

1.Performing Subsystem Inspections

The Guide to Inspections of Quality Systems provides instructions for conducting medical device quality system/GMP inspections. It is to be used in conjunction with the compliance program entitled Inspections of Medical Device Manufacturers (7382.845). The guide was prepared by the Food and Drug Administration (FDA) Office of Regulatory Affairs (ORA), and the Center for Devices and Radiological Health (CDRH). It provides guidance for inspecting medical device manufacturers against the Quality System Regulation (21 CFR Part 820) and related regulations.

This process for performing subsystem inspections is based on a "top-down" approach to inspecting. The subsystem approach is designed to provide you with the key objectives that can help determine a firm's state of compliance. The process was designed to account for the time constraints placed on field investigators when performing device quality system inspections. If you can focus your effort on key elements of a firm's quality system, you can efficiently and effectively evaluate that quality system.

When you begin an inspection by looking at one or more instances of quality problems, such as nonconforming device reports, and work your way back through the firm's quality system, you are doing a "bottom-up" inspection.This method has been helpful in zeroing in on specific problems, and evaluating the firm's actions relating to those problems. However, with the "top-down"

1. 执行子系统检查

质量体系检查指南为医疗器械质量体系/GMP 检查的执行提供了使用说明，它与医疗器械制造商检查用的符合程序指南手册（7382.845）结合使用，它是由食品和药品管理局（FDA）法规事务办公室（ORA）和设备与辐射健康中心（CDRH）制定的，它为检查医疗器械制造商是否违背质量体系法规（21CFR Part820）和相关的法规提供指南。

执行子系统检查过程基于一个"自上而下"的检查方法。此方法的设计是为检查者提供关键的检查目标，从而有助于确定一个公司的符合性状态。该检查过程的设计考虑到了执行现场质量体系检查的审核员的时间限制问题。如果将精力集中在公司质量体系的关键要素上，就可以高效率和有效地对其的质量体系进行评估。

当你开始检查时，看到了一个或多个质量问题，例如不规范的设备报告，然后返回到对公司整个质量体系的评估，那么你所作的是一个"自下而上"的检查。这个方法有助于准确找出特定的质量问题并评估公司对这些问题的处理。但是通过"自上而下"的检查方法，我们可以在确切关注特定的质量问题之

approach, we are looking at the firm's "systems" for addressing quality before we actually look at specific quality problems. In the "top-down" approach, we "touch bottom" in each of the subsystems by sampling records, rather than working our way from records review backwards towards procedures.

前，把公司的质量体系浏览一遍。在"自上而下"的检查方法中，我们可以对每一个子系统通过对记录进行抽样达到"底部"，而不是用记录审核倒退到程序的方法。

The "top-down" approach begins each subsystem review with an evaluation of whether the firm has addressed the basic requirements in that subsystem by defining and documenting appropriate procedures. This is followed by an analysis of whether the firm has implemented the requirements of that subsystem.

"自上而下"的检查方法首先要对各个子系统的了解，并评价公司是否通过制定适宜的程序并形成文件，其中是否包含了该子系统的基本要求，然后分析公司是否执行了子系统要求。

The illustration provided inside the front cover of this book shows the seven subsystems, along with related satellite programs. Based on discussions between the device industry and the agency, we have chosen four major subsystems that are the basic foundation of a firm's quality system. Those four major subsystems are Management Control; Corrective and Preventive Actions (CAPA) (with satellites Medical Device Reporting, Corrections and Removals, and Medical Device Tracking); Design Controls; and Production and Process Controls (P&PC) (with satellite Sterilization Process Controls). We have provided a suggested technique for inspecting each of these four subsystems. In addition, following the chapter of the related subsystem we have provided suggested techniques for inspecting the satellite programs.

本书前封面的插图显示了七个子系统和相应的辅助程序。基于设备生产企业和代理商之间的讨论，我们已经选择了四个主要的子系统，这四个子系统构成公司质量体系的基础，它们是：管理控制、纠正和预防措施（CAPA）（具有辅助的医疗器械报告系统、纠正和移除系统、医疗器械追溯系统）、设计控制、生产和过程控制（P&PC）（具有辅助的灭菌过程控制系统）。我们为这四个子系统的每一个子系统的检查提供建设性的检查技术，同时在紧随相关子系统的章节后我们也提供了辅助程序的建设性检查技术。

The satellite programs were included in the QSIT

由于辅助程序在相关子系统检查过

Inspection due to their correlation in the inspection process with the related subsystem. For instance, the CAPA subsystem is the logical “jumping-off” point to begin inspecting for Medical Device Reporting, Corrections and Removals, and Medical Device Tracking programs which relate to a firm’s postmarket activities. In the case of the CAPA subsystem, if you are covering the satellite programs in your inspection, approximately half a day should be added to your subsystem inspection time frame.

程中的相互关系，所以 QSIT 也包含的这些内容，例如：CAPA 子系统是一个逻辑“开始”点，在对医疗器械报告、纠正和移除系统，与公司上市后活动相关的医疗器械追溯程序进行检查时，都是从这个“开始”点开始进行的。在对 CAPA 子系统进行检查时，如果包含了辅助程序，那么该子系统的检查时间表就需要增加大约半天的时间。

Rather than check every aspect of the firm’s quality system, the subsystem approach focuses you on those elements that are most important in meeting the requirements of the quality system regulation and which are key quality indicators. Between 6-15 inspectional objectives are provided for the review of each subsystem. The review includes both a (broad) review of whether the firm has procedures in place, and appears to meet the requirements, and a closer (detailed) review of some records to verify that the requirements have been implemented in actual production, design and daily quality assurance situations.

在子系统检查中不应该对公司质量体系的各个方面都进行检查，而应该把焦点放在那些在满足质量体系法规要求上最重要的要素上，这些要素也是质量体系法规中关键质量指标。通过提供 6-15 个检查目的，以审核每一个子系统，审核包括一个（广泛的）公司是否有适宜的程序、是否满足要求，也包括密切地（详细地）查看一些记录来验证这些要求是否在实际生产、设计和日常质量保证中执行。

One similarity between “top-down” and “bottom-up” inspectional approaches is record review. Both approaches involve review of raw data, or individual records. In the “top-down” approach, however, we are asking you to use a sampling approach to the record review. With the “topdown” approach, you will sample records in many of the subsystems to verify whether or not the firm is in compliance. In other words, you are doing

“自上而下”和“自下而上”检查方法的一个相似之处是记录的查看，每一种方法都要求查看原始数据或单独记录。但是，在“自上而下”的方法中，我们要求采用抽样的方法来查看记录，要在许多子系统的记录中进行抽样以验证公司是否符合。换句话说，要对原始数据进行了解，就像在过去所作的那样，但是以一种更可控的方式进行。我们可以为

the raw data review as you did in the past, but in a more controlled manner. We have provided sampling tables to assist you in determining how many records you need to review, and what confidence you can have in the potential prevalence of the observed conditions.

审核员提供抽样表格以帮助其确定需要查看多少记录，以及在这种盛行的观察方法下审核员具有多少信心。

One new feature in the "top-down" inspection technique is the use of inspectional objectives and flow diagrams to guide you during the inspection. We have provided inspectional objectives and flow diagrams that are useful in inspecting the four major subsystems. The flow diagrams provide a quick overview of how the inspection of each subsystem should occur.

在"自上而下"的检查方法中，一个新的特点是在检查过程中利用检查目的和流程图来引导审核员。我们四个主要的子系统中提供了有用的检查目的和流程图，其中流程图可使你快速了解子系统的检查应如何进行。

In addition to the inspectional objectives and flow diagrams, we have provided a narrative description describing how to perform the inspection of each subsystem. The narrative description includes a discussion on how to achieve each inspectional objective and reflects the questions contained within the flow diagrams. You are not bound to follow each and every sentence in the narrative. Rather, you should inspect the subsystem with the narrative guidance in mind.

除了检查目标和流程图以外我们还提供了一个解说描述，描述如何开展每一个子系统的检查，包括讨论如何实现每个检查目标以及反映了包含在流程图的问题，检查不必按解说描述中的每一句话进行，而应该在它的指导下检查子系统。

The Quality System Regulation (21 CFR 820.3(k)) defines "Establish" as "define, document (in writing or electronically), and implement". The Quality System Inspection Technique uses the "establish" approach in conducting the inspection. For each subsystem, you will first determine if the firm has defined and documented the requirements (CAPA, Design, etc.) by looking at procedures and policies, and then you will bore down into records,

质量体系法规（21CFR 820.3(K)）定义"建立"的涵义，为"规定、记录（纸质或电子记录）、实施"。质量体系检查技术利用了"建立"进行检查实施。对每一个子系统，首先通过观察公司的程序和方针来确定公司是否已经规定了要求并形成文件（CAPA、设计等），然后查看原始资料并在适当的地方用抽样表格进行记录，确定公司是否满足了他们的

using the sampling tables, where appropriate, looking at raw data to determine if the firm is meeting their own procedures and policies, and if their program for executing the requirement is adequate.

程序和方针，他们执行要求的程序是否充分。

The duration of inspection is related to the depth of the inspection. Keep in mind that the subsystem approach provides you with the key inspectional objectives that can help determine a firm’s state of compliance. At the same time, the guidance was designed to accomplish a complete review of all four subsystems in approximately one week.

While the length of your inspections will vary, using key inspectional objectives will help assure that you look at the most important elements of the firm’s quality system during the inspection.

检查的持续时间与检查的深度有关。应该记住子系统方法提供给你的主要检查目标，可以帮助你确定公司的符合性状态。同时，该指南的设计是为了在大约一周时间内完成对所有四个系统的全面审查。虽然你检查持续的时间会有所不同，但利用主要检查目的可确保你在检查中抓住公司质量体系中最重要的要素。

Most device firms are inspected more than once. By probing different subsystems, different devices or different processes each time, FDA will eventually have covered most of the firm’s quality system. You are not expected to cover everything in the firm and in the narrative each time. You are expected to evaluate the firm’s quality system, but also to do it in an efficient and focused manner. Thus, you should limit the depth of coverage when necessary to meet the time frame suggested. As a general rule of thumb, one day should be sufficient to cover each subsystem when using the “top-down” approach described within this document. In practice, you may find that the inspection of a certain subsystem may take half a day, while another may take one and a half days. This situation would still reflect an overall one day

大多数设备公司都将接受不止一次的检查。通过检查不同的子系统、设备、或程序，FDA 最终能覆盖公司的大多数质量体系。不要求每次审查覆盖公司和叙述的任何事情，而要求评估公司的质量体系，而且是在一个有效的集中的方式下进行。因此，这样审核员应该限制覆盖的深度以满足建议的时间表。根据一般经验，使用本文中提到的“自上而下”的方法，一天时间就能充分覆盖每一个子系统。实际上，你可能会发现对某个子系统的检查可能需要半天，而另一个子系统可能需要一天半的时间。这种情况仍将反映每个子系统的时间表仍是一天。

per subsystem time frame.

By directing your attention to the major areas in a firm’s quality system, you should be better able to determine if the firm’s quality system is in control. Using the subsystem approach, you may find less opportunity to cite minor deviations from the quality system regulation than in the past.

However, you will be citing more serious (systemic) deviations from the regulation.

通过引导注意力到公司质量体系的主要区域上，审核员能更好地判断公司的质量体系是否在控制中。使用子系统的方法，你会发现偏离质量体系法规的机会比以前少，但是有可能更严重地（系统地）偏离法规。

2.PREANNOUNCED INSPECTIONS

2. 检查前通知

The ORA Medical Device Industry Initiatives program encompasses preannounced medical device inspections, FDA 483 Annotation and Postinspectional Notification.

ORA 医疗器械行业启动程序包括医疗器械检查前通知、FDA 483 注释和检查后通告。

The instructions for Preannouncement (including the criteria to be used in determining when preannouncement is appropriate), FDA 483 Annotation and Post-inspection Notification were provided in an April 3, 1996, Federal Register Notice (Volume 61, Number 65). Refer to the Investigations Operations Manual (IOM) for further information.

对检查前通知（包括决定通告时间的标准）、FDA 483 注释和检查后通告的指令是由 1996 年 4 月 3 日的联邦公报通知提供（第 61 卷，65 号码），要获得更多的信息可参考调查操作手册（IOM）

When contacting the firm for the preannounced QSIT Inspection, the investigator should ask for a copy of the firm’s Quality Policy and high level Quality System Procedures (including Management Review Procedures), Quality Manual, Quality Plan or equivalent documents to preview prior to the inspection. The firm is not required to supply these documents. The investigator should tell the firm that the preview of these procedural documents would facilitate the inspection. The documents would be returned at the time of the inspection. If

当与要进行 QSIT 检查前通知的公司接触时，检查者应向公司要质量方针、高层次的质量体系程序（包括管理评审程序）、质量手册、质量计划或其他等同意义文件的副本进行预览，公司并非必须提供这些文件。检查者应告诉公司对这些程序文件的预览有助于检查的进行。在检查的时候这些文件将归还公司，如果发现公司这些文件中存在不足之处，应该在检查后要求要原始文件的副本。

you find deficiencies in these documents, you should request copies of the original documents after you initiate the inspection.

3.GETTING STARTED

It is essential that the firm establishes and maintains a quality system that is appropriate for the specific medical device being manufactured and meets the requirements of the Quality System Regulation. The Management Representative has the responsibility to ensure that the requirements of the Quality System Regulation have been effectively established and maintained. Prior to your review of any subsystem, interview the Management Representative (or designee). The objective of this interview is to obtain an overall view of the subsystem as well as a feel for management ' s knowledge and understanding of the subsystem. An important linkage for this activity is Management Controls (820.20 Management Responsibility)

4.Management Controls Subsystem

4.1 Inspectional Objectives

1.Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.

2. Verify that a quality policy and objectives have been implemented.

3. Review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities and necessary resources.

4. Confirm that a management representative has been appointed. Evaluate the purview of the management representative.

3.开始

建立和保持一个适合于特定医疗器械和满足质量体系法规要求的质量体系，对于一个公司来说是必要的。管理者代表有责任保证质量体系法规要求能被有效地建立和保持。在查看子系统之前审核员应该先会见管理者代表（或指定人员）。与管理者代表会见的目的是对子系统进行整体观察，以及对管理人员的知识和对子系统的理解有一个全面感知。此活动一个重要的连接是管理控制（820.20 管理职责）。

4.管理控制子系统

4.1 检查目的

1.证质量方针、管理评审、质量审核程序、质量计划、质量体系程序和指导书已经建立和记录。

2. 证质量方针和质量目标已经实施。

3. 查看公司建立的组织结构，确认其是否包括职责、权限和必要资源的规定。

4. 确认管理者代表已被任命，并对管理者代表的职责权限进行评估。

5. Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.

6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted. At the conclusion of the inspection....

7. Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained.

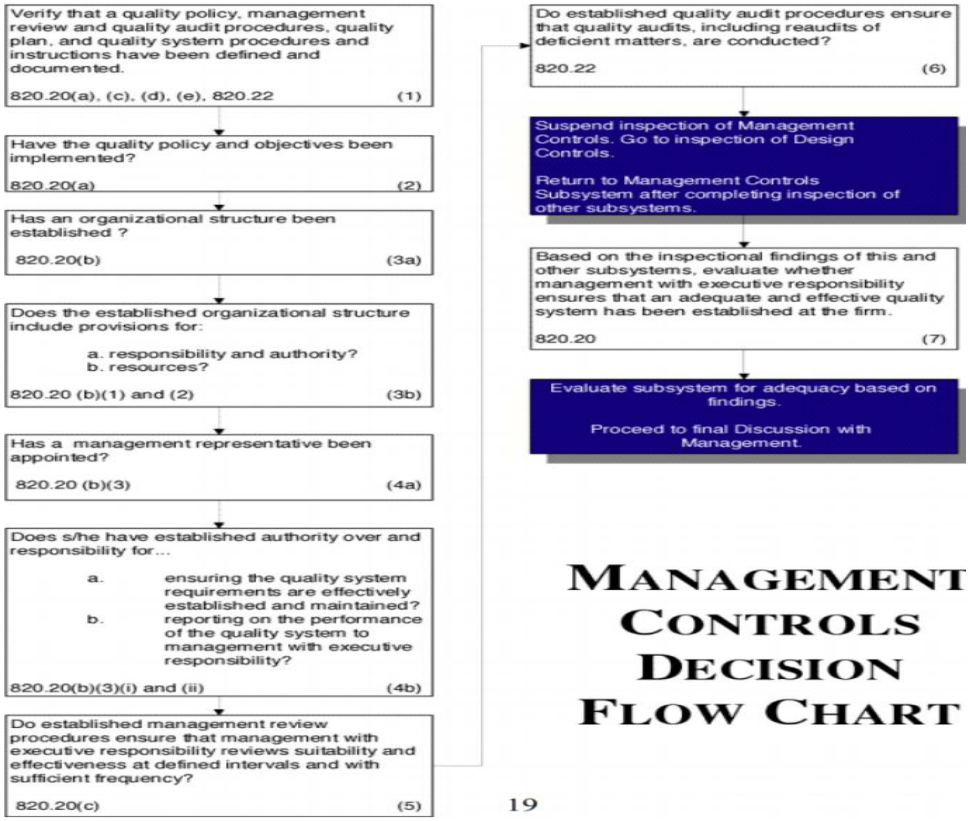
4.2 Decision Flow Chart

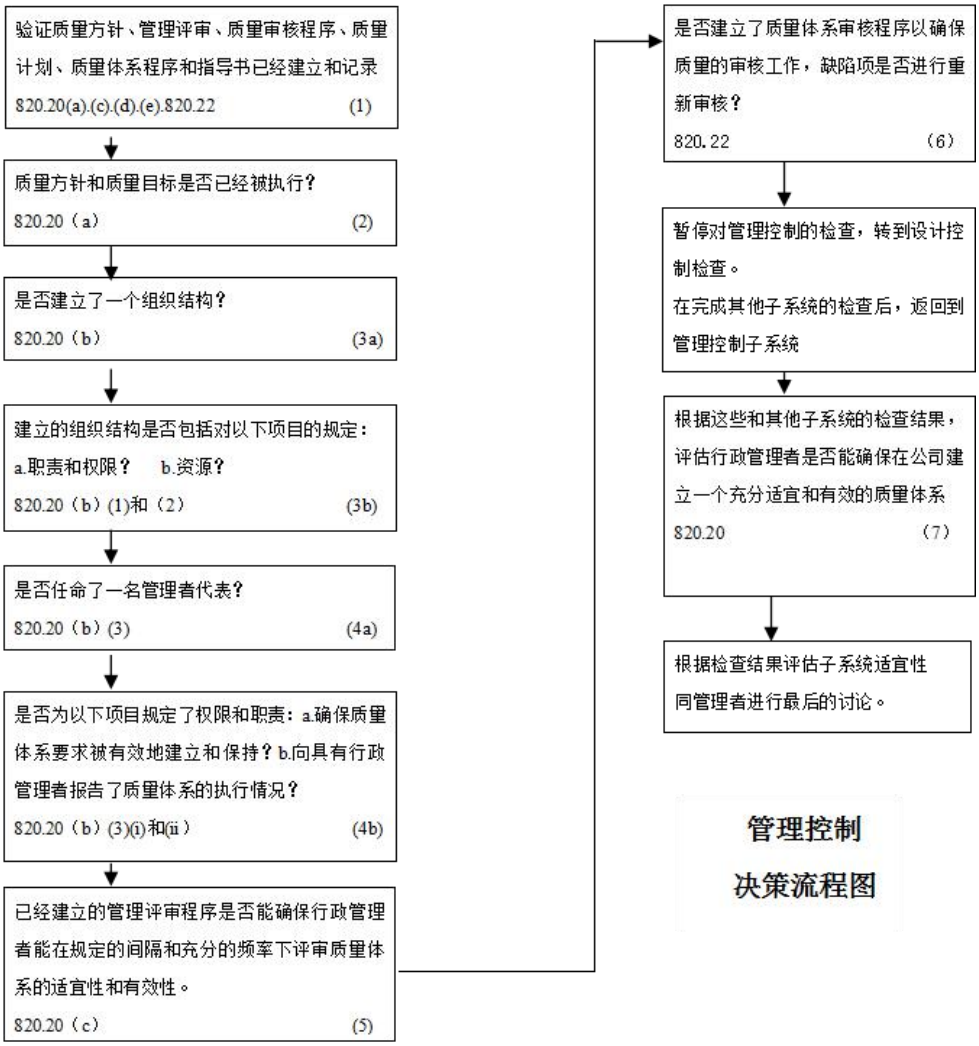
5. 验证进行了管理评审，包括对质量体系的适宜性和有效性的评审。

6. 验证进行了质量体系的质量审核，包括缺陷项的重新审核。在检查结束时……..

7. 评估行政管理者是否能确保建立和保持一个充分适宜和有效的质量体系。

4.2 决策流程图




验证质量方针、管理评审、质量审核程序、质量计划、质量体系程序和指导书已经建立和记录
820.20(a).(c).(d).(e).820.22 (1)
质量方针和质量目标是否已经被执行？
820.20（a） (2)
是否建立了一个组织结构？
820.20（b） (3a)
建立的组织结构是否包括对以下项目的规定：
a.职责和权限？ b.资源？
820.20（b）(1)和（2） (3b)
是否任命了一名管理者代表？
820.20（b）(3) (4a)
是否为以下项目规定了权限和职责：a.确保质量体系要求被有效地建立和保持？b.向具有行政管理者报告了质量体系的执行情况？
820.20（b）(3)(i)和(ii） (4b)
已经建立的管理评审程序是否能确保行政管理者能在规定的间隔和充分的频率下评审质量体系的适宜性和有效性。
820.20（c） (5)
是否建立了质量体系审核程序以确保质量的审核工作，缺陷项是否进行重新审核？
820.22 （6）
暂停对管理控制的检查，转到设计控制检查。
在完成其他子系统的检查后，返回到管理控制子系统
根据这些和其他子系统的检查结果，评估行政管理者是否能确保在公司建立一个充分适宜和有效的质量体系
820.20 （7）
根据检查结果评估子系统适宜性同管理者进行最后的讨论。
管理控制
决策流程图

4.3Narrative

Purpose/Importance

The purpose of the management control subsystem is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; assure the quality system is functioning properly; monitor the quality system; and make necessary adjustments. A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended.

A primary purpose of the inspection is to determine whether management with executive responsibility ensures that an adequate and effective quality system has been established (defined, documented and implemented) at the firm. Because of this, each inspection should begin and end with an evaluation of this subsystem.

(1)Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.

Prior to the start of the inspection, preferably at the time you make the preannouncement of the inspection (if preannounced), you should ask the firm to send you their overall (or top level) quality system policies, objectives, and procedures. This should include their management review procedures, quality policy, and quality plan. If not received prior to the start of the inspection, you will need to review these documents at the start of your inspection

4.3 解释

目的/重要性

管理控制子系统的目的是为设备设计、生产、质量保证、销售、安装和服务活动提供资源；确保质量体系能充分地运行；监视质量体系；并作出必要的调整。一个已经被有效地执行和监控去识别并解决问题的质量体系更有可能生产出达到预期功能的设备。

检查的主要目的是确定行政管理者是否能确保公司建立（建立、记录和实施）了一个充分和有效的质量体系。因此，每一个检查的开始和结束都要有对这个子系统进行评估。

（1）验证质量方针、管理评审和质量审核程序、质量计划、质量体系程序和指导书已经建立和记录。

在开始检查之前，最好在检查前通知时（如果预先通知），要求公司提供全面的（或高级别的）质量体系方针、目标和程序，其中应该包括他们管理评审程序、质量方针、和质量计划。如果在开始检查之前没有收到这些文件，需要在开始检查时对这些文件进行查阅。

Quality Policy and Objectives

The firm must have a written quality policy. The definition of quality policy is provided in the Quality System Regulation. It means the overall intentions and directions of an organization with respect to quality. The firm is responsible for establishing a clear quality policy with achievable objectives then translating the objectives into actual methods and procedures. Management with executive responsibility (i.e. has the authority to establish and make changes to the company quality policy) must assure the policy and objectives are understood and implemented at all levels of their organization. The policy does not need to be extensive. Personnel are not required to be able to recite the policy but they should be familiar with it and know where to obtain it.

质量方针和目标

公司必须有一个书面的质量方针，质量方针的定义是由质量体系法规（QSR）规定的。质量方针意味着组织在关于质量方面的总意图和方向，公司有责任建立一个具有可完成的明确的质量方针，并要把目标转换成实际的方法和程序。行政管理者（例如：具有建立和改变公司质量方针的权利）必须确保方针和目标被公司的各个层次人员所理解和执行。方针不需要太广泛。公司人员不要求能背诵方针，但他们必须熟悉方针和知道在什么地方获得方针。

Management Review and Quality Audit Procedures

Management reviews and quality audits are a foundation of a good quality system. Assure that the manufacturer has written procedures for conducting management reviews and quality audits and there are defined intervals for when they should occur. The firm's quality audits should examine the quality system activities to demonstrate that the procedures are appropriate to achieve quality system objectives, and the procedures have been implemented. A successful implementation of the firm's procedures should result in the firm achieving its quality policy and associated objectives. Whether the quality policy and objectives are "good" may become evident as the other subsystems are reviewed during the inspection.

管理评审和质量审核程序

管理评审和质量审核是一个好的质量体系的基础，确保生产商已经制定出书面的管理评审和质量审核的程序，并已经定好执行它们的时间间隔。公司的质量审核应当检查质量体系的活动，以证明管理评审和质量审核的程序对完成质量体系目标是合适的，且已经被执行。公司程序的成功执行能导致公司实现质量方针和其他相关目标。质量方针和目标是否是适宜的，将在检查期间变成评论其他子系统的一个证据。

Quality Plans

The firm must have a written quality plan that defines the quality practices, resources and activities relevant to the devices that are being designed and manufactured at that facility. The manufacturer needs to have written procedures that describe how they intend to meet their quality requirements.

For firms that manufacture devices as well as other products, there must be a quality plan that is specifically relevant to devices. Much of what is required to be part of the plan may be found in the firm's quality system documentation, such as, the Quality Manual, Device Master Record(s),production procedures, etc. Therefore, the plan itself may be a roadmap of the firm's quality system. The plan in this case would need to include reference to applicable quality system documents and how those documents apply to the device(s) that is the subject of the plan. Quality plans may be specific to one device or be generic to all devices manufactured at the firm. Quality plans can also be specific to processes or overall systems.

Quality System Procedures and Instructions

All manufacturers of medical devices are required to establish and implement a quality system tailored to the device manufactured. Each manufacturer must prepare and implement all activities, including, but not necessarily limited to the applicable requirements of the Quality System Regulation, that are necessary to assure the finished device, the design process, the manufacturing process, and all related activities

质量计划

公司必须制定出一个书面的质量计划，确定将要设计和生产的器械的相关质量规范、资源和活动，制造商需要写出一个程序描述如何满足质量要求。

对于生产器械和其他产品的公司，必须有一个和特定相关器械的质量计划。质量计划的大部分应该能在公司质量体系文件如质量手册、器械主记录、生产程序等中找到。因此，计划本身应该是公司质量体系的一个路标，计划需要包括可适用质量体系文件的参考文件，和如何使这些文件应用到计划的目标器械。质量计划可以是一个医疗器械专用的，也可以广泛适用于公司产生的所有医疗器械。质量计划也可以针对于过程或整个体系。

质量体系程序和作业指导书

所有医疗器械制造商都需要建立和执行一个适合于设备生产的质量体系。每一个制造商都必须制定和执行所有的活动，这些活动包括但不受限于质量体系法规的适用要求。质量体系法规的适用要求在确保成品器械、设计过程、生产过程和所有相关活动满足批准的规范上是必要的。

conform to approved specifications.

The term "quality system" as specified in the Quality System Regulation encompasses all activities previously referred to as "quality assurance" which were necessary to assure the finished device meets its predetermined design specifications. This includes assuring manufacturing processes are controlled and adequate for their intended use, documentation is controlled and maintained, equipment is calibrated, inspected, tested, etc. Some manufacturers may use the terms "quality control" or "GMP Control" or "quality assurance" instead of quality system. It doesn't matter what term is used as long as the quality system concept is understood and implemented.

专用在质量体系法规中的述语“质量体系”包含以前提到的“质量保证”中的所有活动。“质量保证”对于确保成品器械符合预定义的设计规格是必要的，包括：确保生产过程中在控制中且足以满足他们的预期用途；确保文件被控制和保持；确保设备被校正、检查和测试等。一些制造商可能使用术语“质量控制”或“GMP 控制”或“质量保证”来代替质量体系。只要质量体系的概念被理解和执行，使用哪个术语是不重要的。

Written quality system procedures and instructions are required. Any FDA 483 observation regarding Quality System procedures must be specific and point out the controls that are missing or believed inadequate.

书面的质量体系程序和作业指导书是必要的。任何关于质量体系程序的 FDA 483 观察项必须是明确的，并且能从中辨识出缺少的或被认为是不充分的控制。

（2）Verify that a quality policy and objectives have been implemented.

One way to determine whether personnel are familiar with the quality policy is to ask employees directly. This should not be done when the employee is engaged in the actual performance of his/her duties, but could be done when he/she is at break or when he/she has finished a task and before he/she begins his/her next task.

You can also look to see how management has made the policy available. For example: Is it in their Quality Manual or another part of their written procedures? Is

（2） 确认质量方针和目标已经被执行。

检查公司人员是否熟悉质量方针的方法之一是直接向公司职员提问，但是当公司职员正在从事工作时，不应进行提问，当应在其休息时或完成了目前的工作而没用开始另一个工作时，进行提问。

你也可以观察管理者是如何利用这些质量方针的，例如：他们的质量手册或所写的程序中的其他部分是否

it posted at points throughout the building? It doesn't matter how they made the policy known, only that personnel know that there is a policy and where they can read the policy for themselves.

能包含有质量方针？质量方针是否能被张贴在建筑物上？他们是如何宣传质量方针并不是重要的，只要公司员工知道有质量方针和在什么地方能阅读质量方针就可以了。

A review of employee training records to show they have been trained in the firm's quality policy and objectives can also be done. In particular, this should be done for those employees involved in key operations.

对公司职员培训记录查阅，会了解到公司是否能对职员进行关于质量方针和质量目标的培训，特别是那些在关键的工作岗位上的职员更应该接受质量方针和目标的培训。

（3）Review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities and necessary resources. The firm's organizational structure must be adequate to ensure devices are designed and manufactured in accordance with the Quality System Regulation. The organizational structure should ensure the technical, administrative, and human factors functions affecting the quality of a device are controlled. These functions may involve hardware, software, processed materials or services. All such control should be towards the reduction, elimination, or ideally, the prevention of quality nonconformities.

（3）查阅公司建立的组织结构以确认其包括对职责、权限和必须资源的规定。

根据质量体系法规，公司的组织结构必须足够确保器械的设计和制造，组织结构必须确保影响器械质量的技术、管理和人为因素的作用得到控制。这些功能涉及到软件、硬件、已加工材料或服务，所有的控制都应该向减少、消除或预防质量不符合的方向发展。

To determine what the firm's organizational structure is, start by asking the authority and responsibility questions that are the start of every FDA inspection. Review the firm's organizational charts.

通过询问职责和权限的问题来检查公司的组织结构，询问职责和权限是每一个 FDA 检查的开始。查询公司的组织结构图。

The firm's procedures should describe the functional areas or people responsible for performing certain tasks governed by their quality system. They should also include provisions for resources and designating a

公司的程序应该描述在执行特定任务时的功能区域或人员职责，这个特定任务是受质量体系控制的，程序也应该包括对资源和任命管理者代表

management representative.

Determine whether personnel involved in managing, performing or assessing work affecting quality have the necessary independence and authority to perform those tasks. Organizational freedom or independence does not necessarily require a stand-alone group. However, the responsibility, authority and independence should be sufficient to attain the firm's stated quality objectives.

Adequate resources must be available for the quality system to assure the firm's stated quality objectives can be achieved. Resources include money, supplies, personnel, etc. One approach to confirm that adequate resources are available is to ask the management representative how resources are obtained and allocated.

（4）Confirm that a management representative has been appointed. Evaluate the purview of the management representative.

The firm must appoint a management representative who is responsible for ensuring the quality system is effectively established and maintained, and who will report on its performance to management with executive responsibility for review. The appointment must be documented.

To determine whether there is in fact a documented management representative, review the firm's organizational chart(s) or their Quality Manual.

的规定。

确定参与管理、执行或评估影响质量工作的人员是否具有执行这些任务的必要独立性和权威性，组织的自由或独立不是要求组织是一个孤立的团体，而是职责、权利和独立性在公司完成质量目标的过程中应该得到充分的支持。

确保实现公司已制定的质量目标的过程中，获得充分资源是必要的，资源包括：财务、供应品、人员等，一个能确保充分资源的方法是向管理者代表询问资源是如何获得和如何被分配的。

（4）确认管理者代表已被任命，评估管理者代表的权限。

公司必须任命一个管理者代表，他对确保质量体系有效地建立和维护负责，并向负责审核的行政管理者汇报其执行情况。管理者代表的任命必须有文件证明。

判断是否具有关于管理者代表的文件，查阅公司组织结构图或质量手册。

Determine whether the appointed management representative actually has the purported responsibility and authority granted to him/her by the firm's procedures or organizational structure. Ways of reaching this determination include: Whether he/she has sign-off authority for changes to documents, processes, or product designs; whether the people conducting quality audits report or provide him/her with their results; and noting how he/she interacts with corrective and preventive actions, relative design control issues, complaints, MDRs, in-process or finished product failures, etc. In other words, his /her responsibility and authority should be apparent through the review of the other subsystems.

判断被任命的管理者代表是否事实上具有公司程序或组织结构授予他的权利和职责。完成这个判断方法包括：他/她是否签署了更改文件、过程或产品设计的授权？执行质量审核的人员是否向其汇报或提供执行的结果；记录其是如何处理纠正和预防措施、相关的设计控制命令发布、投诉、MDRs；生产中的产品和成品的缺陷问题等。换句话说，管理者代表的职责和权利应在对其他子系统的审核过程中显露出来。

Verify that the management representative is reporting back to the management with executive responsibility on the performance of the quality system. These reports should either be the subject of the management reviews or at least provide the framework for those reviews.

验证管理者代表向行政管理者汇报质量体系的执行情况，汇报的内容应该是有关管理评审的内容，或者最少要提供出这些评审的框架结构。

NOTE: The agency's policy relative to the review of quality audit results is stated in CPG 7151.02 (CPG Manual subchapter 130.300). This policy prohibits FDA access to a firm's audit results. Under the Quality System Regulation, this prohibition extends to reviews of supplier audit reports and management reviews. However, the procedures and documents that show conformance with 21 CFR 820.50, Purchasing Controls, and 21 CFR 820.20(3)(c), Management Reviews, and 21 CFR 920.22 Quality Audit, are subject to FDA inspection.

注意：关于对质量审核结果审核的机构的方针在 CPG7151.02(CPG 手册第 130.300 子章)中描述，这个方针禁止 FDA 访问公司的审核结果。在质量体系法规中，这个禁止延伸到对供应商审核报告的检查和管理评审，但是，这些程序和文件需要符合 21CFR820.50- 采购控制、21CFR820.20(3)(c)- 管理评审、21CFR920.22-质量审核，是 FDA 检查的范围。

（5）Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.

Management reviews must measure the firm's quality system against the Quality System Regulation and the firm's own stated quality objectives as defined in their quality policy. Management reviews must be documented. There must be written procedures for conducting management reviews. These procedures can be inspected and the firm must certify in writing, if requested, that the firm has complied with this Quality System Regulation requirement.

Review the firm's management review schedule to confirm management reviews are being conducted with sufficient frequency. Management reviews should be frequent enough to keep them informed of ongoing quality issues and problems. During your review of the CAPA subsystem, if you find that there are quality issues that do not seem to be known to executive-level management, then the reviews may not be occurring with sufficient frequency.

The dates and results of management reviews must be documented to show dates conducted and whether management with executive responsibility attended the reviews. It is not permissible as explained above for an FDA Investigator to review the firm's actual management review documentation. However, the firm should be able to show you how the reviews are to be documented. Management review procedures or instructions should include a requirement that the results of the reviews be documented and dated.

（5） 验证管理评审正在进行中，包括对质量体系的有效性和适合性的审核。

管理评审必须根据质量体系法规和公司自己的质量方针中规定的质量目标来衡量公司的质量体系。管理评审必须用文件证明，在执行管理管理评审时必须要制定出书面的程序。这些程序必须能够被检查，如有要求，公司必须书面证明公司已符合此质量体系法规要求。

通过审核公司的管理评审计划，确认管理评审正以足够的频率进行。管理评审必须有足够的频率才能使管理者了解不间断的质量问题。在对 CAPA 子系统的审核中，如果审核员发现有些质量问题行政管理者看起来并不知道，就说明公司的管理评审没有达到一定的频率。

对管理者评审的日期和评审的结果需要用文件记录下来，以显示管理评审被执行的日期，和行政管理者是否参加了审核。FDA 检查者不允许审核公司实际的管理评审记录，但是，公司应该能够出示是如何记录管理评审的。管理评审程序或指导书应该包括一个要求，即管理评审的结果都应该用文件记录并标注日期。

（6）Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted.

Review the firm's quality audit schedules to assure quality audits are being conducted with sufficient frequency. It is recommended that the time between quality audits not exceed a 12-month period. More frequent audits may be recommended if the firm has a serious Quality System Regulation problem.

Quality audits should consist of a formal, planned check of all elements in the quality system. They are NOT product audits. Quality audits must be conducted using adequate detailed written procedures by appropriately trained individuals. If conducted properly, a quality audit can detect system defects and, through isolation of unsatisfactory trends and correction of factors that cause defective products, prevent the production of unsafe or nonconforming devices. Without an effective quality audit function the quality system is incomplete and there is no assurance the manufacturer is consistently in a state-of-control.

Evidence of inadequate auditing may exist without gaining access to the written quality audit reports. This evidence may be obtained by relating the audit program to deficiencies observed in other subsystems. If significant quality system problems have existed both before and after the firm's last self-audit, then you should critically review the written audit procedures. The audit procedures should cover each quality system, and should be specific enough to enable the person conducting the audit to perform an adequate audit. The

（6）验证质量体系的质量审核正在实施，包括缺陷事项再审核。

查阅公司的质量审核进度表，以确认公司的质量审核正以足够的频率实施。建议两次质量审核的时间间隔不要超过 12 个月。如果已经知道公司存在着严重的质量体系法规问题，建议提高进行质量审核频率。

质量审核应该在形式和计划上对质量体系所有要素进行检查，而不是产品审核。质量审核必须按照书面制定的足够详细程序，由经过适当培训过的人员进行。正确地执行质量审核，能够发现体系的缺陷，并把有可能导致有缺陷产品的修正因素及不符合趋势分离出来，可以防止生产不安全或不合格器械。没有有效的质量审核功能的质量体系是不完全的，也不能确保制造商持续地处于控制状态。

如果没有使用书面的质量审核报告，那么就存在着没有充分的审核证据，这个证据也可以通过将审核程序与其他子系统中观察到的缺陷联系起来而获得。如果在公司的最后一次自我审核之前和审核之后都存在着显著的质量体系问题，就应该重点审核公司的书面审核程序。审核程序应该覆盖每一个质量体系，并应具体到足以使进行审核的人进行适当的审核。审

auditors must be adequately trained. If it is necessary and possible to interview an auditor, ask how the audits are performed; what documents are examined; how long audits take; etc.

核员必须经过适当的、充分的培训。如果有可能及需要面见审核员，可以向他提出审核如何被执行、检查了哪些文件、审核花费了多长的时间等问题。

Audits should be conducted by individuals not having direct responsibility for matters being audited. One person and other very small firms must generally establish independence, even if it means hiring outside auditors, because the failure to have an independent auditor could result in an ineffective audit. If there are significant FDA 483 observations, and independent audits are being performed, but deficiencies are apparently not being identified by the auditor, then an FDA 483 should contain an observation indicating a lack of adequate audits.

审核应该由那些对被审核的事物没有直接责任的人执行，个体公司及小公司必须建立一个独立的，甚至雇佣外部审核员进行审核，因为如果没有独立的审核员，审核将是无效的。如果存在重要的 FDA 483 观察项，但在执行了独立的审核后，审核员没有观察到比较明显的缺陷，那么，FDA 483 应该包含一个表明缺乏足够的观察项。

Determine whether corrective action by upper management is being taken. Auditors may be asked if they observed any of the ongoing Quality System Regulation deficiencies during their prior audits (ongoing Quality System Regulation deficiencies may also be identified by reviewing prior FDA 483's). If the answer is yes, check the written audit schedule, if available, to determine if a follow up audit is scheduled for the deficient areas. Check the written audit procedure for instructions for review of audits by upper management . For example, do the procedures require quality audit results to be included in the management reviews? Verify that the procedures contain provisions for the re-audit of deficient areas if necessary. A failure to implement followup corrective actions, including re-audits of deficient matters may be listed as a Quality

检查由上级管理者指定的纠正措施是否被采纳，审核员可能会被问到在他们的先前审核中是否观察到存在着一些持续的质量体系法规缺陷（持续的质量法规缺陷项也能通过审核以前的 FDA 483 识别出）。如果回答是“是的”，检查书面记录的审核进度表，如果有的话，检查是否将对缺陷区进行后续的审核。检查上级管理层的审核检查指示的书面审核程序，例如：程序是否要求质量审核的结果被包含在管理评审中？如果有必要，验证程序是否包含对缺陷区域再审核的规定。未有效执行跟进纠正措施，包括对有缺陷的项目的重新审核可能被作为质量体系法规的缺陷列在 FDA483

System Regulation deficiency on the FDA 483.

中。

NOTE: Re-audits of deficient matters are not always required, but where one is indicated, it must be conducted. The reaudit report should verify the recommended corrective action(s) was implemented and effective.

注意：对有缺陷项目重新审核并不是任何时候都是有必要的，但是一旦指明了，就必须坚决执行。重新审核的报告中应该验证推荐的纠正措施已经被有效的执行了。

（7）Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained

（7）评估行政管理者是否确保了一个充分的、有效的质量体系被建立和保持。

At this point in QSIT, you stop your review of the management system. You continue your inspection by evaluating the other subsystems. While you evaluate the other subsystems, keep thinking about what you are finding and whether it indicates that management is appropriately carrying out responsibilities for providing adequate resources and overseeing the quality system to detect problems and address them.

在 QSIT 的这一部分，不需要对管理系统评审，而可以通过评估其他子系统持续你的检查。当在评估其他子系统时，应考虑：什么是需要寻找的，其是否表明管理层恰当地履行了提供足够的资源，监督质量体系，发现问题并解决问题的职责。

From your review of the other subsystems, you have a better idea on whether the management representative has the appropriate authority and responsibility, whether the organizational structure is adequate, whether the quality audits and management reviews are sufficient, whether the quality policy has really been implemented, and whether the training being provided is sufficient.

从对其他子系统的检查中，审核员对以下问题将会有一个比较好的了解：管理者代表是否具有适当的权利和责任，组织结构是否适当的，质量审核和管理评审是否充分的，质量方针是否被确切地执行，对员工的培训是否是足够的。

You need to take the time after reviewing the other subsystems, to evaluate the inspectional findings of the management and other subsystems. You need to determine whether the management representative and

在完成对其他子系统的评估后，需要评估对管理和其他子系统检查时的发现。需要确定管理者代表和行政管理者是否确保了质量体系的充分性和有

management with executive responsibility are ensuring the adequacy and effectiveness of the quality system and whether that system has been fully implemented at this firm.

效性，和质量体系在公司中是否被充分地执行。

If you found major nonconformances (as defined in the Compliance Program, Part V) in your review of the management or other subsystems that indicate management with executive responsibility is not ensuring the establishment and maintenance of an adequate quality system, you may cite this deficiency on your FDA 483. This cite should not be used routinely, but should be used in those situations where major portions of a quality system have not been established and maintained or whenever there is a total lack of a quality system.When you have made that determination and have completed your FDA 483, or decided no FDA 483 is needed, you may proceed to your final discussion with Management, or the official closeout meeting with the firm

如果在对管理或其他子系统的审核中发现重大不符合项（在符合性程序第五部分中定义），意味着行政管理者没有能够确保建立和保持充分的质量体系。审核员可以在 FDA 483 中引证这个缺陷。这个引证不能被正式使用，但是可以在以下形式下使用：质量体系的主要部分没有被建立和保持、或者质量体系是完全缺失的。当判断并完成 FDA 483，或决定不需要 FDA 483 时，审核员可以进行与管理者最后的讨论，或者与公司进行最后的官方会议。

5.Design Controls Subsystem

5.1 Inspectional Objectives

1.Select a single design project.

Note: If the project selected involves a device that contains software, consider reviewing the software's validation while proceeding through the assessment of the firm's design control system.

2. For the design project selected, verify that design control procedures that address the requirements of Section 820.30 of the regulation have been defined and documented.

3. Review the design plan for the selected project to understand the layout of the design and development activities including assigned responsibilities and

5.设计控制子系统

5.1 检查目的

1．选择单独的设计方案

注意：在对公司的设计控制子系统进行评估时，如果选择的方案涉及到包含软件的设备，在评估公司设计控制系统的过程中，考虑审查软件确认。

2．选择设计方案后，应验证符合法规第 820.30 条要求的设计控制程序已被定义和记录。

3．审查选定项目的设计计划，以了解设计和开发活动的开展，包括职责分工和接口。

interfaces.

Note: Evaluate the firm's conduct of risk analysis while proceeding through the assessment of the firm's Design Control system.

4. Confirm that design inputs were established.

5. Verify that the design outputs that are essential for the proper functioning of the device were identified.

6. Confirm that acceptance criteria were established prior to the performance of verification and validation activities.

7. Determine if design verification confirmed that design outputs met
the design input requirements.

8. Confirm that design validation data show that the approved design met the predetermined user needs and intended uses.

9. Confirm that the completed design validation did not leave any
unresolved discrepancies.

10. If the device contains software, confirm that the software was validated.

11. Confirm that risk analysis was performed.

12. Determine if design validation was accomplished using initial production devices or their equivalents.

13. Confirm that changes were controlled including validation or where
appropriate verification.

14. Determine if design reviews were conducted.

15. Determine if the design was correctly transferred.

5.2 Decision Flow Chart

注意：在对公司的设计控制系统进行评估时，要对公司开展的风险分析进行评估。

4．确认已经建立设计输入。

5．验证设计输出被识别，此设计输出对特定的设备功能是必不可少的。

6．确保接收准则的建立在验证和确认活动之前进行。

7．确定设计的验证活动能否确保设计输出满足设计输入的要求。

8．确认设计确认数据能显示已批准的设计是否满足预期用户需求和预期用途。

9．确保已完成的设计确认不会留下任何遗留问题。

10．如果设备包含软件，确保软件被确认过。

11．确保风险分析已被执行。

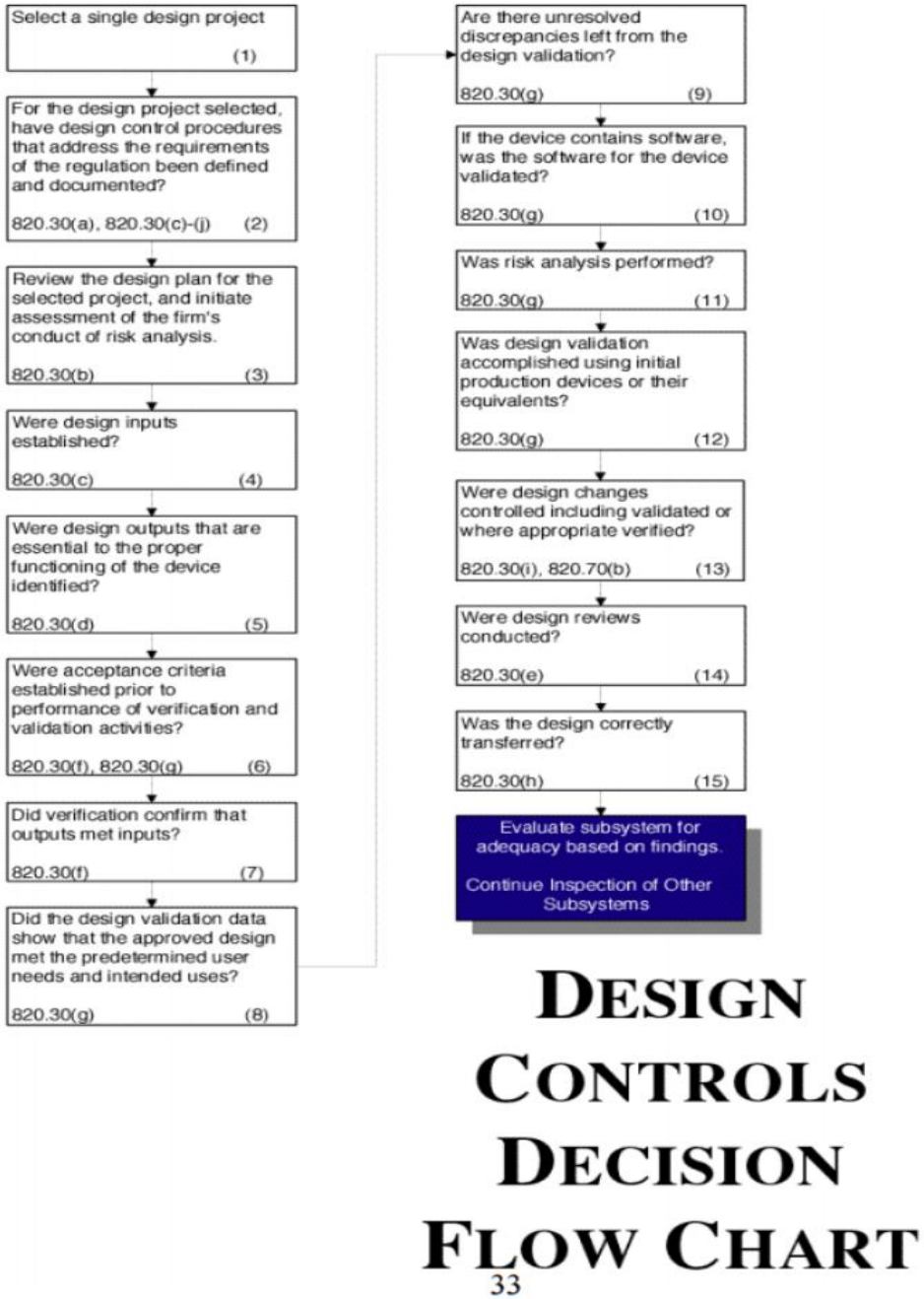
12．确定是否使用最初的设备或其等效物完成设计确认。

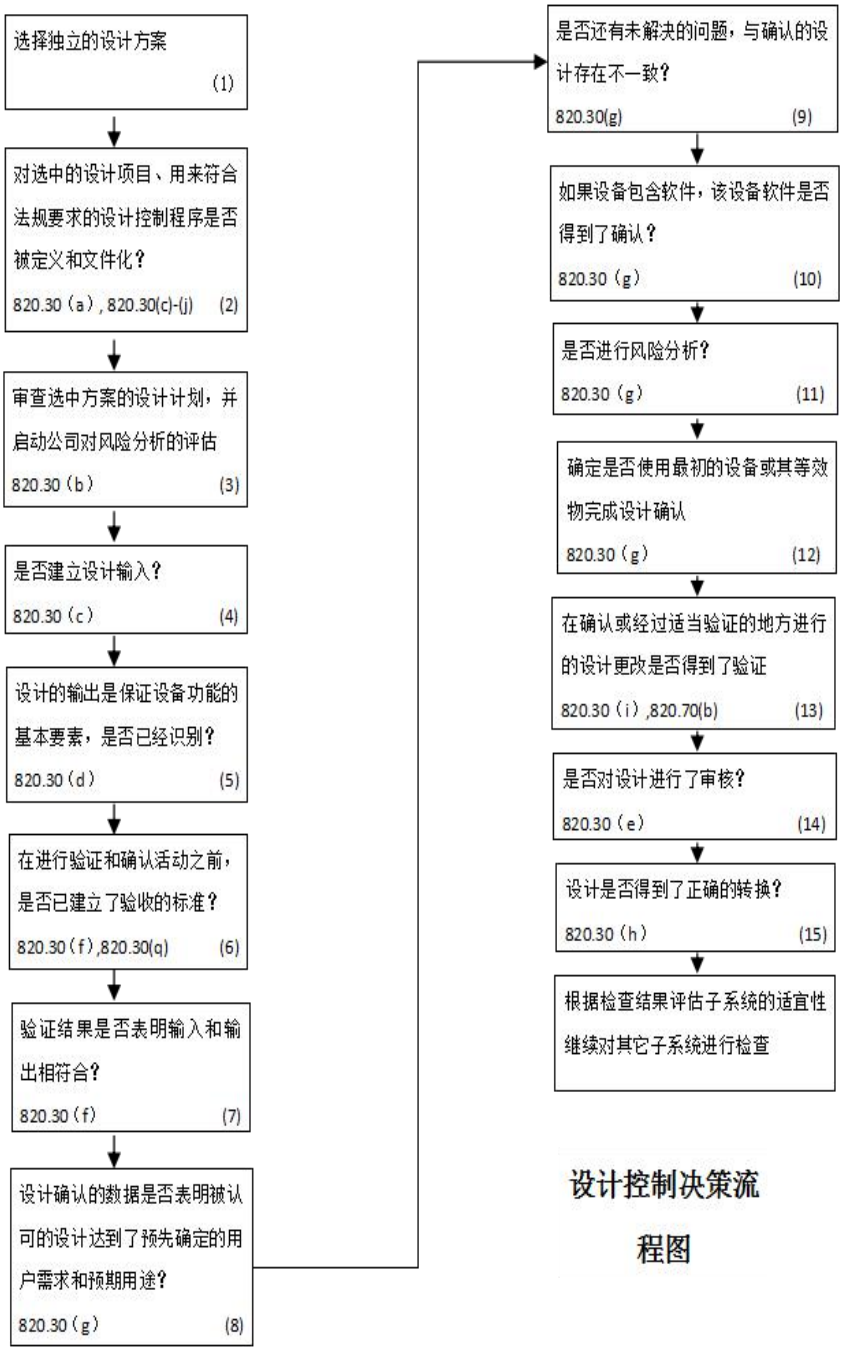
13．确保设计更改被控制，包括确认或经过适当验证的地方。

14．确定设计评审是否被执行，

15．确定设计是否经过正确转换。

5.2 决策流程图


Select a single design project (1)
For the design project selected, have design control procedures that address the requirements of the regulation been defined and documented? 820.30(a), 820.30(c)-(j) (2)
Review the design plan for the selected project, and initiate assessment of the firm's conduct of risk analysis. 820.30(b) (3)
Were design inputs established? 820.30(c) (4)
Were design outputs that are essential to the proper functioning of the device identified? 820.30(d) (5)
Were acceptance criteria established prior to performance of verification and validation activities? 820.30(f), 820.30(g) (6)
Did verification confirm that outputs met inputs? 820.30(f) (7)
Did the design validation data show that the approved design met the predetermined user needs and intended uses? 820.30(g) (8)
Are there unresolved discrepancies left from the design validation? 820.30(g) (9)
If the device contains software, was the software for the device validated? 820.30(g) (10)
Was risk analysis performed? 820.30(g) (11)
Was design validation accomplished using initial production devices or their equivalents? 820.30(g) (12)
Were design changes controlled including validated or where appropriate verified? 820.30(i), 820.70(b) (13)
Were design reviews conducted? 820.30(e) (14)
Was the design correctly transferred? 820.30(h) (15)
Evaluate subsystem for adequacy based on findings.
Continue Inspection of Other Subsystems
DESIGN CONTROLS DECISION FLOW CHART
33


选择独立的设计方案 (1)
对选中的设计项目、用来符合法规要求的设计控制程序是否被定义和文件化？ 820.30（a）, 820.30(c)-(j) (2)
审查选中方案的设计计划，并启动公司对风险分析的评估 820.30（b） (3)
是否建立设计输入？ 820.30（c） (4)
设计的输出是保证设备功能的基本要素，是否已经识别？ 820.30（d） (5)
在进行验证和确认活动之前，是否已建立了验收的标准？ 820.30（f）,820.30(q) (6)
验证结果是否表明输入和输出相符合？ 820.30（f） (7)
设计确认的数据是否表明被认可的设计达到了预先确定的用户需求和预期用途？ 820.30（g） (8)
是否还有未解决的问题，与确认的设计存在不一致？ 820.30(g) (9)
如果设备包含软件，该设备软件是否得到了确认？ 820.30（g） (10)
是否进行风险分析？ 820.30（g） (11)
确定是否使用最初的设备或其等效物完成设计确认 820.30（g） (12)
在确认或经过适当验证的地方进行的设计更改是否得到了验证 820.30（i）,820.70(b) (13)
是否对设计进行了审核？ 820.30（e） (14)
设计是否得到了正确的转换？ 820.30（h） (15)
根据检查结果评估子系统的适宜性继续对其它子系统进行检查

设计控制决策流程图

5.3 Narrative

Purpose/Importance

The purpose of the design control subsystem is to control the design process to assure that devices meet user needs, intended uses, and specified requirements. Attention to design and development planning, identifying design inputs, developing design outputs, verifying that design outputs meet design inputs, validating the design, controlling design changes, reviewing design results, transferring the design to production, and compiling a design history file help assure that resulting designs will meet user needs, intended uses and requirements.

(1) Select a single design project.

Note: If the project selected involves a device that contains software, consider reviewing the software's validation while proceeding through the assessment of the firm's design control system.

The design control requirements of Section 820.30 of the regulation apply to the design of Class II and III medical devices, and a select group of Class I devices. The regulation is very flexible in the area of design controls. The type of design control system and the precise details of implementation are left for each firm to decide based on the complexity and risks associated with their devices.

If design control requirements are applicable to the operations of the firm, select a design project. Unless the inspection assignment directs the inspection of a particular design project, select a project that provides

5.3 解释

目的/重要性

设计控制子系统的目的是控制设计过程，以保证设备符合用户的需求，预期用途及特殊的需求。重视设计和开发策划，确定设计输入和输出，验证设计输出满足设计输入，确认设计、控制设计变更、评审设计结果、将设计转移到生产中，并编制设计历史文件，确保设计结果满足用户需求、预期用途和要求。

(1) 选择单独的设计方案

注：如果项目中的涉及的设备包含有软件，在评估公司设计控制系统的过程中，考虑审查软件确认。

820.30 节中的设计控制要求适用 Class Ⅱ和 Class Ⅲ医疗设备，以及一些特定的 Class Ⅰ设备。
法规有关设计控制的条款是非常灵活的。设计控制系统的类型和一些操作的详细程度由各个公司按照有关设备复杂度和风险决定。

如果设计控制的要求对公司的运作是可行的，可选择一个设计方案 。只要检查没有特定指向一个特别的设计方案，就应该选择一个对公司设计控制

the best challenge to the firm's design control system. This project will be used to evaluate the process, the methods, and the procedures that the firm has established to implement the requirements for design controls.

系统最具有挑战性的方案。这个方案可用来评估公司建立起的为满足设计控制要求的过程、方法和程序。

Do not inspect a device under design control requirements to determine whether the design was appropriate or safe and effective. This is precluded under Section 520(f)(1)(A) of the Act. However, if based on information obtained during an evaluation of the firm's design controls, it appears that the device is unsafe or ineffective, then report those findings in the EIR.

不要在设计控制要求下去检查设备以确定设计是否合适或安全和有效。这个在法案的第 520（f）(1)(A)中是被排除在外的。但是，如果根据对一个公司的设计控制进行评估时，得到设备是不安全或不有效的结论，那么应该将这些结果列入 EIR 报告中。

The requirement for software validation is included in Section 820.30(g) Design Validation. However, if the project selected involves a device that contains software, consider reviewing the software's validation while proceeding through the assessment of the firm's design control system.

软件确认的要求包含在第 820.30（g）部分的设计确认中。不管怎样，当一个选中的方案涉及的设备包含软件时，要求在对公司的设计控制系统进行评估时，对软件确认进行审核。

If the firm has not completed a design project, has no ongoing or planned design projects, and has not made a design change, proceed to the narrative discussion under Objective 2 and limit your review of design controls to those instructions.

如果公司尚未完成一个设计方案，也没有正在进行中或计划中的设计方案，以及没有做设计变更，在目标 2 下进行解释性讨论，并将设计控制的审核局限在审核这些指导书上。

(2) For the design project selected, verify that design control procedures that address the requirements of Section 820.30 of the regulation have been defined and documented.

（2）对于选中的设计方案，验证体系法规中第 820.30 节要求的设计控制的程序是否被定义和文件化。

Firms, including small firms and those who design

设计简单设备的公司、小的企业

simple devices, who are subject to Section 820.30 of the regulation, are required to define, and document, either in writing or electronically, procedures which address the requirements of the regulation. These procedures serve to set the structure for the firm's design control system.

和工厂，遵循法规的第 820.30 节的要求，必须以书面或电子的形式，确定和文件化体现这些法规要求的设计控制程序。在这些程序的基础上将建立起公司的设计控制系统。

However, if the firm has not completed any design projects, has no ongoing or planned design projects, and has not made a design change, it is only required to maintain a defined and documented design change procedure.

但是，如果公司尚未完成一个设计方案，也没有正在进行中或计划中的设计方案，以及没有作设计变更，那么将只要求具备一个定义的和文件化的设计变更程序。

Review the firm's design control procedures and verify that they address the specific requirements of the regulation. As examples, determine if the design input procedures include a mechanism for addressing incomplete, ambiguous, or conflicting requirements; the design output procedures ensure that those design outputs that are essential for the proper functioning of the device are identified; and the design review procedure ensures that each design review includes an individual(s) who does not have direct responsibility for the design stage being reviewed.

审查公司的设计控制程序，并验证他们对法规中特定要求的表述。比如，判断设计输入程序是否包含有一个辨明不完整的、模糊的或矛盾的需求的机制；设计输出程序是否确保了对设备正常运行所必需的那些设计输出进行了识别；设计评审程序是否可以确保每个设计评审都能与被评审的设计阶段联系并没有直接责任个体或多人。

In order to determine if the firm's design control procedures have been implemented, use the selected design project to exercise the firm's procedures and accomplish the following objectives.

为了弄清楚公司的设计控制程序是否得到了落实，可以使用选择的设计方案来运行该公司的程序，以期达到以下的目标。

（3）Review the design plan for the selected project to understand the layout of the design and development activities including assigned

（3）审查选定项目的设计计划，以理解设计和开发活动的开展，包括职责分工和接口。

responsibilities and interfaces.

Note: Evaluate the firm's conduct of risk analysis while proceeding through the assessment of the firm's Design Control system.

注：在对公司的设计控制程序系统进行评估的同时，要对公司的风险管理进行评价。

The firm's development of concepts and the conduct of feasibility studies are not subject to the design control requirements of the regulation. However, once the firm decides that a design will be developed, a design plan must be established. A firm will determine when it will begin to apply design controls. However, design controls must be applied no later than the time the firm approves its first set of inputs.

公司观念的形成和可行性研究不受法规中设计控制要求的约束。但是，一旦公司决定要展开一项设计，必须建立起设计计划，公司要确定什么时候开始实施设计控制。而且设计控制最迟不得晚于公司认可首次设计输入的时间。

Utilize the firm's design plan as a road map for the selected design project. Plans include major design tasks, project milestones, or key decision points. It is not necessary for plans to show starting or completion dates for activities covered by the plan. Plans may vary depending on the complexity of the project and the degree of risk associated with the device. Plans may take the form of a simple flow chart for less complex projects or may be expressed as Program Evaluation and Review Technique (PERT) or Gantt charts for larger projects. However, plans must define responsibility for implementation of the design and development activities and identify and describe interfaces with different groups or activities.

可以利用公司的设计计划，作为选中设计方案的路线图。计划包括主要的设计任务、项目阶段标志、或关键决策点。没有必要在计划里明确计划所涵盖的活动开始或完成的日期，计划会由于方案的复杂程度不同及设备有关的风险差异而不同。对于相对简单的设计，计划可以采取简单流程图表的形式；对于比较大的项目可以用计划评估和审查技术（PERT），或以甘特（Gantt）图的形式来表述计划。但计划必须严格确定完成设计和开发活动实施的职责、划分和表述清楚不同小组或活动的相互关系。

While the requirement for the conduct of risk analysis appears in Section 820.30(g) Design Validation, a firm should not wait until they are performing design validation to begin risk analysis. Risk analysis should

法规第 820.30（g）设计确认章节中对风险分析的实施做了要求。公司不能等到他们开始做设计确认时才进行风险分析，风险分析应列入设计计

be addressed in the design plan and risk should be considered throughout the design process. Risk analysis must be completed in design validation.

When conducting risk analysis, firms are expected to identify possible hazards associated with the design in both normal and fault conditions. The risks associated with those hazards, including those resulting from user error, should then be calculated in both normal and fault conditions. If any risk is deemed unacceptable, it should be reduced to acceptable levels by the appropriate means, for example by redesign or warnings. An important part of risk analysis is ensuring that changes made to eliminate or minimize hazards do not introduce new hazards.

Common tools used by firms to conduct risk analyses include Fault Tree Analysis (FTA), and Failure Modes and Effects Analysis (FMEA).

（4）Confirm that design inputs were established.

Inputs are the requirements of a device. They must be documented. Review the sources used to develop inputs. Determine that relevant aspects were covered. Examples of relevant aspects include: intended use, performance characteristics,risk, biocompatibility, compatibility with the environment of intended use including electromagnetic compatibility, human factors, voluntary standards, and sterility.

划，在整个过程中要考虑风险，必须在设计确认中完成风险分析。

当进行风险分析时，公司需识别与设计有关的正常和故障条件情况下的可能的危害，这些危害相关的风险，包括由于使用者的错误造成危害产生的风险，也应该按正常和故障条件分别计算。假定任何风险的确是不可接受的，要通过合适的方式降低这种风险达到可接受的水平，比如重新设计或设置警示。要注意风险分析中的一个重要方面是确保任何为降低或减少危害而作的变更不能引发新的危害。

公司用来进行风险分析的通用工具有：故障树分析 FTA，故障模式和效应分析 FMEA.

（4） 证实设计输入建立

输入是设备的要求，要将设计输入文件化。评估生成输入的来源，看是否涵盖了相关的方方面面。相关举例有：预期的用途，性能特征，风险，生物兼容性，与预期用途相关的环境兼容性问题（包括电磁兼容性），人的因素，自愿执行标准及无菌问题。

（5）Verify that the design outputs that are essential for the proper functioning of the device were identified.

Design outputs are the work products or deliverables of a design stage. Examples include, diagrams, drawings, specifications and procedures. The outputs from one stage may become inputs to the next stage. The total finished design output consists of the device, its packaging and labeling, and the device master record. Important linkages to consider are Sections 820.80 Receiving, in-process, and finished device acceptance, 820.120 Device labeling, and 820.130 Device packaging.

Design projects can produce a large volume of records. Not all of the records generated during the project are design outputs and as such do not need to be retained in the design history file. Only approved outputs need to be retained.

Outputs must be comprehensive enough to characterize the device design to allow for verification and validation. Also, design outputs which are essential for the proper functioning of the device must be identified. Typically a risk analysis tool such as FTA or FMEA is used to determine essential outputs. For the selected project, verify that essential outputs have been identified. In addition, review the firm's process for determining how the essential outputs were identified and determine if it was done in accordance with their design output procedures. Important linkages to consider are Sections 820.50 Purchasing controls, and 820.100 Corrective and preventive action.

（5）确认识别了对特定的设备功能必不可少的设计输出

设计输出是设计阶段的工作成果或交付物，例如图表，图片，规格和程序。一个阶段的输出可能是下一个阶段的输入。总的最后设计输出包括设备、设备的包装和标识及设备主记录。需要的重要连接可以参见第820.80 节进货设备、过程设备和最终设备接收准则，第 820.120 节设备标签，第 820.130 节设备包装。

设计方案会产生大量的记录，但并不是所有的项目中产生的记录都是设计输出，也就不需要都保留在设计历史文件中，只是把这些记录中得到认可的设计输出保留下来。

输出必须足够广泛和全面描述设备的设计，以得到验证和确认。同时，必须识别作为设备正确功能所必不可少的设计输出。典型的做法是用风险分析工具如 FTA 或 FMEA 来判定基本输出。对于选中的项目，要核实已经进行了基本输出的识别。另外，评审公司的程序，确定如何识别必要的设计输出，并确定是否符合设计输出程序。重要的信息可参考看：第 820.50 节采购控制，第 820.100 节纠错和预防措施。

(6) Confirm that acceptance criteria were established prior to the performance of verification and validation activities.

Verification and validation activities should be predictive rather then empiric. Acceptance criteria must be stated up front. Review the documentation associated with a sample of verification activities and a sample of validation activities as determined using the Sampling Tables. If possible, select activities that are associated with outputs identified as essential to the proper functioning of the device. Confirm that acceptance criteria were established prior to performance of the verification or validation activity.

（6）确保接收准则的建立在验证和确认活动之前进行

验证和确认行为应该是有预见性的而不是经验主义的。可接受标准必须提前说明。使用样本表对与验证和确认样本活动有关的文件进行评审。可能的话，应该选择与设计输出相关的活动，且这些输出必须是被认定为对设备的正常运行至关重要。证实接收准则的建立是否是在验证和确认活动之前。

（7）Determine if design verification confirmed that design outputs met the design input requirements.

Design verification activities are performed to provide objective evidence that design output meets the design input requirements. Verification activities include tests, inspections, analyses, measurements, or demonstrations. Activities should be explicit and thorough in their execution. It is the firm's responsibility to select and apply appropriate verification techniques. Complex designs can require more and different types of verification activities than simple designs. Any approach selected by the firm, as long as it establishes conformance of the output to the input, is an acceptable means of verifying the design with respect to that requirement.

（7）确定设计验证是否证实了设计输出满足设计输入的要求。

实施设计验证活动可以提供客观证据证明设计输出符合设计输入要求，验证活动包括：测试、检查、分析、测量或证明。活动的进行应该是明确和彻底的。公司有责任选择和运用合适的验证技术。和简单的设计相比，复杂的设计需要更多及不同的验证活动。无论公司选择那种方法，只要它能够证明输入满足输出的要求，就应该认为是一种符合要求的设计验证的方法。

Review the documentation of the verification activities associated with a sample of inputs and outputs as determined using the Sampling Tables. If possible, select activities that are associated with outputs

使用样本表，对与输入和输出样本有关的验证活动的文件进行评审。可能的话，应该选择与设计输出相关的活动，且这些输出必须是被认定为

identified as essential to the proper functioning of the device. Confirm that design outputs met design input requirements.

（8）Confirm that design validation data show that the approved design met the predetermined user needs and intended uses.

Design validation is performed to provide objective evidence that device specifications (outputs) conform with user needs and intended use(s). Design validation must be completed before commercial distribution of the device.

Design validation involves the performance of clinical evaluations and includes testing under actual or simulated use conditions. Clinical evaluations can include clinical investigations or clinical trials, but they may only involve other activities. These may include evaluations in clinical or nonclinical settings, provision of historical evidence that similar designs are clinically safe, or a review of scientific literature. Validation activities must address the needs of all relevant parties (i.e. patient, health care worker, etc.) and be performed for each intended use. Validation activities should address the design outputs of labeling and packaging. These outputs may have human factor implications, and may adversely affect the device and its use.

If possible, review the evaluations (clinical or other activities) performed to assist in validating the device design.

（9）Confirm that the completed design validation did not leave any unresolved discrepancies.

对设备的正常运行至关重要，证实设计输出符合设计输入的要求。

（8）确认设计确认数据能显示已批准的设计是否满足预期用户需求和预期用途

设计的确认是要提供客观证据来证明设备规格(输出)满足用户要求和预期用途。设计确认必须在设备进行商业分销前完成。

设计确认涉及临床性能评价，包括在实际或模拟使用条件下的测试。临床评价可以包括临床调查或临床试验，但他们可能仅涉及其他活动。可能包括在临床或非临床环境下的评估，提供类似设计在临床上安全的历史证据，或者是科学文献的审核。确认活动必须详述各方（例如病人、健康护理人员等等）的要求，对每种预期用途都要进行确认。确认活动要涉及标识和包装设计输出，这些输出要考虑人的要素，否则可能会对设备和使用产生不良影响。

如果可能，评审用来确认设备设计的评价活动（临床的或其他活动）。

（9）证实已完成的设计确认没有留下任何未解决的问题。

Design validation may detect discrepancies between the device specifications (outputs) and the needs of the user or intended use(s) of the device. All discrepancies must be addressed and resolved by the firm. This can be accomplished through a change in design output or a change in user need or intended use.

（10）If the device contains software, confirm that the software was validated.

As previously noted, design validation includes the requirement for software validation. If the selected device is software controlled its software must be validated.

（11） Confirm that risk analysis was performed.

As previously noted, risk analysis must be completed in design validation.

(12) Determine if design validation was accomplished using initial production devices or their equivalents.

Initial production units, lots, or batches, or their equivalents are to be used in design validation. Confirm that such production devices or their equivalents were used by reviewing the design validation documentation. If production devices were not used, the firm must demonstrate equivalency to production devices. When the so called "equivalent" devices are used in design validation the manufacturer must document in detail how the device was manufactured, and how the manufacturing is similar and possibly different from initial production. Where there are differences, the manufacturer must justify why design validation results are valid for production units, lots or batches. The regulation is flexible and it does allow for the use of equivalent devices, but the

设计的确认中可能会发现在设备的规格（输出）和用户要求或预期用途之间存在的差异。公司要列出所有差异并逐一解决。可以通过修改设计输出或修改用户要求或预期用途来达到这个目的。

（10）如果设备包含软件，要确认该软件是经过确认的。

正如前文所述，设计确认包括对软件的确认。如果所选择的设备是由软件控制的，必须对软件进行确认。

（11）确认进行了风险分析

如前文所述，在设计确认中要完成风险分析的工作。

（12）确定设计确认是否是用最初的生产设备或其等同的设备完成的。

最初的生产单元、种类、或批次或与他们相关的等价物都会用来对设计进行确认。确认在评审设计确认文件时使用的是这些生产设备或其等同的设备。如果公司没有使用生产设备，公司必须证明与生产设备相当。当在设计验证中使用所谓的“等效”设备时，制造商必须记录设备是如何制造和最初的产品如何相类似或有什么可能的差别的细节。如果存在差异，制造商必须证明设计确认结果对这些产品单元、种类、或批次是有效的。法规是具有很大的的灵活性，允许使用等同设备，但制造商要承担证明该产品的确是同类产品的等效设备。

burden is on the manufacturer to document that the units were indeed equivalent.

Process validation may be conducted concurrently with design validation. Production devices used in design validation may have been manufactured in a production run during process validation.

过程确认可以与设计确认一同进行，在设计确认中使用的生产设备可能就是在过程确认中试生产过程而制造出来。

(13) Confirm that changes were controlled including validation or where appropriate verification.

（13）证实在确认或验证过程中发生的设计更改是受控的。

Change control is not a new requirement. The 1978 GMP regulation Section 820.100(a)(2) required approval of changes made to specifications after final design transfer (post-production changes). The Quality System regulation clarified and relocated the requirement into Section 820.30(i). It expanded the requirement to include changes made during the design process (pre-production changes).

变更控制并不是一个新的要求，在 1978 年 GMP 法规中的第 820.110（a）（2）节中要求在最后的设计转换后（生产后的变更）对规格的变更要得到批准。质量体系法规中更要明确并将要求重新放入第 820.30（i）节中，并将要求扩展到设计过程中的变更（生产前的变更）。

The documentation and control of design changes begin when the initial design inputs are approved and continues for the life of the product. Examples of the application of change control include: changes made to approved inputs or outputs such as to correct design deficiencies identified in the verification and validation activities; labeling changes; changes which enhance the device's capabilities or the capabilities of the process; and changes resulting from customer complaints.

设计变更的文档和控制始于最初批准的设计输入，并贯穿到产品的整个周期。有关变更控制的应用例子有：为了修正在验证和确认活动中识别的缺陷而对已批准的输入或输出进行变更；标志变更；加强设备的能力或过程能力的变更；还有根据客户抱怨引起的变更。

Product development is inherently an evolutionary process. While change is a healthy and necessary part of product development, quality can be ensured only if

产品开发是一种固有的渐进的过程，产品的更改是对产品开发有益和必要的，只有在开发过程以及生产过

change is controlled and documented in the development process, as well as in the production process. The degree of design change control is dependent on the significance of the change and the risk presented by the device. Manufacturers may use their routine post-production change control procedure for pre-production design changes. However, most post-production change control procedures may be too restrictive and stifle the development process. Firms may use a separate and less stringent change control procedure for pre-production design changes.

程中对变更进行控制和文件记录，这样才能对质量有所保证。设计变更控制的程度取决于变更的大小和设备产生的风险。对于生产前的设计变更，制造商可能会使用他们常用的生产后变更控制程序。但是，大多数的生产后变更控制程序非常局限而且限制开发过程。很多公司用一种单独的、不是很苛刻的变更控制程序进行生产前的设计变更。

Post-production design changes require the firm to loop back into the design controls of Section 820.30 of the regulation. This does not mean that post-production changes have to go back to the R&D Department for processing.This track is dependent on what the firm specifies in their change procedure. It is acceptable for the manufacturing department to process the entire design change and to implement the controls of Section 820.30.

生产后设计变更要求公司返回法规第 820.30 节的设计控制中，这并不意味着生产后变更必须回到研发部门进行处理。这种溯源取决于公司是如何制定其变更程序的。允许生产部门处理所有的设计变更并完成第 820.30 节中所述的控制。

The design change control section is linked to and is redundant with Section 820.70(b) Production and process changes of the regulation.

设计变更控制部分和法规的第820.70（b）节生产和过程变更相联系，是这一节的补充内容。

All design changes must be verified. Design changes must also be validated unless the performance of only verification can be justified and documented by the firm. Where a design change cannot be verified by subsequent inspection and test, it must be validated. For example, a change in the intended use of the device will require validation. However, if a firm was

要验证所有的设计更改。设计更改同样也必须进行确认，除非公司以文件形式证明只进行的验证是合理的。当设计更改不能通过相应的检测和测试进行验证，这种更改必须进行确认。比如，对设备的预期用途的改动就要确认。但是公司对设备使用的

making a design change in the material used in the device, then verification through analysis may only be required. The burden is on the firm to justify and document why verification only is appropriate in lieu of validation. Review a pre-production and a post-production design change.

材料进行了设计更改，只需要通过分析进行验证。公司的责任在于证明和记录为什么适当的验证可以替代确认。评审生产前和生产后的设计更改。

(14) Determine if design reviews were conducted.

Formal design reviews are planned and typically conducted at the end of each design stage or phase, or after completion of project milestones. The number of reviews is dependent on the complexity of the design. A single review may be appropriate at the conclusion of the design project for a simple design or a minor change to an existing product. Multiple reviews are typically conducted for projects involving subsystems or complex designs.

（14）确定是否进行了设计评审

正式的设计评审通常是在每个设计阶段结束时实施，或在项目阶段标志完成之后进行。评审的次数是依据设计的复杂性，对一个简单的设计或者对现存产品的微小变更，就可以在设计项目终结时，进行一次审查。多重审查常适用于涉及多个子系统的项目或复杂设计。

Design reviews should provide feedback to designers on existing or emerging problems, assess the progress of the design, and confirm the design is ready to move to the next phase of development. Reviews should focus on the ability to produce the design and whether the design meets the input requirements.The design review process should account for risk analysis and change control where relevant.

设计评审要将以下信息反馈给设计者：存在的或新出现的问题，对设计改进的评估以及设计可以进入下一阶段的确认结论。要集中评审设计的能力和设计是否满足输入要求方面。评审设计的方法要和相应的风险分析和变更控制一致。

Full convened meetings with an agenda, minutes, etc. Need not take place for all design reviews. Meetings may not be necessary for reviews involving simple designs or minor changes. In these cases desk reviews and sign-offs by the various organizational components

并不是所有设计评审都要召集各方开会，并制定会议日程、记录会议摘要等。对于简单的设计或微小的变更就没有必要开会。在这种情况下，可以组织一个小型评审和结束会，参

including an individual not having direct responsibility for the design stage being reviewed may be appropriate. However, such reviews must still be documented and covered by defined and documented procedures.

与会议的是不同的组织成员，包括对被审查的设计阶段没有直接责任的个人。但是，这种审查也要有记录，并需要有已定义和文档化的程序。

Review the records of one design review and confirm that the review included an individual without direct responsibility for the design stage being reviewed. Also, confirm that outstanding action items are being resolved or have been resolved.

评审某个设计评审记录，确认评审各方中含有与被评审设计阶段无直接责任关系的个人。另外，要确认未解决的任务正在处理中或已经解决完毕。

(15) Determine if the design was correctly transferred.

（15）确定设计是否得到了正确的转换。

The transfer process must be a part of the design plan. It is not uncommon for the design to be transferred in phases. Production specifications typically consist of written documents such as assembly drawings, inspection and test specifications, and manufacturing instructions. However, they can also consist of electronic records, training materials such as video tapes or pictures, and manufacturing jigs and molds.

设计计划中必须有转换处理的内容。一般设计不会分阶段地转换，生产规范通常包括一些书面的文件，如装配图、检验和试验规范以及生产说明书。当然，也可以有电子文档、培训资料，如录像带、图片，还有生产夹具和模具等。

Review how the design was transferred into production specifications. Review the device master record. Sample the significant elements of the device master record using the Sampling Tables and compare these with the approved design outputs. These elements may be chosen based on the firm's previously identified essential requirements and risk analysis.

评审设计是如何成为产品规范的。评审设备主记录。利用样本表对设备主记录的重要的元素进行采样，将得到样本与经批准的设计输出进行比较。元素的选取可以依据公司先前确定的基本需求和风险分析。

6. Corrective and Preventive Actions (CAPA)

6. 纠正和预防措施（CAPA）

6.1 Inspectional Objectives

6.1 检查目的

1. Verify that CAPA system procedure(s) that address

1．验证符合质量体系法规要求的

the requirements of the quality system regulation have been defined and documented.

2. Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.

3. Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.

4. Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate and timely.

5. Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.

6. Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.

7. Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.

8. Determine if corrective and preventive actions were effective and verified or validated prior to

CAPA 系统的程序被定义和文件化。

2．确定是否有适当产品和质量问题的来源已经被识别，确认对来自这些来源的数据进行分析，以确定可能需要纠正措施的现有产品和质量问题。

3．确认是否存在显示不利于趋势的产品和质量信息来源被识别，确保这些来源的数据被分析，以识别需要预防措施的潜在的产品和质量问题。

4．评估质量数据信息系统，验证被 CAPA 系统接受的数据是完整的、准确的和及时的。

5．验证使用正确的（必要时）统计学方法检查重复发生的质量问题，测定分析的结果是否对不同数据来源相比较，以鉴定和发现产品和质量问题的范围。

6．确认是否符合故障调查程序，检查被调查的质量问题或不合格产品的程度是否与不合格产品的重要性和风险性相称。检测是否存在为确定根本原因（可能的地方）而执行的不正确的调查，验证是否有对防止不合格产品销售的控制。

7．确认由数据源确定的重大产品和质量问题是否采取了适当的措施。

8．确认纠正和预防措施是否有效，并在实施前是否得到验证或确认，确保

implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.

纠正和预防措施没有对成品器械造成负面影响。

9. Verify that corrective and preventive actions for product and quality problems were implemented and documented.

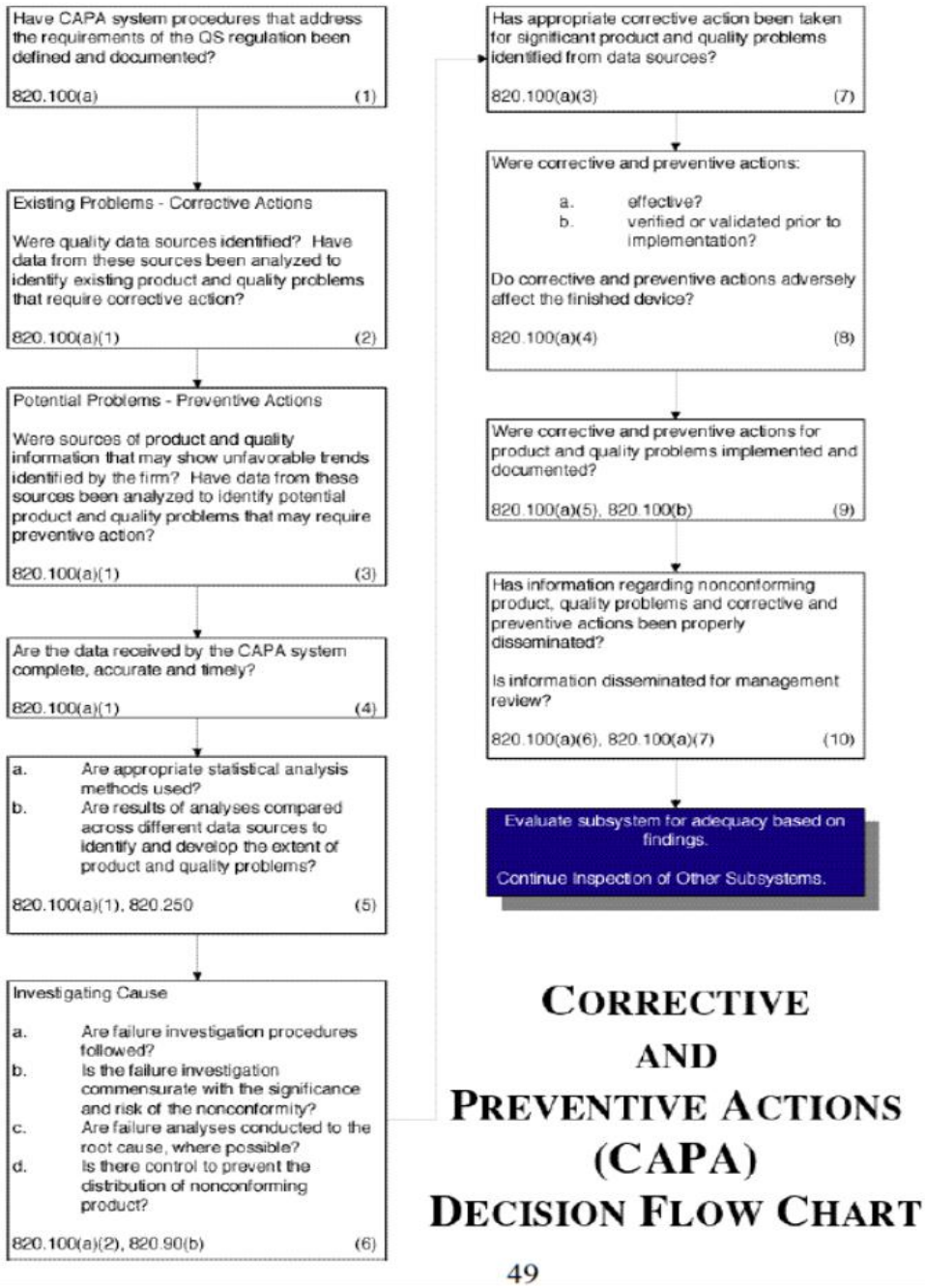
9．验证对产品和质量问题的纠正和预防措施是否被执行且有文件记录。

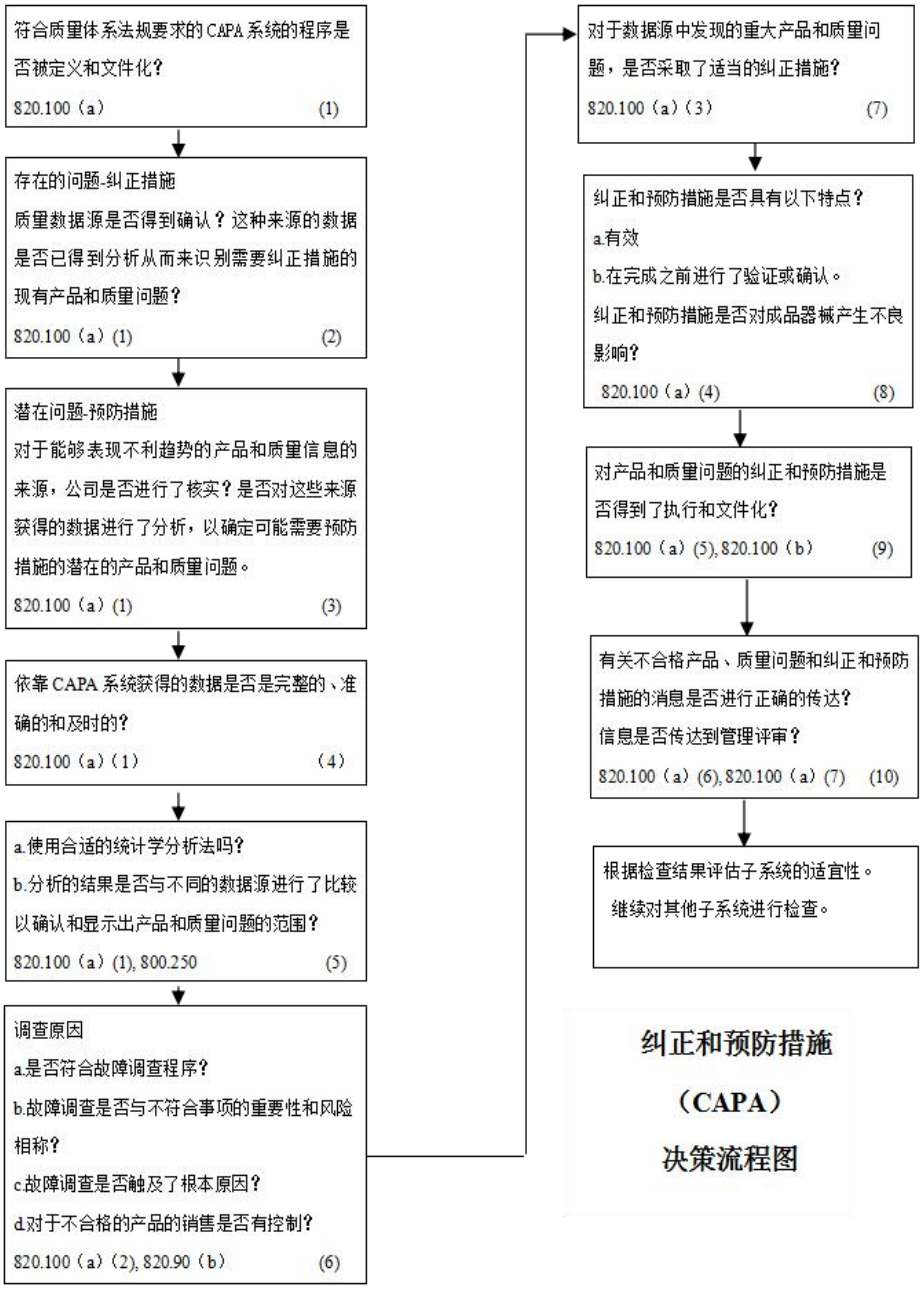
10. Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review.

10．确认关于不合格产品和质量问题、纠正与预防行动的信息是否被正确的传递，包括传递到管理评审。

6.2 Decision Flow Chart

6.2 决策流程图


Have CAPA system procedures that address the requirements of the QS regulation been defined and documented?
820.100(a) (1)
Existing Problems - Corrective Actions
Were quality data sources identified? Have data from these sources been analyzed to identify existing product and quality problems that require corrective action?
820.100(a)(1) (2)
Potential Problems - Preventive Actions
Were sources of product and quality information that may show unfavorable trends identified by the firm? Have data from these sources been analyzed to identify potential product and quality problems that may require preventive action?
820.100(a)(1) (3)
Are the data received by the CAPA system complete, accurate and timely?
820.100(a)(1) (4)
a. Are appropriate statistical analysis methods used?
b. Are results of analyses compared across different data sources to identify and develop the extent of product and quality problems?
820.100(a)(1), 820.250 (5)
Investigating Cause
a. Are failure investigation procedures followed?
b. Is the failure investigation commensurate with the significance and risk of the nonconformity?
c. Are failure analyses conducted to the root cause, where possible?
d. Is there control to prevent the distribution of nonconforming product?
820.100(a)(2), 820.90(b) (6)
Has appropriate corrective action been taken for significant product and quality problems identified from data sources?
820.100(a)(3) (7)
Were corrective and preventive actions:
a. effective?
b. verified or validated prior to implementation?
Do corrective and preventive actions adversely affect the finished device?
820.100(a)(4) (8)
Were corrective and preventive actions for product and quality problems implemented and documented?
820.100(a)(5), 820.100(b) (9)
Has information regarding nonconforming product, quality problems and corrective and preventive actions been properly disseminated?
Is information disseminated for management review?
820.100(a)(6), 820.100(a)(7) (10)
Evaluate subsystem for adequacy based on findings.
Continue Inspection of Other Subsystems.
CORRECTIVE AND PREVENTIVE ACTIONS (CAPA) DECISION FLOW CHART
49


符合质量体系法规要求的CAPA系统的程序是否被定义和文件化？
820.100（a） (1)
存在的问题-纠正措施
质量数据源是否得到确认？这种来源的数据是否已得到分析从而来识别需要纠正措施的现有产品和质量问题？
820.100（a）(1) (2)
潜在问题-预防措施
对于能够表现不利趋势的产品和质量信息的来源，公司是否进行了核实？是否对这些来源获得的数据进行了分析，以确定可能需要预防措施的潜在的产品和质量问题。
820.100（a）(1) (3)
依靠CAPA系统获得的数据是否是完整的、准确的和及时的？
820.100（a）（1） （4）
a.使用合适的统计学分析法吗？
b.分析的结果是否与不同的数据源进行了比较以确认和显示出产品和质量问题的范围？
820.100（a）(1), 800.250 (5)
调查原因
a.是否符合故障调查程序？
b.故障调查是否与不符合事项的重要性和风险相称？
c.故障调查是否触及了根本原因？
d.对于不合格的产品的销售是否有控制？
820.100（a）(2), 820.90（b） (6)
对于数据源中发现的重大产品和质量问题，是否采取了适当的纠正措施？
820.100（a）(3） (7)
纠正和预防措施是否具有以下特点？
a.有效
b.在完成之前进行了验证或确认。
纠正和预防措施是否对成品器械产生不良影响？
820.100（a）(4) (8)
对产品和质量问题的纠正和预防措施是否得到了执行和文件化？
820.100（a）(5), 820.100（b） (9)
有关不合格产品、质量问题和纠正和预防措施的消息是否进行正确的传达？
信息是否传达到管理评审？
820.100（a）(6), 820.100（a）(7) (10)
根据检查结果评估子系统的适宜性。
继续对其他子系统进行检查。
纠正和预防措施
（CAPA）
决策流程图

6.3 Narrative

Purpose/Importance

The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures. One of the most important quality system elements is the corrective and preventive action subsystem.

（1）Verify that CAPA system procedure(s) that address the requirements of the quality system regulation have been defined and documented.

Review the firm's corrective and preventive action procedure. If necessary, have management provide definitions and interpretation of words or terms such as “nonconforming product”, “quality audit”, “correction”, “prevention”, “timely”, and others. It is important to gain a working knowledge of the firm's corrective and preventive action procedure before beginning the evaluation of this subsystem.

NOTE: Corrective action taken to address an existing product or quality problem should include action to:

- Correct the existing product nonconformity or quality problems and;- Prevent the recurrence of the problem.

6.3 解释

目的/重要性

纠正和预防措施子系统的目的是收集信息、分析作息、识别和调查产品和质量问题，采取适当和有效的纠正措施和/或预防措施以防止他们再次发生。验证或确认纠正预防措施，将纠正预防措施活动传达到有关负责人员，向管理评审方提供有关的信息。记录这些活动对于有效处理产品和质量问题、防止其复发、防止或尽量减少设备故障至关重要。

（1）验证符合质量体系法规要求的 CAPA 系统的程序被定义和被文件化。

审查公司的纠正和预防措施操作程序。 必要的话，要求管理层提供定义或单词或术语的解释，比如不合格产品，质量审核，纠正，预防，及时，以及其他的。在开始对这个子系统进行评估之前，获得公司纠正和预防措施程序的工作知识是很重要的。

注：用于陈述一个现在的产品或质量问题的纠正措施要包括以下内容：纠正现在产品不规范项或质量问题，并且防止问题再度发生。

The CAPA procedure should include procedures for how the firm will meet the requirements for all elements of the CAPA subsystem. All procedures should have been implemented. Once you have gained a knowledge of the firm's corrective and preventive action procedure, begin with determining if the firm has a system for the identification and input of quality data into the CAPA subsystem. Such data includes information regarding product and quality problems (and potential problems) that may require corrective and/or preventive action.

（2）Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.

The firm should have methods and procedures to input product or quality problems into the CAPA subsystem. Product and quality problems should be analyzed to identify product and quality problems that may require corrective action. The firm should routinely analyze quality data regarding product and quality problems. This analysis should include data and information from all acceptance activities, complaints, service, and returned product records. Determine if the firm is capturing and analyzing data from acceptance activities relating to component, in-process and finished device testing. Information obtained subsequent to distribution, which includes complaints, service activities and returned products, as well as information relating to concessions (quality and nonconforming products), quality records, and other sources of quality

CAPA 操作程序要包含公司如何达到 CAPA 子系统所有条目要求而所采取的步骤，而且所有的程序都要得到执行。在了解公司的纠正和预防措施程序后，如果公司设立了识别系统，就开始对它进行确认，对 CAPA 子系统输入一个质量数据。这些数据包括有关可能需要纠正和预防措施的产品和质量问题(和潜在问题)的信息。

（2）确认产品和质量问题的合适来源是否的得到了识别。确认是否对这些来源获得的数据进行了分析以识别可能需要实施纠正措施的已经存在的产品和质量问题。

公司应该有相应的方法和程序将产品或质量问题输入 CAPA 子系统。公司要对产品和质量问题进行分析，识别那些需要实施纠正措施的产品和质量问题。公司要经常分析有关产品和质量问题的质量数据。应包括对所有验收活动、投诉、服务和退货记录的数据和信息进行分析。考察公司是否对来自部件、生产中和成品设备的测试中相关的验收活动采集了数据并进行了分析。从销售中，包括客户投诉、客户服务、返回产品以及让步接收（质量和不合格产品）、质量记录中得到的数据，还有从其他途径得到质量数据，公司都要进行采集和分析。举一些其他途径的质量数据源，比如：

data should also be captured and analyzed. Examples of other sources of quality data include quality audits, installation reports, lawsuits, etc.

质量审核、安装报告、法律投诉等等。

NOTE: In accordance with Agency policy (CPG 7151.02), do not request records regarding the results of internal quality audits, management reviews, third party audits (including ISO audits), or supplier audits. However, you will be reviewing raw data that is used by the firm when conducting their quality audits, management reviews, etc. Trending information and results of analyses are generally part of evaluations under the corrective and preventive action requirements. This information is utilized in internal audits and management reviews. Information or data utilized in internal audits and management reviews are considered raw data and should be available for routine review.

注： 依据机构方针（Agency policy ,CPG 7151.02）,不能要求有关内部质量审核、管理评审、第三方审核（包括 ISO 审核）或供应商审核的记录。但是，当对公司进行质量审核和管理评审等活动时要对他们的原始数据进行审查。按照纠正和预防措施的要求，趋势信息和对其分析的结果也是评估的内容，可用于内部审核和管理评审，适用于内部审核和管理评审的信息或数据为原始数据，在例行审查中应能够得到。

（3）Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.

（3）确定具有不利趋向的产品和质量信息是否得到了识别，核实这些来源的数据是否得到了分析以识别需要实施预防措施的潜在的产品和质量问题。

Determine if the firm is identifying product and quality problems that may require a preventive action. This can be accomplished by reviewing historical records such as trending data, corrective actions, acceptance activities (component history records, process control records, finished device testing, etc.) and other quality system records for unfavorable trends. Review if preventive actions have been taken regarding

确定公司是否识别了可能需要采取预防措施的产品和质量问题。可以通过查相关的历史记录来完成，比如趋势数据、纠正措施、验收活动（组件历史记录，过程控制记录，成品设备测试，等等。）和其他不利趋势的质量体系记录。检查是否对产品和质量信息分析中出现的不利趋势采取预

unfavorable trends recognized from the analysis of product and quality information. Product and quality improvements and use of appropriate statistical process control techniques are evidence of compliance with the preventive action requirement.

防措施。产品和质量的改进以及恰当统计处理控制技术的应用都可以被视作符合预防措施要求的证据。

Determine if the firm is capturing and analyzing data regarding in-conformance product. Examples include capturing and analyzing component test results to detect shifts in test results that may indicate changes in vendor processes, component design or acceptance procedures. Identification of these indicators may necessitate a vendor investigation as a preventive action. Monitoring in-process and finished device test results may reveal additional indicators of potential quality problems. For devices where stability is an issue, test results of reserve samples are continually monitored. These monitoring activities may trigger process changes, additional training activities and other changes required to maintain the process within its tolerances and limits.

确定公司是否收集和分析了有关不合格产品的数据。示例包括收集和分析组件测试结果，以检测测试结果中的变化，这些结果可能表明供应商流程、组件设计或验收程序的变化。识别这些指标可能需要供应商调查作为一种预防措施。监控生产中和成品设备的测试结果 可能揭示潜在质量问题的额外指标。对于强调稳定性的设备，要连续监控储存样本的测试结果。这些监视活动可能引起过程变更、额外的培训活动以及将过程维持在其偏差和限度内所需的其他更改。

Determine if the firm is using statistical control techniques for process controls where statistical techniques are applicable. An example would be “Statistical Process Control”(SPC). SPC is utilized to monitor a process and initiate process correction when a process is drifting toward a specification limit. Typically, SPC activities are encountered with large volume production processes such as plastic molding and extrusion. Any continuing product improvements (in the absence of identified product problems such as nonconforming product) are also positive indicators of

确定公司是否在统计技术适用的过程控制中使用统计控制技术。可以说明的例子有“统计过程控制”（SPC）。SPC 用来监控过程并可以过程偏离某个规格极限时启动过程纠正。通常情况下，在大批量生产过程中，比如塑料成型和挤出，可以看到 SPC 活动。任何连续的产品改进（不包括已确定的类似不合格品的产品问题）都可以看做是预防措施的积极指标。这些活动的重要信息见：820.70

preventive actions. Important linkages for this activity include 820.70 Production and Process Controls and 820.250 Statistical Techniques.

生产和过程控制与820.250统计技术。

（4）Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate and timely.

（4）确定质量数据信息系统，验证通过 CAPA 系统得到数据是完整、准确和及时的。

Select one or two quality data sources. Using the sampling tables, review records from the chosen data sources to determine if the data were entered into the CAPA system. In addition, determine whether the data are complete, accurate and entered into the CAPA system in a timely manner.

选择一个或两个质量数据源，用样本表，审查选中的数据源中的记录确认是否这些数据被输入 CAPA 系统。另外确定这些数据是否完整、准确和及时输入到 CAPA 系统中。

Important linkages for this activity include 820.80 Acceptance Activities, 820.90 Nonconforming Product, 820.170 Installation, 820.198 Complaint Files and 820.200 Servicing

以上活动的重要链接：820.80 验收活动，820.90 不合格产品，820.170 安装，820.198 投诉文件和 820.200 服务。

（5）Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.

（5）验证使用正确的（必要时）统计学方法检查重复发生的质量问题，测定分析的结果是否可与不同的来源数据相比较，以鉴定和发现产品和质量问题的程度

The analysis of product and quality problems should include appropriate statistical and non-statistical techniques. Statistical techniques include Pareto analysis, spreadsheets, and pie charts. Non-statistical techniques include quality review boards, quality review committees and other methods.

对产品和质量问题的分析应包括合适的统计和非统计技术。统计学技术包括 PARETO 分析、电子表格和饼图表。非统计学技术包括质量审查委员会和其他方法。

The analysis of product and quality problems should

产品和质量问题分析方法还应包

also include the comparison of problems and trends across different data sources to establish a global, and not an isolated view, of a problem. For example, problems noted in service records should be compared with similar problem trends noted in complaints and acceptance activity information.

括不同来源的问题和趋势的比较，以建立对一个问题的全面的相互联系的观点。比如，在维修记录中发现问题，应和在投诉和验收活动信息中发现的相似的问题趋势进行比较。

The full extent of a problem must be captured before the probability of occurrence, risk analysis and the proper course of corrective or preventive action can be determined.

问题的范围应该在其发生概率前获取，那么风险分析和适当的纠正或预防措施就可以被确定下来。

（6）Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.

（6）确认是否符合故障调查程序，检查被调查的质量问题或不合格产品的问题程度是否与不合格产品的重要性和风险性相称。检测是否存在为确定根本原因（可能的地方）而执行的故障调查，验证是否有对防止不合格产品销售的控制

Review the firm's CAPA procedures for conducting failure investigations. Determine if the procedures include provisions for identifying the failure modes, determining the significance of the failure modes (using tools such as risk analysis), the rationale for determining if a failure analysis should be conducted as part of the investigation, and the depth of the failure analysis.

审查公司实施故障调查的 CAPA 程序。确定审查程序中是否有以下规定：鉴定故障模式的规定；确定故障模式严重程度（使用风险分析工具等）的规定；确定故障分析是否应作为调查的一部分的原理，以及故障分析的深度。

Discuss with the firm their rationale for determining if a corrective or preventive action is necessary for an identified trend regarding product or quality problems.

与公司讨论关于产品或质量问题识别的趋势是否有必要采取纠正或预防措施的决策理由。决策过程可能与

The decision process may be linked to the results of a risk analysis and essential device outputs.

风险分析和基本设备输出的结果相关联。

Using the sampling tables, select failure investigation records regarding more than one failure mode (if possible) and determine if the firm is following their failure investigation procedures.

使用样本表，选择一个以上（如果有的话）的故障模式的故障调查记录,考核公司是否遵循了他们的故障调查程序。

Confirm that all of the failure modes from your selected sample of failure investigations have been captured within data summaries such as reports, pie charts, spreadsheets, Pareto charts, etc.

核实来自故障调查选择的样本中所有的故障模式是否包含在数据汇总，如报告、饼图表、电子数据表、Pareto 图表中。

Determine whether the depth of the investigation (where possible) is sufficient (root cause) to determine the corrective action necessary to correct the problem. Select one significant failure investigation that resulted in a corrective action and determine if the root cause had been identified so that verification or validation of the corrective action could be accomplished.

确认调查的深度(如果可能)是否触及了根本原因，以足够用于确定对于纠正问题的纠正措施的必要性。选择一个导致纠正措施的重要的故障调查，考察这个根本原因是否得到了确认，从而可以完成对纠正措施的验证或确认。

Using the sampling tables, review a number of incomplete failure investigations for potential unresolved product nonconformances and potential distribution of nonconforming product. Unresolved problems that could be of significant risk to the patient or user may require product recall if the problem cannot be resolved.

用样本表，审查一些未完成的故障调查，看是否有潜在未解决的不合格产品以及潜在不合格产品的销售。如果问题不能解决，对于可能给病人或用户带来重大风险的未解决的问题可能需要产品召回。

Using the sampling tables, review records regarding nonconforming product where the firm concluded corrective or preventive action was not necessary. As noted above, verify that the firm is not continuing to

用样本表审查公司认定的无需采取纠正或预防措施的不合格产品的记录，按照前面所述的办法，核实公司没有继续销售不合格产品。这可能是

distribute nonconforming product. This may be an important deficiency based on the class of, and the risk associated with, the product.

一个重要的缺陷，基于产品的类别，以及相关的风险。

Important linkages for these activities include 820.20 Management Responsibility, 820.25 Training, 820.30 Design Controls, 820.90 Nonconforming Product and possibly 820.250 Statistical Techniques.

以上这些活动的链接包括：820.20 管理责任，820.25 培训, 820.30 设计控制, 820.90 不合格产品以及可能性，还有 820.250 统计技术。

Using the sampling tables, review nonconforming product and quality concessions. Review controls for preventing distribution of nonconforming products. Product and quality concessions should be reviewed to verify that the concessions have been made appropriate to product risk, within the requirements of the quality system and not solely to fulfill marketing needs. Important linkages regarding these activities include 820.20 Management Responsibility and 820.90 Nonconforming Product.

用样本表审查不合格产品和质量让步。审查防止不合格产品销售的控制。审查产品和质量让步，确认这种让步对于产品的风险是适宜的，是在质量体系的允许范围之内，并不是仅仅为了满足市场需要。有关的活动可以链接：820.20 管理责任和 820.60 不合格产品。

（7）Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.

（7）审查对通过数据源识别出的重大产品和质量问题是否采取了合适的措施。

Where appropriate, this may include recall actions, changes in acceptance activities for components, in-process and finished devices, etc.

在适当的情况下，可能包括召回措施、部件，生产中和成品设备的验收活动中的更改等。

Using the sampling tables, select and review significant corrective actions and determine if the change or changes could have extended beyond the action taken. A significant action would be a product or process change to correct a reliability problem or to bring the product into conformance with product

用样本表选择和审查重要的纠正措施，判断一个或多个变更是否超出了纠正措施的控制。这种重要的措施可能是对产品或过程的变更，用以纠正可靠性问题，或使产品与产品规格保持一致。和公司讨论他们不扩大措

specifications. Discuss with the firm their rationale for not extending the action to include additional actions such as changes in component supplier, training, changes to acceptance activities, field action or other applicable actions. Investigators should discuss and evaluate these issues but be careful not to say anything that could be construed as requesting a product recall.

施的理由，包括增加措施，例如零部件供应商的变更、培训、验收活动变更、现场措施或其他可采用的措施。调查者要讨论和评估这些事项，但要避免说任何可以被解释为要求产品召回的话。

(8) Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.

(8) 确认纠正和预防措施是否有效，并在方案实施之前进行了验证获确认；确定纠正和预防措施不会对成品器械产生不良影响。

Using the selected sample of significant corrective and preventive actions, determine the effectiveness of these corrective or preventive actions. This can be accomplished by reviewing product and quality problem trend results.Determine if there are any similar product or quality problems after the implementation of the corrective or preventive actions. Determine if the firm has verified or validated the corrective or preventive actions to ensure that such actions are effective and do not adversely affect the finished device.

用选择的重要的纠正和预防措施的样本，确定这些纠正或预防措施的有效性。可以通过审核产品和质量问题趋势完成上述任务。审查在实施了纠正或预防措施后是否还会有相似的产品或质量问题。审查公司是否已验证或确认了纠正或预防措施，以确保这些措施的有效性，且不会对成品器械产生不良影响。

Corrective actions must be verified and (if applicable) validated. Corrective actions must include the application of design controls if appropriate. Good engineering principles should include: establishing a verification or validation protocol; verification of product output against documented product requirements and specifications; ensuring test instruments are maintained and calibrated; and that test results are maintained, available and readable.

纠正措施必须得到验证和确认(如适用)。如果可能的话，纠正措施必须包括设计控制的应用。好的操作原则包括:建立一个验证或确认方案；依据已经建立的产品需求和规格验证产品输出；确保测试设备保养良好而且得到了校准；保存测试结果存取方便。有关 CAPA 组成链接；820.30 设计控制和 820.70(b)生产和过程控制。

Important linkages regarding this CAPA element include 820.30 Design Control and 820.70(b) Production and Process Control.

(9) Verify that corrective and preventive actions for product and quality problems were implemented and documented.

Using the sampling tables, select and review records of the most recent corrective or preventive actions (this sample may consist of or include records from the previously selected sample of significant corrective actions). To determine if corrective and preventive actions for product and quality problems and changes have been documented and implemented it may be necessary to view actual processes, equipment, facilities or documentation.

(10) Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review.

Determine that the relevant information regarding quality problems, as well as corrective and preventive actions, has been submitted for management review. This can be accomplished by determining which records in a recent CAPA event were submitted for management review. Review the raw data submitted for management review and not the actual results of a management review.

Review the CAPA (and other procedures if necessary) and confirm that there is a mechanism to disseminate

（9）验证产品和质量问题纠正和预防措施是否得到了执行和文件化。

用样本表，选择和审查最近的纠正或预防措施记录(这个样本可以由之前选择中的重要纠正措施的样本组成或包括这个样本)。确定对产品和质量问题以及变更的纠正和预防措施是否被执行和文件化，有必要去观看实际的处理、设备、工具或文件。

（10）考察有关不合格产品和质量问题，以及纠正和预防措施的信息是否恰当地得到了传达，包括传达到管理评审。

要确认与质量问题和纠正和预防措施相关的信息被提交管理评审，可以通过审查最近提交管理评审的CAPA事件的记录完成这个确认。审查提交管理评审的原始数据，而不是管理评审后的实际结果。

审查CAPA程序（必要的话可以包括其他程序），核实是否有机制将

relevant CAPA information to those individuals directly responsible for assuring product quality and the prevention of quality problems.

Review information related to product and quality problems that has been disseminated to those individuals directly responsible for assuring product quality and the prevention of quality problems. Using the sample of records from Objective 9 above, confirm that information related to product and quality problems is disseminated to individuals directly responsible for assuring product quality and the prevention of quality problems. An important linkage to this CAPA element is 820.20 Management Responsibility.

6.4 Medical Device Reporting

6.4.1 Inspectional Objectives

1. Verify that the firm has MDR procedures that address the requirements in 21 CFR Part 803.17.
2. Verify that the firm has established and maintains MDR event files that comply with 21 CFR Part 803.18.
3. Confirm that the appropriate MDR information is being identified, reviewed, reported, documented and filed.
4. Confirm that the firm follows their procedures and they are effective in identifying MDR reportable deaths, serious injuries and malfunctions.

6.4.2 Decision Flow Chart

相关的 CAPA 信息传达给与产品质量保证和质量问题预防有直接责任的个人。

审查与产品和质量问题相关的信息是否被传递给直接负责产品质量保证和质量问题预防的个人。用上文中目标 9 用所述的样本表，核实与产品和质量问题有关的信息是否被传递给直接负责产品质量保证和质量问题预防的个人。与 CAPA 组成有关的重要链接：820.20 管理责任。

6.4.医疗器械报告

6.4.1 检查目的

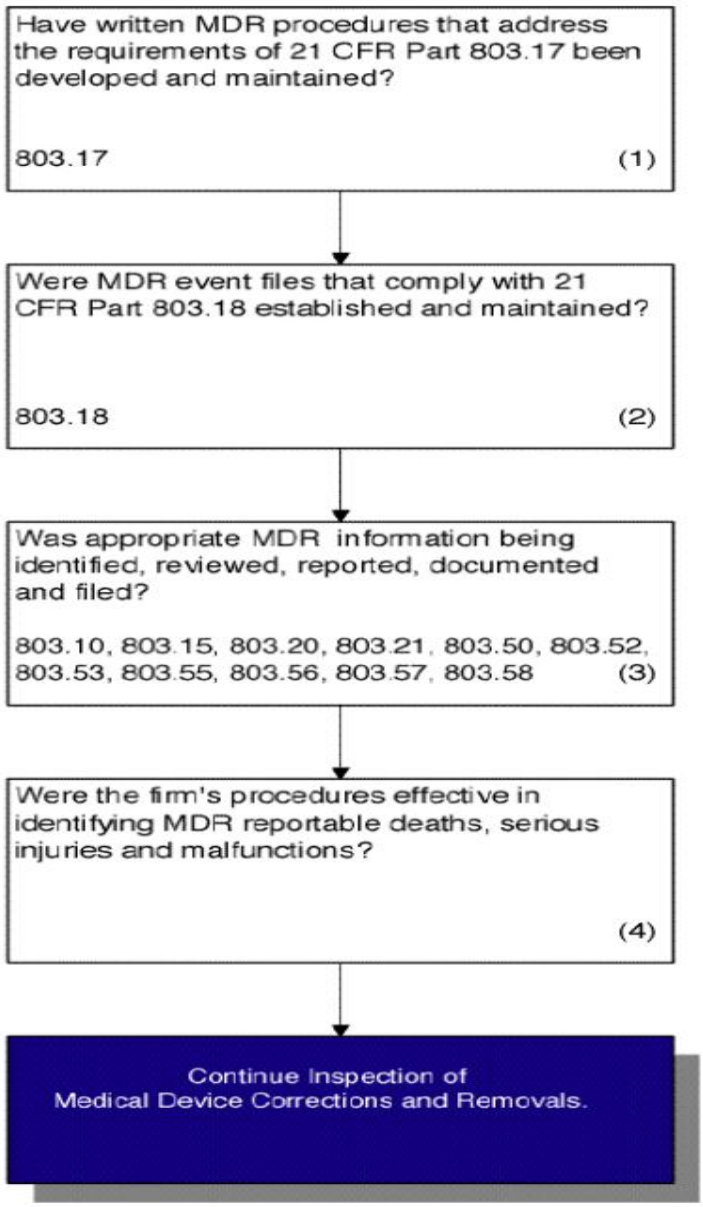
1．验证公司具有满足 21CFR 803.17 部分的 MDR 程序。

2．验证公司已建立和维护 MDR 事件文件，此文件遵照 21CFR803.18 部分。

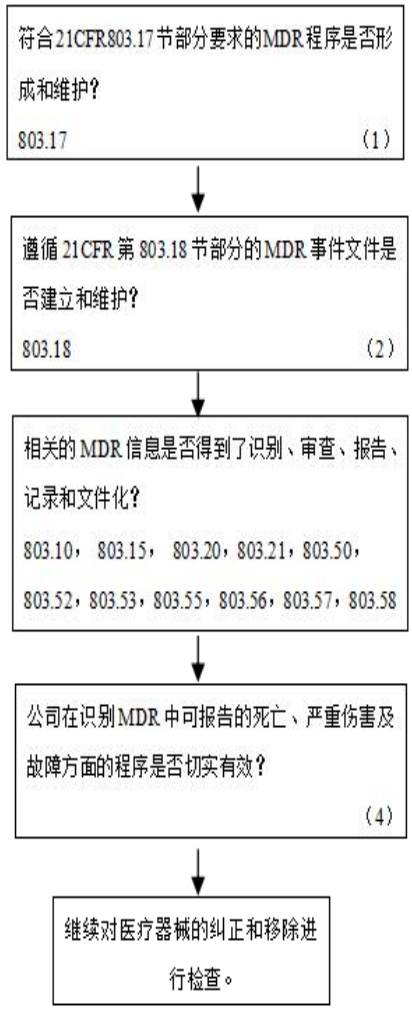
3．确认正确的 MDR 信息被识别、审评、报告、记录和文件化。

4．确认公司遵循其程序，确认这些程序在识别 MDR 所报告的死亡、严重伤害、出现故障时是有效的。

6.4.2 决策流程图



MEDICAL DEVICE REPORTING DECISION FLOW CHART



医疗器械报告决策流程图

6.4.3 Narrative

Purpose/Importance

The Medical Device Reporting (MDR) Regulation requires medical device manufacturers, device user facilities and importers to establish a system that ensures the prompt identification, timely investigation, reporting, documentation, and filing of device-related death, serious injury, and malfunction information.

The events described in Medical Device Reports (MDR's) may require the FDA to initiate corrective actions to protect the public health. Therefore, compliance with Medical Device Reporting must be verified to ensure that CDRH's Surveillance Program receives both timely and accurate information.

1. Verify that the firm has MDR procedures that address the requirements in 21 CFR Part 803.17.

Review and confirm that the firm's written MDR procedures address:

A. Internal systems that provide for the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting.

B. A standard review process/procedure for determining when an event meets the criteria for MDR reporting and ensuring the timely transmission of complete device reports to FDA.

C. Documentation and recordkeeping regarding: information evaluated to determine if an event is reportable; all MDR reports and other information submitted to the FDA; and systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

2. Verify that the firm has established and

6.4.3 解释

目的/重要性

医疗器械报告(MDR)法规要求医疗器械制造者、设备的用户和进口商建立起一个系统，来确保随时的识别、及时的检查、报告，以及使设备相关的死亡、严重伤害和故障信息文件化及归档。

医疗器械报告(MDR)中描述的事件可能要求 FDA 启动纠正措施以确保公众的健康。因此，医疗器械报告的符合性必须被验证，以确保 CDRH 的监管程序接收信息的及时准确。

1.验证公司具有满足 21CFR 803.17 部分的 MDR 程序。

审查和核实公司的书面 MDR 程序体现了以下内容：

A. 内部系统：内部系统，用于及时、有效地识别、传达和评估可能符合医疗器械报告的事件。

B. 标准的审查过程/程序：确定事件何时符合 MDR 报告标准并确保及时向 FDA 提交完整的设备报告

C. 文件和记录保存：要将以下的信息保存下来并文件化：用来进行评估以决定一个事件可否报告的信息；上交给 FDA 的所有的 MDR 报告和其他信息；确保获得 FDA 及时跟踪和检查的信息系统。

2.验证公司已建立和维护 MDR 事件

maintains MDR event files that comply with 21 CFR Part 803.18

Using the sampling tables, select a number of MDR event files. Review and verify that the MDR event files (hard copy or electronic) are prominently identified and easy to access. MDR files may be maintained as part of the 820.198 complaint file IF the two aforementioned criteria are met.

Confirm that the MDR event files contain: information from any source that describes a device-related death, serious injury or malfunction; the firm's evaluation of this information including decisions to submit or not to submit an MDR report; and copies or references to supporting documentation (e.g., failure analysis, lab reports, etc.).

Decisions not to submit an MDR report for a device-related death, serious injury or malfunction must be documented in the MDR file.

When applicable, the files will also contain copies of MDR death, serious injury, malfunction and five-day reports submitted on FDA form 3500A, Supplemental Reports (3500A), Baseline Reports (3417) and MDR-related correspondence.

3. Confirm that the appropriate MDR information is being identified, reviewed, reported, documented and filed.

Using the sampling tables, select a number of MDR reports that were submitted to the FDA.

Compare the firm's written procedures to the way it

文件，此文件遵照 21CFR803.18 部分。

使用样本表，选择一组 MDR 事件文件，审查和验证这些 MDR 事件文件（硬拷贝或电子媒体）能显著识别且易于获得。如果达到了上述两个标准，MDR 文件可以作为第 820.198 部分的投诉文件的部分保存下来。

确认 MDR 事件文件包括以下内容：描述与设备相关的死亡、严重损伤或故障的任何来源的信息；公司对这些信息的评估包括是否递交 MDR 报告决定；支持文件的复印件或证明（比如故障分析、实验室报告等等）。

不向上递交与设备相关的死亡、严重伤害或故障的 MDR 报告的决定，必须写入 MDR 文件中。

如果可行，该文件还包含 MDR 死亡，严重伤害，故障和以 FDA 表 3500A 提交的 5 天报告、补充报告（3500A），基线报告（3417）和与 MDR 相关的通讯录的副本。

3. 确认正确的 MDR 信息被识别、审评、报告、记录和文件化。

用样本表，选取一组递交给 FDA 的 MDR 报告。

将识别、处理、评估、报告和归

identified, processed, evaluated, reported and filed the reports. Note any discrepancies between the firm's practice/written procedures and any failure to follow or obtain information required by the regulation and form 3500A (e.g., timely reporting,
complete investigation, consistency, etc.)

4. Confirm that the firm follows their procedures and they are effective in identifying MDR reportable deaths, serious injuries and malfunctions.

Using the sampling tables, select a number of unreported complaints and records from one additional source of quality data (service reports, repair reports, returned goods files, etc.).

Review these records and confirm that they do not contain information relating to MDR reportable events (device-related deaths, serious injuries or malfunctions).

If unreported events are identified, determine the firm's rationale for not submitting MDR reports. If the firm has failed to identify these events, or does not provide an adequate rationale for not submitting an MDR report (an adequate rationale may be that the firm's investigation determined that it was in fact another manufacturer's device involved in the event), then this may be a significant MDR related observation.

6.5 Reports of Corrections and Removals

6.5.1 Inspectional Objectives

1. Determine if corrections or removals of a device were initiated by the manufacturer.

档报告的方式与公司的书面程序进行比较，注意公司的书面程序和操作程序中的每一个差异，以及未能跟踪和获取法规和表3500A要求的任何信息（比如及时的报告、全面的调查、一致性等等）。

4. 确认公司遵循其程序，确认这些程序在识别MDR所报告的死亡、严重伤害、出现故障时是有效的。

使用样本表，选取一组来源其它质量数据的未报告的投诉和记录（客服报告、维修报告、返回产品文件等等）。

审查这些记录，证实他们不包含与MDR可报告的事件（设备相关死亡、严重伤害或故障）相关信息。

如果查实了未报告事件，审查公司不递交MDR报告的基本原因。如果公司未能就这些事件进行识别，或不提供一个不递交MDR报告的充分理由（一个充分的理由可能是，该公司的调查确定，它实际上是另一个制造商的设备参与的事件），那么可能是MDR的一个重要观察项。

6.5.纠正和移除报告

6.5.1 检查目的

1.确定设备的纠正或移除是否被制造商启动。

2. Confirm that the firm's management has implemented the reporting requirements of 21 CFR Part 806.

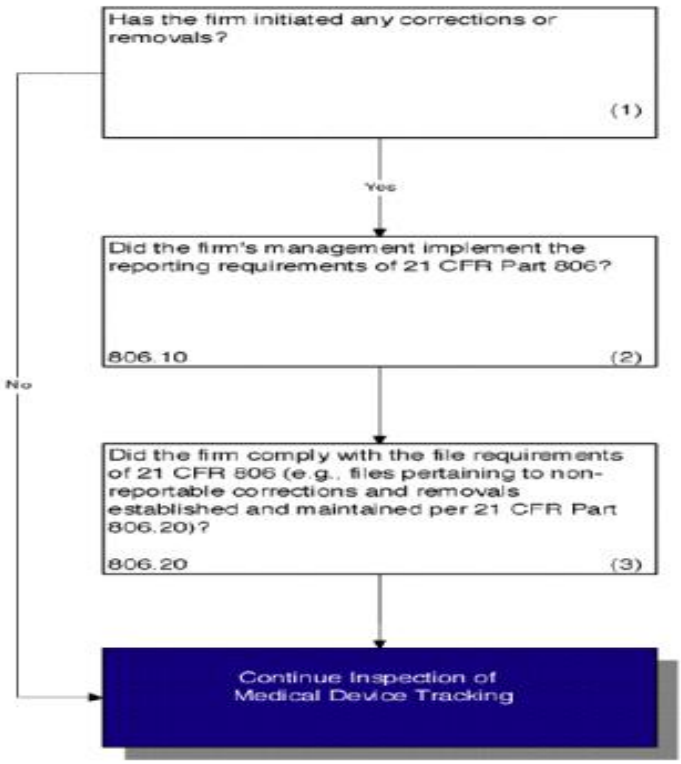
3. Verify that the firm has established and continues to maintain a file for all non-reportable corrections and removals per 21 CFR Part 806.20. Also verify that the firm is complying with the other file-related requirements of 21 CFR Part 806.

6.5.2 Decision Flow Chart

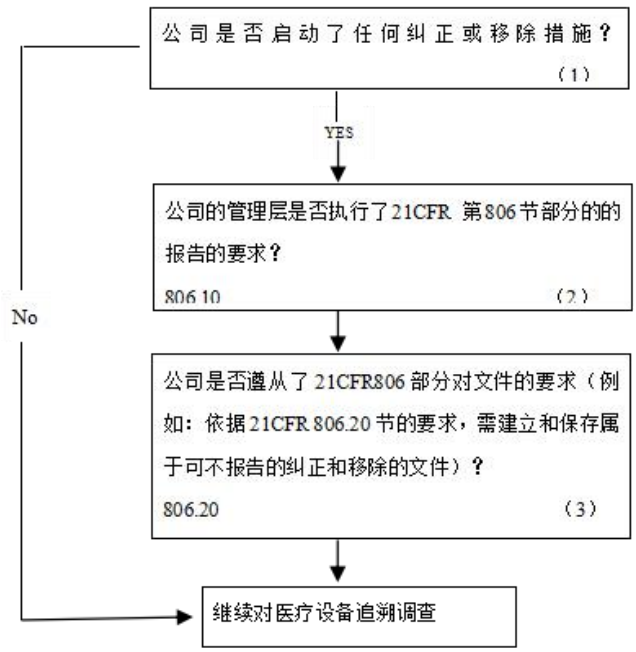
2.确认公司的管理者已经进行了关于21CFR806 部分的要求的报告。

3.确认公司经 21 CFR 806.20 部分，已建立并继续保持对所有非报告的纠正和移除的文件，同时确认公司符合 21 CFR 806 部分相关文件的要求。

6.5.2 决策流程图



REPORTS OF CORRECTIONS AND REMOVALS DECISION FLOW CHART



纠正和移除报告

决策流程图

6.5.3 Narrative

Purpose/Importance

The Corrections and Removals (CAR) Regulation requires medical device manufacturers and importers to promptly notify FDA of any correction or removal initiated to reduce a risk to health. This early notification improves FDA's ability to quickly evaluate risks and, when appropriate, initiate corrective actions

6.5.3 解释

目的/重要性

纠正和移除（CAR）法规要求医疗器械制造商和进口商及时向 FDA 通报任何试图降低对健康的风险而作的纠正或移除措施，提早向 FDA 通报可以提高 FDA 快速评估风险的能力，在合适的时间，启动纠正措施以保护

to protect the public health.

1. Determine if corrections or removals of a device were initiated by the manufacturer.

If the firm has not initiated any corrections or removals, no inspection under Reports of Corrections and Removals is necessary, proceed to the inspection of Medical Device Tracking. However, state in the EIR that Reports of Corrections
and Removals were considered for inspection. If the firm has initiated any corrections or removals, proceed to Objective 2.

2. Confirm that the firm's management has implemented the reporting requirements of 21 CFR Part 806.

Using the sampling tables, select a number of files relating to corrections or removals that have been reported to the FDA.

Review the files and verify that the firm: (1) is submitting written correction and removal reports to the appropriate FDA District Office within 10 days of initiating the actions; and (2) has provided all the information required in the written report per 806.10.

Using the sampling tables, select a number of corrective action files in general (e.g., CAPA files). Review the files. If you identify any apparent Class I or Class II recalls that have not been reported to the appropriate FDA District Office, discuss the discrepancy with the firm. It may be necessary to list unresolved discrepancies on your FDA 483. All observations must be consistent with current FDA

大众的健康

1.确定设备的纠正或移除是否被制造商启动。

如果公司没有进行任何纠正或移除，就没有必要为纠正和移除报告进行检查。直接进行医疗设备追溯的检查。不过，在 EIR 的陈述中要求就纠正和移除报告进行检查。

如果公司实施了某些纠正或移除，向下进行目标 2.

2.确定公司的管理已经执行了 21 CFR 806 部分的报告要求。

使用样本表，选取一些已上报了 FDA 的与纠正或移除有关的文件。

审查这些文件并验证公司：（1）是否在开始措施的 10 天内向相应的 FDA 地区办公室上报了书面的纠正和移除报告。（2）是否提供了 806.10 中对书面报告要求的所有信息。

使用样本表，选取一些通用的纠正措施文件（比如 CAPA 文件）。审查这些文件，如果发现有任何明显的Ⅰ级或Ⅱ级召回行为没有向 FDA 地区办公室报告，与公司讨论这个差异。可能有必要将未解决的差异问题列入你的 FDA 483（报告）中。所有观察项都要与现行 FDA 法规和程序一致。

policies and procedures.

3. Verify that the firm has established and continues to maintain a file for all non-reportable corrections and removals per 21 CFR Part 806.20. Also verify that the firm is complying with the other file-related requirements of 21 CFR Part 806.

3.确认公司经 21 CFR 806.20 部分，已建立并继续保持对所有非报告的纠正和移除，同时确认公司符合 21 CFR 806 部分相关文件的要求。

Using the sampling tables, select a number of files relating to non-reportable corrections or removals (806.20 files).

使用样本表，选取一些与不用报告的纠正或移除相关的文件（806.20 文件）。

NOTE: Part 806 does not require firms to establish and maintain files for corrections and removals reported to the FDA. However, documentation of corrective actions is required by the Quality System Regulation (21 CFR 820.100, Corrective and Preventive Action and 21 CFR 820.198, Complaint Files).

注意：806 部分不要求公司建立和维护提交给 FDA 的纠正和移除文件，但是，质量体系法规（21 CFR 820.100，纠正和预防措施和 21 CFR 的 820.198，投诉文件）对纠正措施文件做了要求。

Review the 806.20 files and verify that the records contain all the information required in 806.20. This review must include confirmation that the files are retained for the appropriate period of time (2 years beyond the expected life of the device).

审查 806.20 文件，验证这些记录包含了 806.20 中所要求的信息。审查要确认文件是否保存了适当长的时间（一般文件要保存到设备预期效期 2 年后）

Confirm that these files also do not contain evidence of unreported (apparent) Class I or Class II recalls. Determine whether the files contain evidence of unreported (apparent) Class III voluntary recalls under 21 CFR Part 7. Also, verify that the firm is complying with the other file-related requirements of 21 CFR Part 806.

核实这些文件不包括（明显）未报告的Ⅰ级或Ⅱ级召回行为的证据，审查文件是否包括（明显）未报告的依据 21CFR 第 7 部分中的Ⅲ级自愿召回行为。另外，核实公司遵从了 21 CFR 806 中其他对文件相关的要求。

Confirm any claims for exemption from 806 as a result

确认任何由 MDR 法规或放射卫

of a submission under either the MDR regulation or Radiological Health requirements. If you need assistance, contact the District Recall Coordinator.

生要求而提交的任何豁免 806 的要求。如果你需要协助，可以联系地区召回协调员。

If the device has been sold to another firm, verify that the 806.20 files have been transferred to the new manufacturer or importer.

如果设备被销售到其他公司，验证 806.20 文件也被传送到这个新的制造商或进口商手中。

If compliance with the above requirements cannot be confirmed, discuss the discrepancy with the firm. It may be necessary to list unresolved discrepancies on your FDA 483. All observations must be consistent with current FDA policies and procedures.

如果不能确定符合了以上要求，与公司讨论这些差异。可能有必要将未解决的差异问题列入你的 FDA 483（报告）中，所有观察项都要与现行 FDA 法规和程序一致。

NOTE: If the device has been sold to a firm that is not in your District, forward an assignment request to the appropriate District Office requesting confirmation that the 806.20 files have been transferred to the new manufacturer or importer.

注意：如果设备被销售到了一个公司所在区域的之外地方，应向相关的地区办公室提出指派申请，要求查证 806.20 文件是否被传递到了新的制造商或进口商手中。

6.6 Medical Device Tracking

6.6.1 Inspectional Objectives

1. Determine if the firm manufactures or imports a tracked device.
2. Verify that the firm has established a written standard operating procedure (SOP) for tracking that complies with the requirements in 21 CFR Part 821.25(c).
3. Verify that the firm's quality assurance program includes audits of its tracking system within the appropriate timeframes specified in 21 CFR Part 821.25(c)(3).

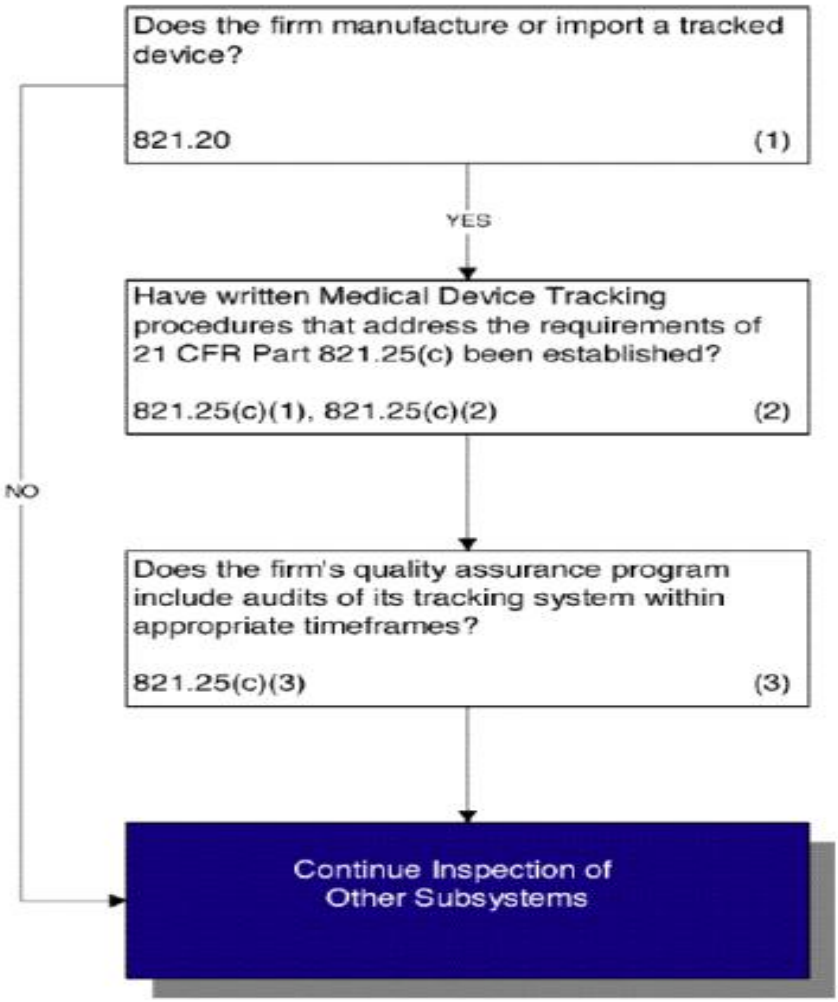
6.6 医疗器械追溯

6.6.1 检查目的

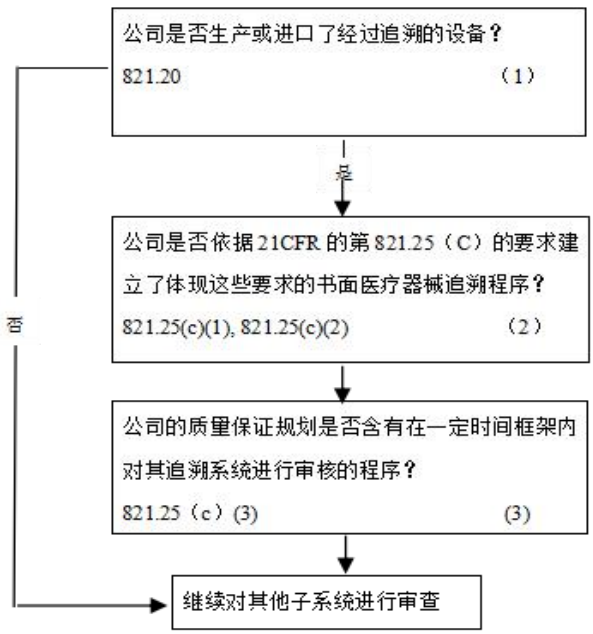
1.检查公司是否生产或进口了一个被追溯的设备
2.验证公司为追溯建立了一个符合 21 CFR 821.25(C) 的书面的标准操作程序（SOP）。
3.验证公司的质量保证程序，包括对其追踪系统的审核，在 21 CFR 821.25(c)(3)部分指定的适当的时间框架内。

6.6.2 Decision Flow Chart

6.6.2 决策流程图



MEDICAL DEVICE TRACKING DECISION FLOW CHART



医疗器械追溯

决策流程图

6.6.3 Narrative

Purpose/Importance

The purpose of the Medical Device Tracking Regulation is to ensure that manufacturers and importers of certain medical devices can expeditiously locate and remove these devices from the market and/or notify patients of significant device problems.

1. Determine if the firm manufactures or imports a tracked device.

Ask the Management Representative (or designee) whether the firm manufactures or imports any device subject to the Medical Device Tracking Regulation (21 CFR Part 821). If the firm does not manufacture or import a device subject to the tracking regulation, you can terminate your tracking inspection.

If the firm does manufacture or import a device subject to the tracking regulation, verify via discussions with the Management Representative (or designee) or the review of es-tablished procedures, that the firm is aware of its tracking obligations.

Verify that the firm is aware of its obligation to: (1) notify FDA if it goes out of business and provide copies of its tracking records to its FDA District Office; (2) transfer tracking records to a firm purchasing its tracked device(s); and (3) continue tracking a device the firm stops manufacturing or importing if the firm remains in business.

If the firm's tracked device was purchased from another firm, confirm (where applicable) that the firm

6.6.3 解释

目的/重要性

医疗器械追溯法规的目的是要确保某种医疗器械的生产商和进口商能够迅速地定位和移除市场上的这些设备，并能向病人报告重大的设备问题。

1.确定公司是否生产或进口经过追溯的设备。

询问公司的管理者代表（或公司的指派人）公司是否生产或进口任何受医疗设备追溯法规（21CFR 的第 821 部分）约束的设备。如果公司没有生产或进口受追溯法规约束的设备，可终止追溯审查。

如果公司确实生产或进口了受追溯法规约束的设备，与公司的管理者代表（或公司的指派人）讨论或审查已建立的程序，核实公司是否知道追溯职责。

验证公司是否知道其义务：（1）如果公司已停止经营，要向 FDA 报告并向 FDA 地区办公室提供其追溯记录复印件。（2）向购买受追溯的设备的公司传送追溯记录。（3）如果公司仍在经营中，继续对其已停止销售或进口的设备进行追溯。

如果公司受追溯的设备购自另一家公司，如果可行，应证实公司得到并保

has obtained and maintains the prior manufacturer's tracking records or equivalent information.

存着原始生产商的追溯记录或相关信息。

2. Verify that the firm has established a written standard operating procedure (SOP) for tracking that complies with the requirements in 21 CFR Part 821.25(c).

2.考察公司是否为实施追溯建立了书面的标准操作程序（SOP）,这种程序遵从了 21CFR 第 821.25（c）部分的要求。

Review the firm's written tracking SOP(s) and confirm (if possible) that they address the firm's capability to: (1) identify the location and other required data, for tracked devices undistributed to a patient within three working days after a request by FDA, and (2) identify the location and other required data for tracked devices distributed to a patient, within 10 working days after receipt of a request from FDA.

审查公司书面的追溯标准操作程序（SOP），可行的情况下，同时核实程序提及的公司所应具有以下的能力：（1）在 FDA 提出要求后 3 个工作日之内，能够对未分销到病人手中的受追溯设备，确定其位置和获得必要的信息；（2）在接到 FDA 要求后 10 个工作日之内，对已分销到病人手中的受追溯的设备，应该能够确定其位置和获取到其他必要的数据。

If applicable, select one or two files containing tracking information requested by the FDA and confirm that the appropriate information required by 821.25(a)(1) –821.25(a)(3) was provided within the appropriate time-frame(s).

如果可以操作的话，选择一个或两个包含有 FDA 要求的追溯信息的文件，核实这些是 821.25（a）(1)和 821.25（a）(3)条款所需要的相关信息，并且这些信息能够在要求的时间期限内提交出来。

Confirm that the written tracking SOP(s) address the remaining 821.25(a), 821.25(b), and 821.25(c) requirements for the collection, maintenance and auditing of tracking data.

核实书面的追溯标准操作程序（SOP）文件覆盖了 821.25（a）,821.25(b)和 821.25(c)条款中关于收集、保存、和审核追溯数据的要求。

3. Verify that the firm's quality assurance program includes audits of its tracking system within the appropriate time-frames specified in 21 CFR Part 821.25(c)(3).

3.验证公司的质量保证程序，包括对其追踪系统的审核，在 21 CFR 821.25(c)(3)部分指定的适当的时间框架内

Confirm that the audit procedure addresses both the functioning of the tracking system and the accuracy and completeness of the data within the system.

证实审核程序不仅能描述出追溯系统的运行，而且能辨明系统内数据是否精确和完整。

Confirm that the firm has conducted audits of its tracking system at the appropriate time intervals (no less than every six months for the first three years of tracking and annually thereafter).

证实公司是否在规定的时间间隔内执行了对其追溯系统的审核（在追溯的第一个三年，审核时间间隔不得长于六个月，之后，每年进行一次审核）。

NOTE: The agency's policy relative to the review of quality audit results is stated in CPG 7151.02 (CPG Manual Sub Chapter 130.300). This policy prohibits FDA access to a firm's quality audit results. However, the audit procedures and documents that demonstrate that the audits have been conducted at the appropriate time intervals are subject to FDA inspection.

注意：关于质量审核结果的审核的机构的政策在 CPG7151.02(CPG 手册子章节 130.300)中。这个政策不允许 FDA 介入公司的质量审核结果。但是，证明审核按照规定的时间间隔得到执行相关的审核程序和文件，受 FDA 的检查约束。

7. Production and Process Controls

7. 生产和过程控制（P&PC）

7.1 Inspectional Objectives

7.1 检查目的

1. Select a process for review based on:

1.基于下列条件为审核选择一个过程

a. CAPA indicators of process problems;

a.过程问题的 CAPA 指示；

b. Use of the process for manufacturing higher risk devices;

b.生产高风险设备使用的过程；

c. Degree of risk of the process to cause device failures;

c.导致设备故障的过程的风险程度；

d. The firm's lack of familiarity and experience with the process;

d.公司对过程的经验缺乏和不熟悉；

e. Use of the process in manufacturing multiple devices;

e.生产多种设备时使用的过程；

f. Variety in process technologies and Profile classes;

f.过程技巧和外形种类的变化；

g. Processes not covered during previous inspections;

g.在先前检查中过程的检查没有被覆盖；

h. Any other appropriate criterion as dictated by the assignment

h.被委派者指示的其他合适的标准。

Note: If the process chosen is sterilization, evaluate the process according to the "Sterilization Process Controls" chapter of this handbook.

注意：如果选择的过程是灭菌过程，对这个过程的评估依据本书的"灭菌过程控制"章节。

2. Review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

2.审查为生产过程选择的特定程序以及控制与监视过程的方法，确保过程被控制和被监视。

Note: Control and monitoring procedures may include in-process and or finished device acceptance activities as well as environmental and contamination control measures.

注意：如同环境和污染的控制措施一样，控制和监视的程序应包括过程中或成品的验收活动。

3. If review of the Device History Records (including process control and monitoring records, etc.) reveals that the process is outside the firm's tolerance for operating parameters and/or rejects or that product nonconformances exist:

3.如果对设备历史记录（包括过程控制和监视记录等）的审查显示了此过程超出公司对操作参数的限度，或者提示产品有缺陷，应：

a. Determine whether any nonconformances were handled appropriately;

a.证实不合格品是否被适当处理；

b. Review the equipment adjustment, calibration and maintenance; and

b.审查设备的调试、校准和维护；

c. Evaluate the validation study in full to determine whether the process has been adequately validated.

c.全面评估确认研究，以确定过程是否得到充分确认。

4. If the results of the process reviewed cannot be fully verified, confirm that the process was validated by reviewing the validation study.

4.如果过程审核的结果不能被完全被验证，通过审核确认研究确认过程是被确认的。

5. If the process is software controlled, confirm that the software was validated.

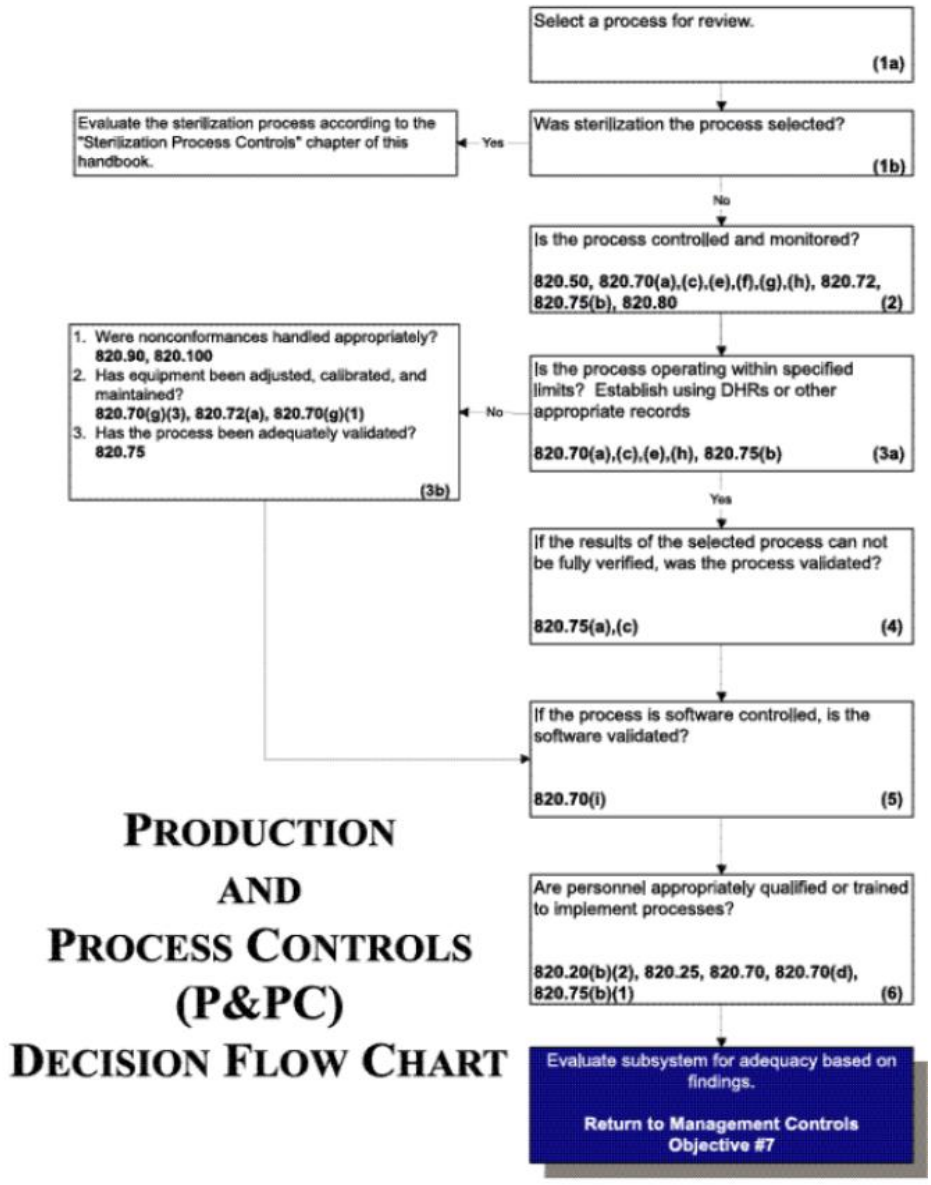
5.如果过程是由软件控制的，确保软件是经过确认的。

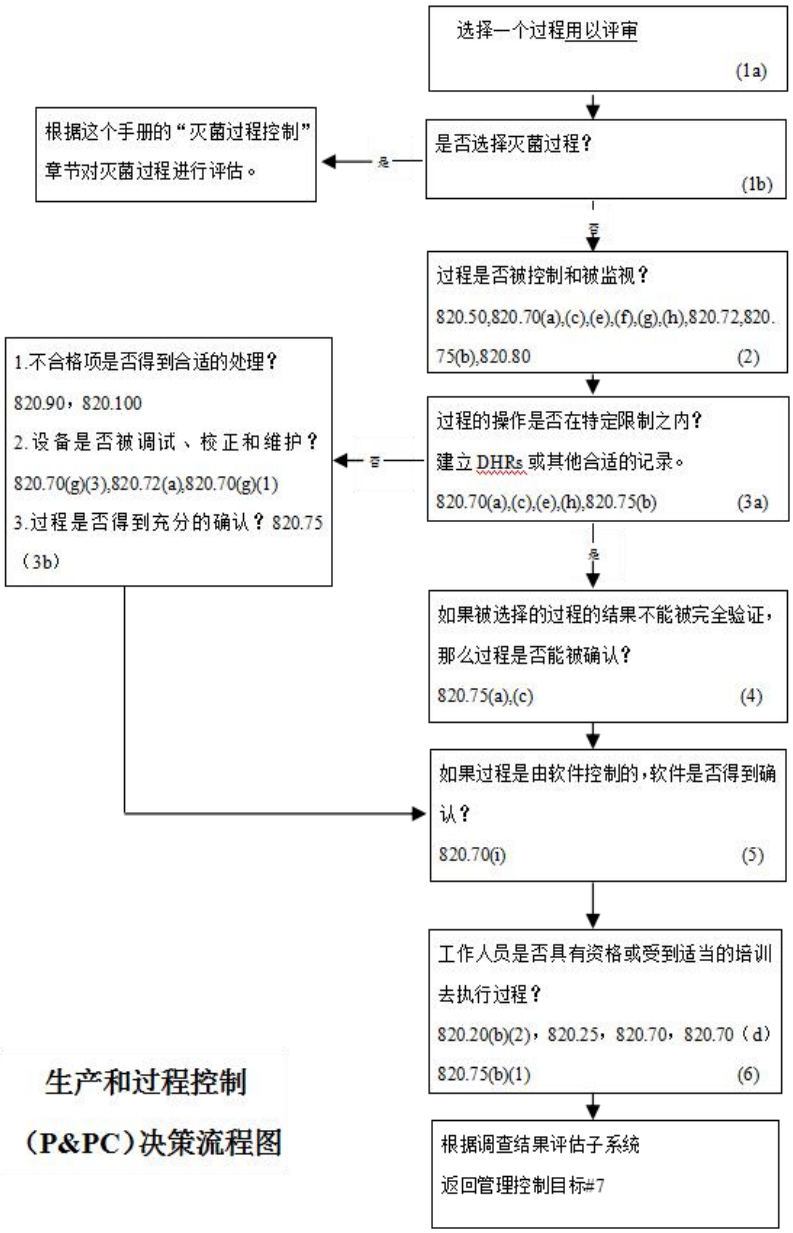
6. Verify that personnel have been appropriately qualified to implement validated processes or appropriately trained to implement processes which yield results that can be fully verified.

6.确认所有工作人员已具有资格进行实施确认，或经过适当的培训，确认工作人员所进行的确认结果是完全有效的。

7.2 Decision Flow Chart

7.2 决策流程图




选择一个过程用以评审
(1a)
是否选择灭菌过程？
(1b)
是
根据这个手册的“灭菌过程控制”章节对灭菌过程进行评估。
否
过程是否被控制和被监视？
820.50,820.70(a),(c),(e),(f),(g),(h),820.72,820.75(b),820.80 (2)
过程的操作是否在特定限制之内？
建立 DHRs 或其他合适的记录。
820.70(a),(c),(e),(h),820.75(b) (3a)
否
1.不合格项是否得到合适的处理？
820.90，820.100
2.设备是否被调试、校正和维护？
820.70(g)(3),820.72(a),820.70(g)(1)
3.过程是否得到充分的确认？820.75（3b）
是
如果被选择的过程的结果不能被完全验证，那么过程是否能被确认？
820.75(a),(c) (4)
如果过程是由软件控制的，软件是否得到确认？
820.70(i) (5)
工作人员是否具有资格或受到适当的培训去执行过程？
820.20(b)(2)，820.25，820.70，820.70（d）
820.75(b)(1) (6)
根据调查结果评估子系统
返回管理控制目标#7
生产和过程控制
（P&PC）决策流程图

7.3 Narrative

Purpose/Importance

The purpose of the production and process control subsystem is to manufacture products that meet specifications. Developing processes that are adequate to produce devices that meet specifications, validating (or fully verifying the results of) those processes, and monitoring and controlling the processes are all steps that help assure the result will be devices that meet specifications.

1. Select a process for review based on:

a. CAPA indicators of process problems;
b. Use of the process for manufacturing higher risk devices;
c. Degree of risk of the process to cause device failures;
d. The firm's lack of familiarity and experience with the process;
e. Use of the process in manufacturing multiple devices;
f. Variety in process technologies and profile classes;
g. Processes not covered during previous inspections;
h. Any other appropriate criterion as dictated by the assignment

Note: If the process chosen is Sterilization, evaluate the process according to the "Sterilization Process Controls" chapter of this handbook.

In order to meet the Production and Process Control requirements of the Quality System Regulation, the firm must understand when deviations from device specifications could occur as a result of the

7.3 解释

目的/重要性

生产和过程控制子系统的目的是生产出符合规格的产品。对能够足够生产出满足规格要求的设备的过程进行开发、并对这些过程进行确认（或完全验证这些过程的结果）、以及监视和控制过程是能帮助确保产品符合规格的所有步骤。

1.基于下列条件为审核选择一个过程：

a.过程问题的 CAPA 提示；
b.生产高风险设备使用的过程；
c.导致设备故障的过程的风险程度；
d.公司对过程的经验缺乏和不熟悉；
e.生产多种设备时使用的过程；
f.过程技巧和外形种类的变化；
g.在先前检查中没有被覆盖的；
h.被委派者指示的其他合适的标准。

注意：如果选择的过程是灭菌过程，对这个过程的评估要依据本书的"灭菌过程控制"章节。

为了符合质量体系法规的生产和过程控制要求，公司必须了解，由于生产过程或环境的结果，设备规格的偏差什么时候会发生。

manufacturing process or environment.

Discuss with the Management Representative (or designee) the firm's system for determining whether deviations from device specifications could occur as a result of the manufacturing process or environment. The firm may accomplish this requirement via Product and Process Risk Analyses. Important linkages for these activities include 820.20 Management Responsibility and 820.30 Design Controls.

与管理者代表讨论（或指定人员），公司对于确定由于生产过程或环境的结果，器械规格偏差是否会发生的系统，公司可以通过产品和过程风险分析来完成这个要求。与这些活动有关的重要链接包括 820.20 管理职责和 820.30 设计控制.

Select for evaluation a manufacturing process where deviations from device specifications could occur as a result of the process or its environment. The selection of the manufacturing process for evaluation should be based upon one or more of the criteria listed above. Important linkages to consider at this point include 820.30 (g) Design Validation (risk analysis) and 820.100 Corrective and Preventive Action.

选择评估由于过程或环境的结果导致发生设备规格偏离的生产过程。为评估选择的生产过程应当基于以上所列出的一个或多个标准。考虑的重要链接包括：820.30（g）设计确认(风险分析)和 820.100 纠正和预防措施。

2. Review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

2.审查为生产过程选择的特定程序以及控制与监视过程的方法，确保过程被控制和被监视

Note: Control and monitoring procedures may include in-process and or finished device acceptance activities as well as environmental and contamination control measures.

注意：如同环境和污染的控制措施一样，控制和监视程序应包括过程中和成品器械的验收活动。

All processes that may cause a deviation to a device's specification and all validated processes must be monitored and controlled in accordance with established procedures. Just because a process is validated, does not mean verification activities utilized to monitor and control the process are unnecessary.

所有可能导致产品偏离规范的过程和所有经确认的过程，都必须根据建立的程序加以监视和控制，不能因为仅仅一个过程被确认，就认为被用来监视和控制过程的验证活动是不必要的。与经确认的过程相联系的一些

Examples of some verification activities associated with validated processes include review of process parameters, dimensional inspections, package performance tests, sterility and EO residual testing.

验证活动例子包括：对过程参数的审核、尺寸的检查、包装性能测试、无菌和环氧乙烷残存量检测。

For the process chosen, confirm that the established Process (and where applicable Environmental and Contamination) Control, Monitoring and Product Acceptance Procedures maintained by the shop floor are the most current approved revision contained within the Device Master Record (DMR). Most firms maintain a "Master List" of the most currently approved documents. This list can be verified against the DMR and brought to the shop floor to compare with the currently available documents.

对于选择的过程，应该确认已建立的过程（包括适合环境污染的过程）控制、由车间维护的监视和产品验收程序，必须包含在设备主记录（DMR）中，且必须是最近认可的修订本。大多数公司保持一个最近认可文件的“主要目录”，这个目录可能被证实是与生产场所使用的 DMR 不一致。

Verify that the building is of suitable design and contains sufficient space to perform necessary operations.

验证建筑物的设计是合理的，确认其有足够的空间可以完成必要的操作。

Verify that the control and monitoring activities demonstrate that the process is currently operating in accordance with the DMR. This should be done on the shop floor by reviewing work instructions, product acceptance criteria and results, control charts, etc.

验证控制和监视活动以证明：过程正在根据 DMR 运行，这个过程可以根据生产场所审核工作指导、产品接受标准和结果、控制图等完成。

While on the shop floor, make note of one significant piece of process equipment and one significant piece of inspection, measuring or test equipment (preferably from a finished device acceptance activity). Prior to concluding the inspection, confirm that applicable maintenance activities (preventive maintenance, cleaning, adjustment etc.) are performed as scheduled for the chosen piece of processing equipment. Also

当在生产车间时，应记录重要的过程设备和检查、测量或测试设备（更适宜于成品验收活动）。在检查之前，确认适用的维护行为（预防性的维护、清洁、调试等）已按照进度进行执行，同时确认检查、测量或测试的设备是受控制的且已校准。

confirm that the piece of inspection, measuring or test equipment was controlled and calibrated.

NOTE: Control and monitoring procedures may include in-process and/or finished device acceptance activities as well as environmental and contamination control measures.

注意：控制和监视程序可能包括过程产品和/或成品的验收活动，以及环境和污染控制措施。

Once you've reviewed the process control and monitoring activities on the shop floor, use the sampling tables and select for review a number of Device History Records (DHR's including monitoring and control records, etc.) from recent production runs. If the process is run over more than one shift, your review should include DHR's from all shifts. Verify that the product was manufactured in accordance with the Device Master Record.

一旦已经在车间对过程控制和监视活动进行了审核，使用抽样表并对从最近的生产批中选择若干设备历史记录（包括监视和控制记录等）。如果过程的运行不止一个轮班，那么需要审核所有班次的设备历史记录(DHR)。验证产品是依照设备主记录生产的。

This verification must include a review of the purchasing controls and receiving acceptance activities regarding at least one component or raw material (preferably determined essential for the proper functioning of the device).

验证必须包括对至少一个组件或原材料的采购和验收控制（最好是对产品特定功能是必不可少的组件或原材料）

In addition, this verification must include a review of in-process and final finished device acceptance activities and results as well as environmental and contamination control records (if applicable). Verify that sampling plans for process and environmental control and monitoring activities are based upon a valid statistical rationale.

而且，这些验证还必须包括对生产线上的产品和成品的验收活动和结果的审核，还有对环境和污染控制记录的审核(如适用)，验证为过程、环境控制和监视活动而制定的抽样计划是基于适宜统计学原理。

If your review of the device history records reveals no

如果对设备历史记录的审核没有

anomalies proceed to Objective 4.

If evidence that the process or environment are not controlled and monitored (no control and monitoring activities, not operating within most currently approved parameters or reject limits, etc.) is observed, this may be a major production and process control deficiency. Important linkages to consider at this point include Documents, Records & Change Controls, (820.40 Document Controls, 820.180 Records, 820.181 Device Master Record, 820.184 Device History Record,), Facilities and Equipment Controls (820.72 Inspection, Measuring, and Test Equipment), Material Controls (820.50 Purchasing Controls, 820.60 Identification, 820.65 Traceability, 820.80 Receiving, In-process, and Finished device acceptance, 820.86 Acceptance Status, 820.130 Packaging, 820.140 Handling, 820.150 Storage, 820.160 Distribution) and 820.250 Statistical Techniques.

3. If review of the Device History Records (including process control and monitoring records, etc.) reveals that the process is outside the firm's tolerance for operating parameters and/or rejects or that product nonconformances exist:

a. Determine whether any nonconformances were handled appropriately;

b. Review the equipment adjustment, calibration and maintenance; and

c. Evaluate the validation study in full to determine whether the process has been adequately validated.

If process or product nonconformance(s) are identified based upon these activities, determine whether the nonconformance(s) were recognized by the firm,

发现异常，那么转向目标 4.

如果有证据证明，过程或环境没有被控制和监视（没有监视和控制活动，没有在最近经核准的参数或限制下进行操作），这将是一个生产和过程控制的主要缺陷。关于这一点的重要联结包括：记录和变更控制（820.40 文件控制，820.180 记录，820.181 设备主记录,820.184 设备历史纪录）、设施和设备控制（820.72 检查、测量和测试设备），材料控制（820.50 采购控制、820.60 标识、820.65 追溯、820.80 进货产品、过程产品和成品的验收、820.86 验收状态 820.130 包装、820.140 搬运、820.150 存储、820.160 销售）和 820.250 统计技术。

3. 如果对设备历史纪录（包括过程控制和监视记录等）的审核表明，此过程超出公司对操作参数的限制，或者产品存在缺陷：

a.检查不合格项是否经适当处理；

b.审核设备的调试、校准和维护；

c.全面评估确认研究，以确定过程是否得到充分确认。

如果根据这些活动，过程或产品的不符合项被识别出，检查不符合项是否被公司识别出、是否得到适当处理和

handled appropriately and fed into its CAPA system. Review (if appropriate) the firm's nonconforming product control, review and disposition activities and any CAPA's indicated. If the firm's Quality System failed to recognize the process or product nonconformance(s) or take appropriate CAPA, this may be a major CAPA deficiency.

记录在 CAPA 系统中。审核公司不合格产品控制、评审和处置活动和任何 CAPA 提示。如果公司的质量体系未能识别出过程或产品中不符合项，或未能进行适当的 CAPA，那么将是一个重大 CAPA 缺陷。

NOTE:

1.If the firm engages in a number of manufacturing processes, Investigators should avoid repeatedly selecting the same process every time the firm is inspected.

2.If Device Labeling is the process chosen, include in your inspection coverage of the requirements of "820.120 Device Labeling".

注意：

1. 如果公司从事多种生产过程，调查者应该避免在每次对公司进行检查时选择同样的过程。

2. 如果选择的检查过程是器械标识，那么检查过程应符合 820.120（器械标识）。

Review the firm's equipment adjustment, maintenance and calibration records for the process and (if appropriate) comprehensively evaluate the Validation Study as described in the "Note" contained within the narrative discussion of Objective 4. These activities may provide further insight into the cause of the nonconformance. If the firm has recognized and implemented appropriate CAPA's regarding the observed nonconformance(s), then the quality system was effective. Proceed to Objective 5. Important linkages to consider at this point include Corrective and Preventive Action, Material Controls (820.90 Nonconforming product), and Facilities and Equipment Controls (820.72 Control of inspection, measuring and test equipment).

审核公司所作设备的调试、维护和校对记录，并充分评估在目标 4 的描述讨论中在备注中描述的确认研究。这些审核活动有助于对公司的不符合项的原因进行进一步的了解。如果公司已经识别和执行了适当的有关观察的不符合项的 CAPA 活动，那么质量体系是有效的，转向目标 5。

重要链接包括：纠正和预防措施、材料控制（820.90 不合格产品），设施和设备控制（820.72 检查、测量和测试设备的控制）。

4. If the results of the process reviewed cannot be fully verified, confirm that the process was

4.如果过程的结果不能被完全验证，通过审核确认研究来确认是否过程

validated by reviewing the validation study.

If the results of the process can be fully verified, proceed to Objective 5.

If the chosen process requires process validation, review the established Process Validation Procedure(s). The regulation does not require a general Process Validation Procedure. Therefore, separate procedures may be established for each individual Process Validation Study. Remember, the definition of "Product" contained within the regulation includes components, in-process devices and finished devices. Verify via a review of the Process Validation Study Summary (if available) and Approval, that objective evidence has demonstrated that the process will consistently generate a product or result meeting its predetermined specifications. With respect to process validation, an example of a "result" is a Sterility Assurance Level (SAL). If a Validation Study Summary and Approval is not available, a review of objective evidence within the validation study will be necessary.

NOTE:

If there are indications (via review of DHR's, the Process Validation Study Summary and Approval, the assignment, CAPA system, etc.) of unresolved, potential problems with a validated process, in addition to a review of process monitoring and control activities, a comprehensive validation study review should be conducted. This review should include determining whether:

1. The instruments used to generate the objective

已经被确认。

如果过程的结果被完全验证，转向目标 5。

如果所选择的过程需要过程确认，审核已经建立的过程确认程序。法规不需要整体上的过程确认程序，因此应该为每一个单独的过程确认研究建立单独的程序。需要注意的是，"产品"在法规中的定义包括产品的元部件、过程中产品和成品。通过审核过程确认研究摘要（如果有的话）和批准，验证客观证据表明该过程将始终如一地生成符合预定规格的产品或结果。一个有关过程确认的例子是确认无菌保证水平（SAL）。如果确认研究的总结和批准（VSS&A）是没有的话，那么需要对确认研究中的客观证据进行审核。

注意：

如果一个已经过确认的过程显示出未解决的和潜在的问题（通过评审设备主记录，确认研究的总结和批准，任命，CAPA 系统等），应在过程监视和控制活动评审的基础上，进行广泛的确认研究的评审。这个审核应该包括对以下问题的判断：

1. 在确认研究之前，在产生

evidence were properly calibrated and maintained prior to the validation study;

2. Predetermined product specifications were established;

3. Test sample sampling plans were based upon a statistically valid rationale;

4. Objective evidence demonstrates predetermined product specifications were met consistently;

5. Process tolerance limits were challenged;

6. Process equipment was properly installed, adjusted and maintained;

7. Process monitoring instruments are properly calibrated and maintained;

8. Changes to the validated process were appropriately challenged; and,

9. Process operators are appropriately qualified.

If the objective evidence demonstrates that the process is not capable of consistently producing a product or result meeting its predetermined specifications, this is a major process validation deficiency. Important linkages to consider at this point include Management Responsibility (including 820.25 Personnel), Design Controls (820.30(h) Design Transfer), Corrective and Preventive Action, and Facilities and Equipment Controls (820.72 Inspection, Measuring and Test Equipment) and 820.250 Statistical Techniques.

5. If the process is software controlled, confirm that the software was validated.

If the process chosen is NOT controlled with software, proceed to Objective 6.

If the process chosen is automated with software,

客观证据中使用的工具是否得到校准和维护；

2.是否预先确定产品规格；

3.抽样计划的制定是否基于统计学原理；

4.客观证据是否能够证明产品始终满足预定的产品规格；

5 过程允许偏差限度是否具有挑战性的；

6 过程中设备是否被使当地安装、调试和维护；

7.过程中监视设备是否被适当地校准和维护；

8.经确认的过程的变更是否得到具有适当的挑战性。

9.过程的操作者是否具有合适的资格。

如果客观证据证明过程不能持续产生符合预定规格的产品或结果，这将是一个主要的过程确认缺陷。在这里需要考虑的重要联接包括：管理职责（包括 820.25-人员）、设计控制（820.30（h）-设计转换）、纠正和预防措施、设施和设备控制（820.72-检查、测量和测试设备）和 820.250 统计技术。

5.如果过程是由软件控制的，确保软件是经过确认的。

如果选择的过程不是由软件控制的，转向目标 6。

若果选择的过程是在软件控制下

review the software requirements document, software validation protocol, software validation activities, software change controls and software validation results to confirm that the software will meet user needs and its intended use. If multiple software driven systems are used in the process, challenge one based upon significance.

自动运行的，对软件需求的文件、软件确认方案、软件确认活动、软件更改控制和软件确认结果进行审核，以保证软件符合用户需求和预期用途。如果过程中使用到了多个软件驱动系统、根据重要性选择一个最重要的软件。

An important linkage to consider at this point is Material Controls (820.50 Purchasing Controls). For example, for software developed elsewhere, confirm that appropriate software and quality requirements were established and provided to the vendor and that purchasing data (and validation results) support that the requirements were met.

在这里要考虑的重要联接是材料控制（820.50 采购控制）。例如：若软件开发是在其它地方，确保将合适的软件和质量要求提供给卖主，以及支持需求被满足的采购数据（和确认结果）。

6. Verify that personnel have been appropriately qualified to implement validated processes or appropriately trained to implement processes which yield results that can be fully verified.

6.确认所有工作人员已具有资格实施确认过程，或经过适当的培训，已确保确认结果是完全有效的。

Using the sampling tables, select a number of training and qualification records for process operators and employees conducting Q.C. activities related to the chosen process. Where a process is operated over more than one shift, training records from all shifts should be included within your review. Confirm that the employees are aware of the device defects that may occur as a result of improper performance of their assigned responsibilities. Confirm that employees conducting Q.C. inspections and tests are aware of the defects and errors that may be encountered while performing their assigned responsibilities.

使用采样图表，选择若干培训和资格认定记录，这些记录涉及过程操作者和实施与选择的过程相关的 QC 活动的工作人员。如果所选择的过程需要不止一个班次进行操作时，那么审核中应包括所有班次的培训记录，确认职工是否了解设备的缺陷，而这些缺陷可能是由于他们在执行职责范围内的不适合操作而引起的。确认进行 QC 和测试的工作人员了解他们工作中可能遇到的缺陷和错误。

An important linkage to consider at this point is Management Responsibility (820.25 Personnel).

7.4 Sterilization Process Controls

7.4.1 Inspectional Objectives

1. Confirm that the sterilization process was validated by reviewing the validation study.

2. Review the specific procedure(s) for the sterilization process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

3. If review of the Device History Records (including process control and monitoring records, acceptance activity records, etc.) reveals that the sterilization process is outside the firm's tolerance for operating or performance parameters:

a. Determine whether the nonconformances were handled appropriately; and

b. Review the equipment adjustment, calibration and maintenance

4. If the sterilization process is software controlled, confirm that the software was validated.

5. Verify that personnel have been appropriately qualified and trained to implement the sterilization process.

7.4.2 Decision Flow Chart

在这里要考虑的一个重要的连接是管理职责（820.25-人员）。

7.4 灭菌过程控制

7.4.1 检查目的

1.通过审核确认的研究来确保灭菌过程是有效的。

2.审核所选择的灭菌过程的特定程序、控制和监视过程的方法。验证过程被监视和控制的。

3.如果审核设备历史记录（包括过程控制和监视记录，验收活动记录等）表明灭菌过程超出公司运行或性能参数的限制：

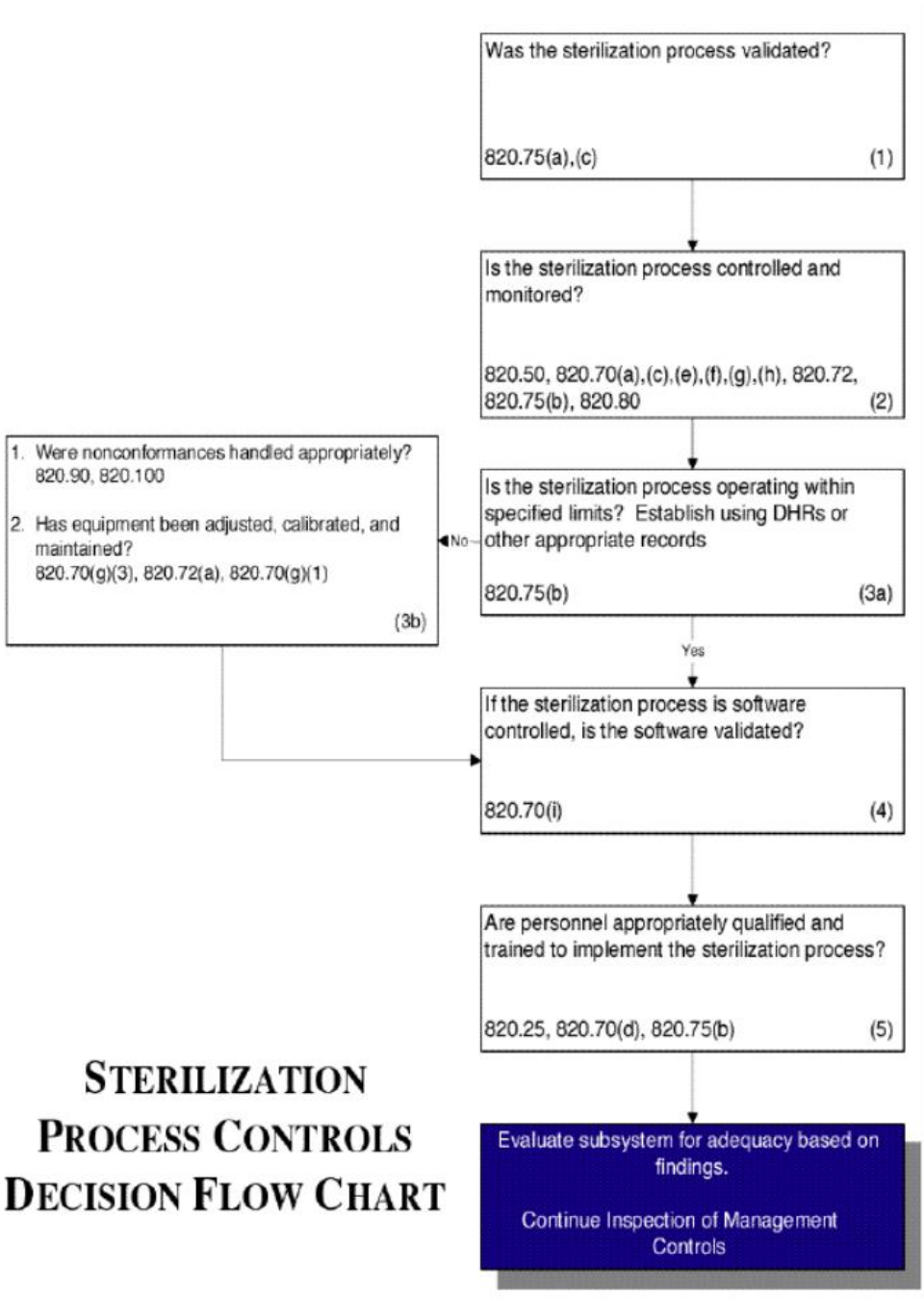
a.确认不符合项是否经适当处理；

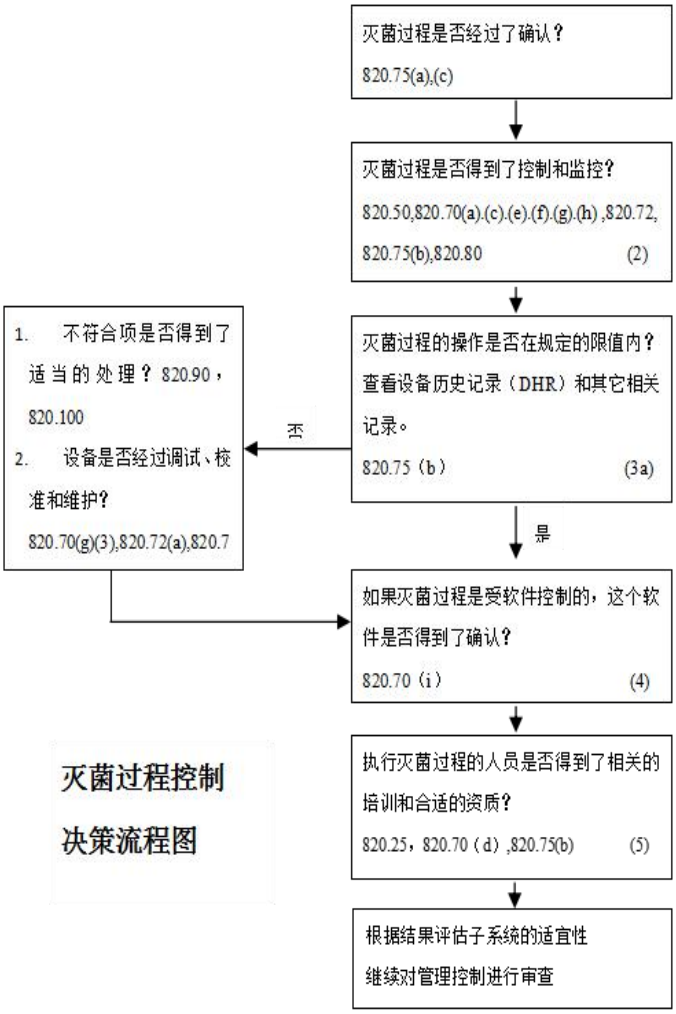
b.审核设备的调试、校准和维护。

4.如果灭菌过程由软件控制，确认该软件是否经过确认的。

5.验证人员是否有适当的资格并接受培训以实施灭菌过程。

7.4.2 决策流程图


Was the sterilization process validated?
820.75(a),(c) (1)
Is the sterilization process controlled and monitored?
820.50, 820.70(a),(c),(e),(f),(g),(h), 820.72, 820.75(b), 820.80 (2)
Is the sterilization process operating within specified limits? Establish using DHRs or other appropriate records
820.75(b) (3a)
No
1. Were nonconformances handled appropriately? 820.90, 820.100
2. Has equipment been adjusted, calibrated, and maintained? 820.70(g)(3), 820.72(a), 820.70(g)(1)
(3b)
Yes
If the sterilization process is software controlled, is the software validated?
820.70(i) (4)
Are personnel appropriately qualified and trained to implement the sterilization process?
820.25, 820.70(d), 820.75(b) (5)
Evaluate subsystem for adequacy based on findings.
Continue Inspection of Management Controls
STERILIZATION PROCESS CONTROLS DECISION FLOW CHART



灭菌过程控制决策流程图

7.4.3 Narrative

Purpose/Importance

The purpose of the production and process control subsystem (including sterilization process controls) is to manufacture products that meet specifications. Developing processes that are adequate to produce devices that meet specifications, validating (or fully verifying the results of) those processes, and monitoring and controlling the processes are all steps that help assure the result will be devices that meet specifications. For sterilization processes, the primary device specification is the desired Sterility Assurance Level (SAL). Other specifications may include sterilant residues and endotoxin levels.

If you are inspecting a contract sterilizer, Inspectional Objectives 2 through 5, described below, are applicable and must be performed. Inspectional Objective 1 regarding validation is applicable only in so far as the contract sterilizer has assumed any responsibility for validation of the process, as indicated in the written agreement between the device manufacturer and the contract sterilizer.

1. Confirm that the sterilization process was validated by reviewing the validation study.

Validation studies (according to established procedures) are required for sterilization processes.

The review of the sterilization process validation study may be limited to a review of the Validation Study Summary (if available) and Approval if the complete validation study was assessed during the previous inspection and there have been no significant changes in the process, product or package that may impact

7.4.3 解释

目的/重要性

生产和过程控制子系统（包括灭菌过程控制）的目的是生产满足规范的产品。开发适应生产出符合规格的设备的过程，确认这些过程（或全面验证过程结果），监视和控制这些过程，是确保生产出的设备符合规格的所有步骤。对于灭菌过程，最基本的设备规格是无菌保证水平（Sterility Assurance level-SAL），另外的规格包括灭菌残余量和内毒素水平。

如果你是检查一个灭菌合约商，要执行检查适用的目标 2 到 5 的内容。目标 1 适用于以下情况的灭菌过程的确认：合约灭菌商承担了对灭菌过程进行确认的责任，并且在器械生产商和合约灭菌商的协议进行了明确

1.通过审核确认研究来考察灭菌过程是有效的。

灭菌过程必须具有确认研究（根据建立的程序）。

如果上次检查中评估了全面的确认研究，并且可能会影响灭菌有效性的过程、产品或包装没有发生重大变更，对灭菌过程确认研究的审查，可能仅限于对确认研究摘要（如果有）和批准的审查。

sterilization effectiveness.

When conducting a complete sterilization process validation study assessment, the items included in the narrative note under Objective 4 of the Production and Process Controls chapter of this Handbook apply. A complete sterilization process validation study assessment must include a review of the established validation procedures and verification (via a review of objective evidence) that: 1. Based upon the bioburden of the product, the defined sterilization process parameters will consistently be effective in obtaining a predetermined Sterility Assurance Level (SAL); and

2.The defined process parameters will not adversely affect product and package performance.

当对灭菌过程的确认研究执行一个完整的评估时，项目包括本手册中生产和过程控制章节中目标 4 所叙述的内容。一个完整的灭菌过程确认研究的评估，应该包括对建立的确认程序和验证的审查（通过审查客观证据）：1.基于产品的生物负载特性，为获得预定的无菌保证水平（SAL），设置的灭菌过程参数要保持长期有效；2.设置的过程参数对产品和包装性能不会产生不良影响。

Objective evidence that the sterilization process parameters will consistently be effective in obtaining a predetermined Sterility Assurance Level (SAL) includes records documenting:

1. The determination of product bioburden;
2. The establishment of process parameters and tolerances;
3. The definition of acceptance criteria for a successful validation study;
4. The process challenge studies (e.g. half cycle runs for Ethylene Oxide, verification dose experiments for radiation, or media fills for aseptic processing); and
5. The results of process control and monitoring and acceptance activities (control charts, Biological Indicators, Dosimeters, etc.) used to demonstrate that predetermined acceptance criteria had been met.

灭菌过程参数要保持长期有效且达到预定的无菌保证水平（SAL）的客观证据，包括以下文件记录：

1.对产品生物负载确定；
2.过程参数和容差的建立；
3.对一个成功的确认研究的可接收标准的定义；
4.过程挑战研究（例如：环氧乙烷的半周期运行、辐射的验证剂量实验，或无菌操作的培养基灌装试验）；
5.用来证实达到了预定接收标准的过程控制和监视和验收活动的结果（控制图表、生生物指示剂、剂量仪等）

NOTE:

Many firms sterilize their products according to the

注意：

许多公司以共识标准（例如：

guidance provided within consensus standards (e.g. AAMI/ANSI/ISO standards). These standards are specific to various types of sterilization processes. FDA recognizes many of these standards. This means FDA finds them acceptable. A list of recognized sterilization standards appears at FDA's Center for Devices and Radiological Health (CDRH's) web site located at: www.fda.gov/cdrh/modact/recstand.html Firms may elect to comply with these standards. However, compliance to the standards is voluntary. When a firm claims to comply with one of the recognized standards, the requirements of the standard must be met. If a firm does not claim to comply with a recognized standard, it must provide a scientific rationale supporting the method used for validating and processing its sterilization loads.

AAMI/ANSI/ISO 标准）作为他们产品灭菌的指导。这些标准专门应用于不同类型的灭菌过程，FDA 也认可其中许多标准，也就是说 FDA 认为他们是可接受的。FDA 认可的灭菌标准在 FDA 的 CDRH 网站可查询，其网址是：www.fda.gov/cdrh/modact/resctand.html 公司会选择遵循这些标准，但是，符合标准应该是自愿的。当一个公司声明遵循某一认可的标准，必须满足标准的要求。如果公司没有宣称满足认可标准的要求，其必须为支持确认和处理灭菌负载的方法提供一个科学的解释。

Objective evidence that process parameters will not adversely affect product and package performance include records documenting performance testing of the product and packaging following the sterilization process or multiple sterilization processes (if applicable).

有关过程参数不会对产品和包装性能产生不良影响的客观证据，包括是在进行了灭菌过程或多重灭菌过程（如果有）后开展的产品和包装性能测试记录文件。

Determine whether periodic assessments (e.g. revalidations, sterility dose audits, etc.) of the adequacy of the sterilization process are conducted. Review the records of one periodic assessment of the adequacy of the sterilization process.

确定是否定期对灭菌过程的充分性进行评估（例如：再确认、灭菌剂量审查等等）。审核灭菌过程充分性周期性评估的记录。

NOTE:

Many device manufacturers use contract sterilizers for sterilization of their devices. These manufacturers retain the responsibility for the sterility of the finished

注意：

许多设备生产商使用合约灭菌商对他们的设备进行灭菌，尽管灭菌过程没有用他们自己的灭菌设施，但是

devices even though sterilization processing is not performed at their own facilities. Therefore, your inspection of a manufacturer that uses the services of a contract sterilizer must verify that the manufacturer has assumed that responsibility. Inspectional Objectives 1 through 3 are applicable in this situation because the manufacturer must be able to provide to you the documentation regarding sterilization validation and processing of its devices regardless of the location of these activities. Although the manufacturer may not have detailed records regarding Objectives 4 and 5 for the contractor's software and personnel, he must have assured the adequacy of these activities by the contractor, through activities such as an audit of the contractor, visits to the contractor, or review of documentation from the contractor. Objective 5 regarding qualifications of the manufacturer's own Q.C. personnel should be covered during your inspection of the manufacturer.

制造商仍然对成品设备的无菌性负责。因此在对一个接受合约灭菌商服务的生产厂商进行检查时，必须核实厂商是否承担上述的责任。检查目标 1 到 3 适用于这种情况，不管灭菌活动是在什么地方实施的，制造商都必须能够提供关于灭菌确认和器械加工的文件。即使生产商可能没有如目标 4 和 5 中所述的有关合约商的软件和个人的详细记录，但必须能够通过对合约商的审查、随访或审查来自的合约商的资料的这些活动，确保合约商的这些活动是足够的。目标 5 涉及到对生产商本身 QC 人员的资质，在检查中需要包含该方面。

2. Review the specific procedure(s) for the sterilization process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

2.审查被选中的灭菌过程的特定的程序，审查控制和监视过程的方法，核实过程是否得到了控制和监视。

The sterilization process must be validated. However, this does not mean that verification activities utilized to monitor and control the process are unnecessary.

灭菌过程必须得到确认。但这并不表示，对监视和控制过程的验证活动就不必要。

If performed at this location, confirm that the sterilization process, associated environmental and contamination controls, and monitoring and acceptance procedures maintained by the shop floor are the most current approved revision contained within the Device

如果是在现场考核，确定车间采用的包括有关环境和污染控制、监视与验收程序在内的灭菌过程，是依据的最近得到批准的设备主记录（DMR）中的。很多生产商持有现行

Master Record (DMR). Most firms maintain a "Master List" of the currently approved documents. This list can be verified against the DMR and brought to the shop floor to compare with the currently available documents.

的经批准的文件的主要目录，这个目录与 DMR 可互相比照，可以持有这个目录和车间使用的文件资料进行比较。

Verify that the building is of suitable design and contains sufficient space to perform necessary operations.

验证建筑物是否经过适当的设计，拥有进行工作的充足的空间。

Verify that the control and monitoring activities demonstrate that the process is currently operating in accordance with the DMR. Sterilization parameters which may need to be monitored and controlled include: time, temperature, pressure, load configuration, and humidity. Several of these parameters may require monitoring and control prior to, during and after sterilization processing (e.g. preconditioning, conditioning and aeration in Ethylene Oxide processing).Verification activities used to monitor and control the sterilization process may include: bioburden testing, Biological Indicator (BI) testing, Chemical Indicator (CI) testing, process control record review, sterilant residue testing, and endotoxin testing.

验证控制和监视活动，以确定现行过程是否与 DMR 要求一致。需要监视和控制的灭菌参数包括：时间，温度，压力，负载设置和湿度。要求在灭菌前、中、后对这些参数进行监视和控制（例如：在环氧乙烷处理前、处理中及通风阶段）。用于监视和控制灭菌过程的验证活动包括：生物负载测试、生物指示剂（BI）测试、化学指示剂测试、过程控制记录的审查、灭菌剂残留测试和内毒素测试。

Additionally, packaging integrity verification activities must be reviewed for every inspection during which sterilization is covered. This review of the control and monitoring activities should be done on the shop floor by reviewing work instructions, product acceptance procedures, control charts, etc.

另外，如果每一个检查牵涉到了灭菌的环节，必须进行包装完整性验证活动的审查。通过审查工作指令、产品验收程序、控制图表等，审核监视和控制活动，须在车间完成。

While on the shop floor, make note of one piece of

在车间进行审查时，认真记录一

significant sterilization process equipment and one significant piece of inspection, measuring or test equipment (preferably from a finished device acceptance activity). Prior to concluding the inspection, confirm that the applicable maintenance activities (preventive maintenance, cleaning and adjustment, etc.) are performed as scheduled for the chosen piece of sterilization process equipment. Also, confirm that the piece of inspection, measuring, and test equipment was controlled and calibrated.

组主要灭菌过程设备和一组重要的检查、测量或测试设备（最好来自是成品器械的验收活动）。在结束检查前，核实被审查的灭菌过程设备是否按照计划进行了适宜的保养活动（预防性的保养、清洁和调试等等）。另外，核实这一组重要的检查、测量及测试设备也得到了控制和校准。

After you have reviewed the process control and monitoring activities on the shop floor, use the sampling tables and select for review a number of Device History Records (DHRs, including monitoring and control records, acceptance testing records, etc.) from recent production runs. If the process is run over more than one shift, your review should include DHRs from all shifts. Verify that the product was sterilized in accordance with the DMR. Your review of the selected records should include all applicable verification activities (see above) including records of process parameter monitoring, and in-process and final device acceptance activities and results.

在完成了车间中对过程控制和监视活动的审查之后，使用样本表，从最近的生产运行批中选择一些设备历史记录（DHRs，包括监视和控制记录，验收测试记录等等）进行审查。如果过程运行了超过一个轮班，必须审查所有班次的设备历史记录。验证产品的灭菌是符合 DMR 要求。对所选择记录的审查，要包括所有可行的验证活动（见上），这些查证活动包括过程参数的监视记录、过程中和成品验证活动和结论。

Your evaluation must also include a review of the firm’s purchasing controls and receiving acceptance activities regarding at least one component, material or service. Examples include: the sterilant, sterilization indicators, and services provided by contract sterilizers or contract laboratories. In addition, review environmental and contamina tion control records (e.g. bioburden sampling, testing and results). Verify that the

评估也要包括对公司的采购控制和至少一个部件、材料或服务的验收活动的审查。例如：灭菌剂、灭菌剂指示剂以及合约灭菌商或合约实验室提供的服务。另外，审查环境和污染控制记录（例如：生物负载采样、测试和结果），核实过程、环境控制和监视活动的采样计划是否有有效的统

sampling plans for process and environmental control and monitoring activities are based upon a valid statistical rationale.

计学理论支持。

If your review of the Device History Records reveals no anomalies, proceed to Objective 4.

如果对设备历史记录的审查没有发现违规的情况，继续进行目标 4 的内容。

If evidence that the process or environment are not controlled and monitored (no control and monitoring activities, not operating within most currently approved parameters, etc.) is observed, this may be a major production and process control deficiency.

如果发现了过程或环境没有得到控制和监视的证据（没有控制和监视活动、没有按照最近批准的参数进行操作等等），这将是一个生产和过程控制的主要缺陷。

Important linkages to consider at this point include: Documents, Records and Change Controls (820.180 Records, 820.181 Device Master Record, 820.184 Device History Record, 820.40 Document Controls); Facilities and Equipment Controls (820.72 Inspection, Measuring, and test Equipment); Material Controls (820.50 Purchasing Controls, 820.80 Receiving, In-process, and finished device acceptance, 820.140 Handling, 820.150 Storage, and 820.160 Distribution, and 820.250 Statistical Techniques, 820.60 Identification, 820.65 Traceability, 820.86 Acceptance Status); 820.130 Packaging; and 820.250 Statistical Techniques.

有关这个问题的重要连接：文件、记录和变更控制（820.180 记录，820.181 设备主记录，820.184 设备历史记录，820.40 文件控制）；设施和设备控制（820.72 检查、测量和测试设备）；材料控制（820.50 采购控制，820.80 进货产品、过程产品和成品的收,820.140 运输，820.150 存储，820.160 销售以及 820.250 统计技术，820.60 标识，820.65 可追溯，820.86 验收状态）；820.130 包装；820.250 统计技术。

3. If review of the Device History Records (including process control and monitoring records, acceptance activity records, etc.) reveals that the sterilization process is outside the firm's tolerance for operating or performance parameters:

3.如果对设备历史记录（包括过程控制和监视记录、验收活动记录，等等）的审查发现灭菌过程超出了公司的运行或性能参数指标的限制，那么：

a. Determine whether the nonconformances were handled appropriately; and

a. 确定不合格项是否得到适当处理；

b. Review the equipment adjustment, calibration and maintenance

If process or product nonconformance(s) are identified based upon these activities, determine whether the nonconformance(s) were recognized by the firm, handled appropriately and fed into its CAPA system.

Review (if appropriate) the firm's nonconforming product control, review and disposition activities and any CAPA's indicated. If the CAPA included a retest, review the firm's rationale for invalidating the original test results. If the CAPA included resterilization, confirm that the effects of the resterilization process on the product and package are understood. For example, did a validation study provide objective evidence that resterilization was acceptable?

If the firm's Quality System failed to recognize the process or product nonconformance(s) or take appropriate CAPA, this may be a major CAPA deficiency. Review the firm's equipment adjustment, maintenance and calibration records for the process. These activities may provide further insight into the cause of the nonconformances.

Examples of nonconformances and sterilization process failures the investigator may encounter include: Test Failures (e.g. Positive Biological Indicators, high EO residues, high bioburdens, out of specification endotoxin results); Parametric Failures (process failures such as unspecified well times, low pressure, low EO gas weights, loss of humidity, etc.); and Packaging Failures. Packaging Failures

b.审查设备的调试、校准和维护。

如果从中发现产品或过程的不符合项，确定公司是否识别不符合项，是否得到了适当的处置，是否输入了 CAPA 系统。

如果可行，审查公司的不合格产品控制、评审和处置活动和任何 CAPA 内包含的内容。如果 CAPA 中有再测试的内容，审查公司判定原测试结果无效的理由。如果 CAPA 中有重复灭菌的内容，确定对产品和包装的重复灭菌过程的效果得到了认同。例如，在确认研究中是否提供了重复灭菌是可以接受的客观证据？

如果公司的质量体系没有识别出过程或产品的不符合项或没有采取适宜的 CAPA，这是一个较大的 CAPA 缺陷。审查公司用于过程的设备的调试、保养和校准记录，这些活动也许有助于进一步的分析不符合项的原因。

审核员可能会遇到的不符合项和灭菌过程失败的事例有：测试失败（例如,生物指示计呈阳性，环氧乙烷残留高，生物负载高，内毒素超标）；参数失准（过程失误包括贮留时间没有限定、压力低、环氧乙烷气重量低、湿度小等等）；还有包装失效。包装失效可以说明一个灭菌过程参数问题

may be an indication of a sterilization process parameter problem (vacuum) or a packaging process problem (validation, sealer set up, etc.).

（真空）也可以是一个包装过程问题（确认、封装机设置等）。

Important linkages to consider at this point include Corrective and Preventive Actions, Material Controls (820.90 Nonconforming product), and Facilities and Equipment Controls (820.72 Control of inspection, measuring, and test equipment).

考虑这些问题的重要连接包括：纠正和预防措施，材料控制（820.90 不合格品），设施和设备控制（820.72 检查、测量和测试设备）。

4. If the sterilization process is software controlled, confirm that the software was validated.

4.如果灭菌过程受软件控制，确定这个软件是经过确认的。

If the sterilization process chosen is NOT controlled with software, proceed to Objective 5.

如果考查的灭菌过程不是受软件控制的，进行目标 5 的内容。

If the sterilization process is automated with software, review the software requirements document, software validation protocol, software validation activities, software change controls and software validation results to confirm that the software will meet user needs and its intended use. If multiple software driven systems are used in the sterilization process, challenge one based upon significance.

如果灭菌过程是由软件控制自动操作的，审查软件需求文件、软件确认方案、软件确认活动、软件更改控制和软件确认结果，以确定软件符合用户需求和预期用途。如果在灭菌过程中，使用了多个软件驱动系统，基于重要性选择具有挑战性的一个。

An important linkage to consider at this point is Material Controls (820.50 Purchasing Controls). For example, for software developed elsewhere, confirm that appropriate software and quality requirements were established and provided to the vendor and that purchasing data (and validation results) support that the requirements were met.

考虑这些情况可参考重要的链接；材料控制（820.50 采购控制）。例如，对其他地方开发的软件，考虑是否建立了合适的软件和质量规范，并将规范以及支持符合规范的采购数据（和确认结果）提供给销售商。

5. Verify that personnel have been appropriately qualified and trained to implement the sterilization

5.验证人员是否有适当的资格并接受培训以实施灭菌过程。

process.

Using the sampling tables, select a number of training and qualification records for process operators and employees conducting Q.C. activities related to the sterilization process. Where a process is operated over more than one shift, training records from all shifts should be included within your review. Confirm that all employees are aware of the device defects that may occur as a result of improper performance of their assigned responsibilities. Confirm that employees conducting Q.C. inspections and tests are aware of the defects and errors that may be encountered while performing their assigned responsibilities.

使用采样图表，选择若干培训和资格认定记录，这些记录涉及过程操作者和实施与相关灭菌过程相关的 QC 活动的工作人员。如果所选择的过程需要不止一个班次进行操作时，那么审核中应包括所有班次的培训记录，确认职工是否了解设备的缺陷，而这些缺陷可能是由于他们在执行职责范围内的不适合操作而引起的。确认进行 QC 和测试的工作人员了解他们工作中可能遇到的缺陷和错误。

An important linkage to consider at this point is Management Responsibility (820.25 Personnel).

在这里要考虑的一个重要的连接是管理职责（820.25-人员）。

NOTE:

Information that must be reported with the Establishment Inspection Report (EIR) includes:

1. The identification of all sterilization processes used by the firm (e.g. Ethylene Oxide, Gamma irradiation, etc.);
2. The identification of the sterilization process covered;
3. The identification of any standard that the firm claims to follow for the process covered (if applicable);
4. The location of the sterilization sites;
5. The division of responsibilities for sterilization services (e.g. contract testing labs, sterilizer, finished device manufacturer, packaging, labeling etc.);
6. The SAL ; and,
7. whether or not parametric release is utilized.

注意：

在建立检查报告中（EIR）必须报告的信息有：

1.公司使用的所有灭菌过程的确认（例如，环氧乙烷，Gamma 射线辐射等）；
2.识别覆盖的灭菌过程；
3.核对所有公司声明遵从的灭菌过程标准（如果可行）；
4 灭菌过程的地点；
5.灭菌服务责任的分配（例如，测试合约实验室、灭菌商、成品设备生产商、包装、标识等）；
6.灭菌确保水平-SAL；
7.是否使用了参数发布。

8.Sampling Plans: Instructions &Tables

8.1 Sampling Plan Instructions

Note: Factors to consider when selecting a sampling table and sampling size may include the risk of the device being inspected or the records being sampled, and the amount of time you have allocated to this portion of the inspection.

1. Select the table based upon how sure you want to be about what is observed. For example, if you are reviewing Device History Records of a life supporting device, you may choose to use Table 2 (99% Confidence). You may choose to use Table 1 (95% Confidence) for the review of Device History Records regarding a device with lower risk.

2. Select a sample size. If the population of records to be sampled is small (approximately thirty or less), you may choose to review all of the records.

3. Review the sample of records selected. You can terminate your review of the entire sample if you observe objectionable conditions beyond the number stated in the column header[1]. However, if you do not review all of the records in the sample, you may not report additional information that could be useful in further understanding the potential prevalence of the objectionable condition observed, or you may not recognize whether other objectionable conditions exist.

[1]If you choose to terminate your review prior to completing the review of the entire sample, in addition to the information contained in instruction 4, report in the Establishment Inspection Report how many records were reviewed prior to your termination of the review.

4. When objectionable conditions are observed based

8. 抽样计划说明&表格

8.1 抽样计划说明

注：选择抽样表以及抽样大小应考虑的因素包括接受检查器械的风险或者抽样记录，以及分配给次检查部分的时间。

1.根据你要观测的设备选择合适的表。例如：如果你要审查一个维持生命的设备的历史记录，你应该选择表 2（99％信任度）；如果你审查一个低风险设备的历史记录，你应选择表 1（95％信任度）。

2.选择样本大小，如果可供记录的群体比较小（大约 30 或更少），你应选择审查所有的记录。

3.审核对选择记录的抽样，如果你观察到的不利条件的数量超过列标题中陈述的数量[1]，你可以终止对整个样本的审核。但是如果你没有审核样本中的所有记录，你不能报告附加的信息，这些信息可能有助于进一步了解观察到潜在的不利条件，或者你可能不知道是否有其他不良情况存在。

[1] 如果你选择了在完成查看总体样本之前终止你的审核，除了指令 4 中包含的信息外，你还必须在建立检查报告中汇报出在终止检查前你观察到了多少记录。

4.当在使用这些表格的抽样记录中观

upon samples chosen using these tables, report in the Establishment Inspection Report: (a) the total number of records included in the population from which the sample was chosen; (b) the table used to select your sample; (c) the row used to select your sample; and, (d) the sample size selected[2].

[2]The information requested in instruction 4 must be reported whenever an Official Action Indicated (OAI) endorsement is considered. Reporting this information may not be necessary when Voluntary Action or No Action is indicated. However, caution is advised when using this reporting discretion because Voluntary Action Indicated endorsements are sometimes elevated to Official Action Indicated.

察到不利条件时，在建立检查报告中应作出如下报告：（a）包括在样品群体中的记录总数；（b）用于选择样品的表格；（c）用于选择样品的行；（d）所选择样品的尺寸[2]。

[2]只要由官方的行为指示（QAI）被签署，在说明 4 中需要的信息就必须汇报，当自愿行为或者没有行为指示时这些信息就不必汇报.但是需要注意的是，有时自愿行为指示可上升到官方行为指示。

NOTE:

A. There are no “acceptable” violations of the Quality System Regulation. All Quality System Regulation violations encountered must be handled appropriately according to current FDA policies and procedures. When using the “1 out of:” and “2 out of:” columns, it does not mean no more than that number of Quality System Regulation violations per the appropriate sample size is acceptable. It will only give you an initial understanding of how prevalent the problem may be.

B.When at all possible, all samples should be chosen at random.

注意：

A.任何违背质量体系法规的事件都是不可接受，遇到的违背质量体系法规的事件都必须按照目前的 FDA 政策和程序正确处理。当我们使用专栏 1 和专栏 2 时，并不意味着对于相应的样本大小，违背质量体系法规的事件的数量不超过规定的数量时就可以接受，它仅仅使你对如何预防可能存在的问题有一个初步的理解;

B.在可能的情况下，所有样品的选择都应该是随机的。

8.2 Table

Table 1

Binomial Staged Sampling Plans

Binomial Confidence Levels

Confidence Limit .95≤		0 out of:	1 out of:	2 out of:
A	.30 ucl*	11	17	22
B	.25 ucl	13	20	27
C	.20 ucl	17	26	34
D	.15 ucl	23	35	46
E	.10 ucl	35	52	72
F	.05 ucl	72	115	157

8.2 表格

表 1:二项式阶段抽样计划（Binomial Staged Sampling Plans）二项式置信度级别（Binomial Confidence Levels）

Confidence Limit .95≤		0 out of:	1 out of:	2 out of:
A	.30 ucl*	11	17	22
B	.25 ucl	13	20	27
C	.20 ucl	17	26	34
D	.15 ucl	23	35	46
E	.10 ucl	35	52	72
F	.05 ucl	72	115	157

Table 2
Binomial Staged Sampling Plans
Binomial Confidence Levels

Confidence Limit .99≤		0 out of:	1 out of:	2 out of:
A	.30 ucl*	15	22	27
B	.25 ucl	19	27	34
C	.20 ucl	24	34	43
D	.15 ucl	35	47	59
E	.10 ucl	51	73	90
F	.05 ucl	107	161	190

*ucl = Upper Confidence Level

CRC Handbook of Probability and Statistics: Second Edition

Binomial Sampling may be used when trying to make a decision about an endpoint that only has two potential outcomes (e.g., The device history record is compliant or the device history record is noncompliant).

表 2:二项式阶段抽样计划（Binomial Staged Sampling Plans）二项式置信度水平（Binomial Confidence Levels）

Confidence Limit .99≤		0 out of:	1 out of:	2 out of:
A	.30 ucl*	15	22	27
B	.25 ucl	19	27	34
C	.20 ucl	24	34	43
D	.15 ucl	35	47	59
E	.10 ucl	51	73	90
F	.05 ucl	107	161	190

*UCL＝Upper Confidence Level 上级置信度标准

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二项式抽样可以被用于尝试进行只有两个潜在结果的决策中（例如：设备历史记录是合格的或设备历史记录是不合格的）。

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