



**POINTS TO CONSIDER WHEN PREPARING FOR
AN FDA INSPECTION UNDER THE QSIT
MANAGEMENT CONTROLS SUBSYSTEM**

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Important Information

This document is the October 6, 1999 version of HIMA's "Points to Consider When Preparing for an FDA Inspection under the Management Controls Subsystem." This replaces the September 9, 1999 final draft. This version references FDA's August 1999 "Guide To Inspections of Quality Systems", which replaces the FDA's draft "QSIT Inspection Handbook." This document also references the "Draft Compliance Program Guidance Manual: Inspection of Medical Devices 7382.845," which is being revised.

HIMA will continue to update this document as companies and FDA get more experience with the Quality System regulation and FDA finalizes the "Draft Compliance Program Guidance Manual: Inspection of Medical Devices 7382.845.

To be sure you are using the latest edition of this document, please continue to check the FDA/EPA page on HIMA's Web site at www.himanet.com

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Points to Consider When Preparing for an FDA Inspection under the QSIT Management Controls Subsystem

Introduction

Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the FDA to conduct biennial good manufacturing practice (GMP) inspections of firms that manufacture class II or class III medical devices except those that have been exempted from the Quality System regulation (21 CFR Part 820). Traditionally, an FDA investigator took a “bottom up” approach to medical device inspections. He/she typically began an inspection by examining instances of quality problems and on the basis of that review determining if deviations from the Quality System regulation existed.

In an attempt to decrease the time spent and increase the focus of FDA medical device inspections, the FDA in consultation with industry developed a new approach for conducting inspections under the Quality System regulation. Called the Quality System Inspection Technique (QSIT), the investigator utilizes a “top down” approach to inspections. He/she starts the inspection by determining if procedures that address the requirements of the Quality System regulation have been defined and documented. The investigator then samples records to determine if the procedures are being followed.

Under the QSIT, the quality system requirements are divided into subsystems. The FDA, by directing its attention to the subsystems in a firm’s quality system, is better able to determine if the firm’s quality system is operating in a state of control. The QSIT focuses on four of the major subsystems in the Quality System regulation: management controls, design controls, corrective and preventive actions, and production and process controls. **This document discusses only the management controls subsystem.**

The concept behind the QSIT is that, for each subsystem, the FDA investigator will determine whether the firm has the appropriate* controls in place and is following its procedures to ensure it is producing products that conform to its specifications. From these observations, the FDA will form an impression of the overall adequacy of the firm’s quality system. Using the QSIT, an FDA investigator will examine different products and different processes during each inspection. By focusing on the four major subsystems that link to the three remaining subsystems, the QSIT provides comprehensive coverage of the firm’s quality system.

By adopting QSIT, the FDA is adopting practices more in line with those recommended by the Global Harmonization Task Force. Also note that QSIT is an FDA inspection method and manufacturers are required to audit all subsystems in their quality system and all requirements in the Quality System regulation.

* N O T E: The word “appropriate” is interpreted to mean that the procedures are suitable for the size of the company and the scope and nature of the activities performed.

Responsibility of Management

Under the FD&C Act, the top management of a company is responsible for ensuring that the requirements of the Act are performed. This concept is codified in the Quality System regulation. Inspections under the QSIT determine if top management is fulfilling its responsibilities. FDA officials have repeatedly stated that the commitment of top management is key, and the management controls subsystem is the central subsystem because it is the “glue that holds the quality system together.” It is also individuals in top management that the FDA will typically seek to enjoin, fine, or prosecute in the event of major noncompliance.

This exposure is not theoretical. The titles of medical device company corporate officials named in Section 305 notices under the FD&C Act (antecedent to a criminal prosecution) by FDA or prosecuted by the Department of Justice for violation of the Act have included:

- ❑ Chief Executive Officer
- ❑ President
- ❑ Executive Vice President
- ❑ Vice President, Quality Assurance
- ❑ Vice President, Production
- ❑ Vice President, Corporate Regulatory Affairs
- ❑ General Counsel

Recent cases illustrate all of the above. *See, for example, United States v. Prigmore*, 1996 WL 46430 (D. Mass, 1996); *United States v. C.R. Bard, Inc.* 848 F. Supp. 287 (D. Mass. 1994); and *United States v. Pagones*, No. 88-0581-CR (S.D. Fla. 1988).

FDA QSIT inspections will both begin and end with an examination of the management controls subsystem. Throughout the inspection, an investigator will determine whether “management with executive responsibility” has fulfilled its obligation to ensure that the firm has established an adequate and effective quality system.

Form FDA 483 Observations

In an attempt to evaluate the effectiveness of the QSIT approach, the FDA conducted a study between October 1998 and February 1999. Forty-two QSIT inspections of medical device firms were conducted during the study, in Los Angeles District, Minneapolis District, and Denver District. Analysis of the results showed that the FDA issued form FDA 483 observations to 66% of the firms that were inspected under the study. The management controls subsystems accounted for over 28% of the total deviations, and 40% of the top ten deviations. Specifically, the breakdown of management control deviations in the firms that received QSIT form FDA 483 observations were associated with the following topics:

- 43% Conduct of quality audits.
- 32% Conduct of management reviews.
- 29% Defining and documenting the quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions.
- 21% Organizational structure.
- 18% Appointment of the “management representative.”
- 11% Implementation of the quality policy.

To help companies avoid similar QSIT form FDA 483 observations, HIMA has prepared this question and answer document.

References

In compiling this document, we relied principally on the following sources: Federal Food, Drug, and Cosmetic Act; relevant case law; the Quality System regulation, 21 CFR Part 820; the Preamble to the Quality System regulation, which provides insight into the FDA’s interpretation of the regulation (61 FR 52654); the FDA Draft Compliance Program Guidance Manual: Inspection of Medical Devices 7382.845; Trautman, K.A., FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, 1997, Milwaukee, Wisconsin; the FDA’s August 1999 “Guide to Inspections of Quality Systems”*; Draft Guidance for FDA Staff on Civil Money Penalty Policy; and other FDA publications.

* N O T E: The FDA’s August 1999 “Guide to Inspections of Quality Systems,” can be accessed at: www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

Important Information

Manufacturers can comply with the requirements for the management controls subsystem in the Quality System regulation in several ways depending on the size of the company, the types of products it manufactures, and the company culture. Examples are included herein. **This document is not legal advice nor is it a standard. Companies must compare their individual practices and procedures with the documents listed above and obtain legal advice from their company or outside attorneys. Contact Nancy Singer, special counsel, for more information.**

Questions and Answers

Preinspections

- Q.1 Prior to the start of a QSIT inspection, when requested by an FDA investigator, should a medical device company provide the FDA with its overall or top level quality system policies and procedures including its management review procedures, quality policy, and quality plan?**

- A.1 Medical device companies should seriously consider providing these documents to the FDA as it will improve the efficiency of the inspection and establish a cooperative atmosphere. Company officials should ensure that these documents are returned before the end of the close-out meeting. As appropriate, such documents should be clearly marked “Confidential.” During the inspection, an FDA investigator has access to, and is entitled to make copies of individual documents. Providing these documents in advance may help reduce in-plant time. If these documents include specific information about a new design that has not been submitted in an IDE, 510(k), PMA, or PDP, then such information should not be given to or discussed with FDA.

Quality Policy

Q.2 Who is responsible for establishing a quality policy and seeing that the policy is being followed?

- A.2 The preamble to the October 7, 1996, Quality System regulation provides insight into how FDA interprets various provisions of the regulation. In comment 45 of the preamble, which relates to management responsibility, FDA cites two cases* to support the statement that “it is the responsibility of the highest level of management to establish the quality policy and to ensure that it is followed.” (underlining added).

* N O T E: Under the FD&C Act, top company officials can be held criminally liable for not complying with FDA law and regulations whether or not they had knowledge of those particular provisions. This principle was upheld by the Supreme Court in two decisions, United States v. Dotterweich, 320 U.S. 277 (1943) and United States v. Park, 421 U.S. 658 (1975). The Supreme Court, in discussing the duty of the president of the corporation, explains that a corporate official will be found liable if the official, “had by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct the violation complained of, and that he failed to do so.” 421 U.S. at 674. The Safe Medical Devices Act of 1990 provided that company officials could be subject to civil money penalties for violations of the law.

FDA regulations, 21 CFR 820.3(u), calls those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer’s quality policy and quality system, “management with executive responsibility*.” The FDA has prosecuted medical device corporate officials ranging from the Chief Executive Officer, President, Vice President and General Counsel to other officials at more junior levels within the organization for a company’s failure to comply with the requirements of the FD&C Act.

* N O T E: The Quality System regulation does not require that firms document the appointment of “management with executive responsibility.”

Establish

Q.3 How does the Quality System regulation define the term “establish”?

- A.3 The Quality System regulation in 21 C.F.R. 820.3(k) defines the term “establish” to mean “define, document (in writing or electronically), and implement.” For evidence of implementation, an FDA investigator will look to see if the written procedures are actually performed. He/she will determine how the firm deals with in process and product failures, how quality deviations are handled, and how responsive the corrective and preventive actions are.

Quality Policy

Q.4 May responsibility for the quality policy and quality system be delegated?

- A.4 “Management with executive responsibility” is responsible for establishing its policy and objectives for, and commitment to, quality. Additionally, “management with executive responsibility” shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization. Although “management with executive responsibility” cannot delegate away its accountability, it can delegate to another individual the authority and responsibility for ensuring that the quality system requirements are effectively established and maintained and to report on the performance of the quality system to “management with executive responsibility.” The regulation refers to this individual as the “management representative” (21 CFR 820.20(b)(3)).

Management with Executive Responsibility

Q.5 What might “management with executive responsibility” do to fulfill its obligation under 21 CFR 820.20(a)?

- A.5 21 CFR 820.20(a) states, “Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality.” It is interesting to note that while the term, “quality policy” is defined as the overall intentions and directions of an organization with respect to quality as established by “management with executive responsibility” (21 CFR 820.3(u)), the terms “quality objectives” and “commitment to, quality” are not defined in the Quality System regulation. Note, however, 21 CFR 820.20-25 contains an extensive list of requirements or “quality tools” to aid management in establishing and monitoring a quality system.

The quality policy and objectives should emphasize the company’s commitment to quality and should be written in appropriate language(s) and at a level of complexity appropriate for the intended audience(s). All employees should have access to it. The quality policy as well as the objective should be an integral part of the business objectives to emphasize that the company does not see quality as simply an FDA or ISO 9000 requirement, but rather as an essential condition for the company’s success.

Each company is unique because of the products it makes, the patients and customers it serves, the people it employs, and the community in which it is located. Thus, a company will fashion its quality policy according to its own needs and values. Bearing in mind the need for brevity and clarity, a company might consider including **some** or all of the following concepts in its quality policy and objectives:

- ❑ **A statement that the company is committed to providing high quality products that are safe and effective for their intended purposes.**
- ❑ **A statement that the company is committed to complying with all applicable laws and regulations.**
- ❑ **A statement that the company is committed to providing training on its quality policy and procedures.**

A company might also consider including a statement about its duty to its stakeholders (the patients, the public, the customers, the employees, the stockholders, the community, the payers, and the government) and its moral obligation to release safe and effective products for use in humans.

Quality Policy

Q.6 What evidence might be shown to an FDA investigator to demonstrate that the quality policy has been disseminated?

A.6 Examples of evidence include:

- ❑ Notations in employee* training records.
- ❑ Leaflets distributed to employees.
- ❑ Signage located around the company.
- ❑ Articles in company newsletters.
- ❑ Notices on the company's Intranet.

* N O T E: The term "employee" refers to permanent, contract, and temporary employees.

Organizational Structure

Q.7 What elements might be included in an organizational structure to ensure that it includes provisions for responsibilities, authorities, independence, and necessary resources for implementing the quality system?

A.7 Elements in the organizational structure that would contain provisions for responsibilities, authorities, independence, and necessary resources for implementing the quality system might include:

- ❑ Designation of an individual in the organizational chart or job description as the "management representative."
- ❑ Individuals' authority to deploy resources.

- ❑ Procedures through which key officials (for example, “management with executive responsibility,” “management representative,” or other employees) are able to control the release of products, and, when necessary, authorize appropriate corrective and preventive action to be taken to prevent or eliminate non-conformities.

A manufacturer should also consider informing employees of the methods by which they can report instances of either failure to meet specifications or noncompliance. These methods may include:

- ❑ Talking to management.
- ❑ Obtaining the advice of company counsel.
- ❑ Contacting the human resources department.
- ❑ Calling the company hotline.
- ❑ Using the company suggestion box.
- ❑ Talking to the “management representative.”
- ❑ Talking to individuals in the quality department.

Q.8 What evidence might be shown to an investigator to demonstrate that the firm’s organizational structure contains provisions for responsibilities, authorities, independence, and necessary resources for implementing the quality system?

A.8 Evidence to show that the firm’s organizational structure contains provisions for responsibilities, authorities, independence, and necessary resources for implementing the quality system might include:

- ❑ Pertinent parts of the organization chart.
- ❑ Position descriptions.
- ❑ Pertinent pages of the quality manual.
- ❑ Procedures by which specified individuals are authorized to control the release of product and, when necessary, authorize appropriate corrective and preventive action to control, reduce, or eliminate non-conformities.

When discussing resources with an FDA investigator, remember that section 704 of the FD&C Act provides that an inspection will not extend to financial data or personnel information. However, an FDA investigator is authorized to see information related to the experience and training of personnel relative to their job responsibilities.

Quality Plan

Q.9 What might be elements of a quality plan?

A.9 Quality plans may be general and address all aspects of the quality system or specific and relating to only one product or process. Elements of a general quality plan might include:

- Design and development plan,
- Device master record,
- Production procedures and process flow diagram, and
- Results of management reviews and internal audits as demonstrated in corrective and preventive action projects.

Elements of quality planning that relate to a specific product might include a compilation of procedures, or references to procedures, intended to ensure that the product conforms to its specifications. These procedures may include sampling, testing, and acceptance criteria for receiving, in-process, and finished device inspections.

Quality System Procedures and Instructions

Q.10 What evidence might be shown to an FDA investigator to demonstrate that quality system procedures and instructions have been established?

A.10 Evidence to show an FDA investigator that quality system procedures and instructions have been established might include:

- Quality System Record as defined in 21 CFR 820.186, "...which include[s], or refer[s] to the location of, procedures and the documentation of activities... that are not specific to a particular type of device(s)..."
- A document control system that contains an outline of the structure of the documentation used in the quality system.
- Procedures showing how documents are controlled (e.g. the issuance and withdrawal of documents and the chronology of written changes), maintained, and are accessible in terms of form, content, style, and suitability.
- Procedures relating to all aspects of the process and quality assurance functions from the design to testing and release and servicing of finished devices that are in compliance with the quality system requirements including:
 - control of manufacturing processes,
 - calibration, inspection and testing of equipment,

- ❑ systematic review of procedures for accuracy, applicability and compliance with the regulatory requirements, and
- ❑ approval of policies and procedures by the appropriate level of personnel in the appropriate functional areas.

Management Representative

Q.11 What elements might be included in the designation of a “management representative”?

A.11 The company should appoint a specific individual (by title and/or name) as the “management representative.” Comment 49 to the preamble of the Quality System regulation provides that the “management representative” need not be “management with executive responsibility.” This individual would be responsible for ensuring that the quality system is effectively established and maintained. He/she would be responsible for reporting on the performance of the quality system to “management with executive responsibility.” The company should consider whether it wants this individual to be designated as the chair of the management review committee.

Companies should consider documenting the appointment of the individual in one or more of the following:

- ❑ Organization chart.
- ❑ Individual’s job description.
- ❑ Quality manual.
- ❑ Corporate memo.

Companies should ensure that the individual:

- ❑ Has the appropriate background.
- ❑ Is properly trained, which includes being familiar with the documents listed in “References” referred to on page 3 of this document.
- ❑ Is fully informed that the consequences for noncompliance with the law could include civil and criminal penalties to the individual and to the organization.

In designating the “management representative,” “management with executive responsibility” should consider the profile of the individual and the position.

Consideration should include:

- ❑ His/her ability to effectively influence the organization at all levels.
- ❑ His/her analytical and communication skills.

- ❑ The amount of support that “management with executive responsibility” will provide to help the individual be effective in the position.

In accordance with 21 CFR 820.100, companies should provide the “management representative” and “management with executive responsibility” relevant reports such as:

- ❑ Quality audits.
- ❑ Summaries or analysis of :
 - ❑ complaints,
 - ❑ adverse event reports and medical device reports (MDRs),
 - ❑ corrective and preventive actions relative to design control,
 - ❑ corrective and preventive actions relative to in-process or finished product failures, and
 - ❑ acceptance and rejection rates from inspection activities and other indicators of process and product control.

Such reports may be provided in more detail or with greater frequency to the “management representative” than they would be to “management with executive responsibility” during the management reviews.

Companies should consider delegating authority and responsibility to the “management representative” to recommend, authorize, or approve:

- ❑ Key substantive changes to documents that reflect changes to major policies or procedures.
- ❑ Major changes to product designs.
- ❑ Major changes to processes.
- ❑ Stopping production.
- ❑ Stopping shipment.
- ❑ Conducting a recall.

Companies should consider documenting authority and responsibility of the “management representative” in one or more of the following:

- ❑ Individual’s job description.
- ❑ Firm’s quality manual.

- ❑ Relevant procedures.

Companies should consider having a procedure that describes the role of the “management representative” in management reviews.

Companies should consider having a procedure or requirement to periodically review, revise, and/or reaffirm the designation of the “management representative.”

Management Representative

Q.12 What evidence might be shown to an FDA investigator to demonstrate that a “management representative” has been appointed and that his/her purview and authority are appropriate?

A.12 Evidence that might be shown to an FDA investigator that a specific individual has been officially designated as the company’s “management representative” and that his/her purview and authority are appropriate include:

- ❑ Job descriptions.
- ❑ Organization charts.
- ❑ Quality manual.
- ❑ Relevant procedures.
- ❑ Corporate memo.

Management Review

Q.13 What elements might be included in management review procedures?

A.13 Management review procedures are required. They might include:

- ❑ A statement that management reviews will take place on both a periodic and *ad hoc* basis.
- ❑ Schedules for management reviews.
- ❑ The procedure or requirement for reviewing the appropriateness of the frequency of management reviews based on the findings of previous management reviews.
- ❑ A description of the level and scope of authority of the people who will attend the management reviews and the necessity for a quorum.
- ❑ A statement that “management with executive responsibility” or qualified designate will attend the management reviews.

- ❑ The procedure or requirement for the “management representative” or qualified designate to report on the status of the quality system at management reviews.
- ❑ The procedure or requirement for reviewing such items as supplier audits, internal audit reports, quality problems, and quality data.
- ❑ The procedure or requirement for initiating, documenting and following-up on corrective and preventive actions, including those from previous management reviews.
- ❑ The procedure or requirement for reviewing/evaluating product and process variations and nonconforming product.
- ❑ The procedure or requirement for examining the organizational structure, including adequacy of staffing, resources, and training; the status of the quality system; and the quality of the finished device in relation to:
 - ❑ the quality policy and quality objectives,
 - ❑ quality data including internal and customer feedback in terms of the process and product (including servicing) performance, and
 - ❑ trends and changes that could affect the quality system such as new technologies, quality concepts, market strategies, and social or environmental conditions.
- ❑ The procedure or requirement to ensure that the minutes from management reviews are accurate and contain appropriate language.
- ❑ The procedure or requirement that minutes from management reviews are to be stamped confidential, are not required to be, and should not be disclosed during a routine inspection.

Companies with multiple business units or groups should consider the need for holding senior level management reviews across business units. When making this decision, companies should consider setting up procedures that outline:

- ❑ The frequency of the management reviews,
- ❑ The content of the material to be discussed at those management reviews, and
- ❑ The level of those in attendance.

Minutes from management reviews should be maintained in accordance with the company’s document retention procedures.

Q.14 What evidence might be shown to an investigator that management reviews are being conducted?

A.14 Evidence that management reviews are being conducted might include:

- Procedures for management reviews that contain standard agendas with headings that discuss review of:
 - supplier audits,
 - internal audits,
 - quality problems,
 - corrective and preventive action, and
 - follow-up.
- Agendas relating to the review of the quality system, and dates and attendance lists for management reviews that have taken place.
- Corrective actions* that resulted from the management reviews.
- Schedules of management reviews (past and present).

The Quality System regulation provides that the requirement to make records under the Quality System regulation available for inspection and copying by FDA officials does not apply to management reviews, quality audits and supplier audits (21 CFR 820.180(c)). **However, comment 182 of the preamble to the Quality System regulation provides that FDA may seek production of management reviews and quality audit reports “... in litigation under applicable procedural rules or by inspection warrant where access to the records is authorized by statute.”**

A designated FDA employee under 21 CFR 820.180(c) may request that, under the requirements of the regulations, “management with executive responsibility” certify in writing that management reviews and quality audits have been performed and documented, the dates on which they were performed, and that “any required corrective action has been undertaken.” If an FDA employee makes this request, **seek the assistance of legal counsel before providing this certification.** When providing the certification concerning whether or not “any required corrective action has been taken,” counsel should consider including language, “to the best of my knowledge, on the basis of the facts before me, it appears that a good faith effort has been made to ensure that any required corrective action deemed necessary by management has been undertaken.”

* N O T E: In the course of a follow-up investigation for a recall, safety alert, or other corrections, an FDA investigator may seek to obtain information on how a nonconformity was detected, or to review general procedures for corrective and preventive action. Under some circumstances, this could lead to requests for information relating to internal management reviews. Firms should develop an internal policy and/or procedure on how to handle these requests.

Quality Audit Procedures

Q.15 What might be elements of quality audit procedures?

A.15 Quality audits include quality system audits, process audits, product audits (new and released), and supplier audits. (Repetitive product audits are not part of the quality system audit specified by 21 CFR 820.22. The procedures for product audits, particularly those for verification and validation in 21 CFR 820.30, are part of the required quality system documentation and subject to a quality system audit.) Elements of quality audit procedures might include:

- ❑ The systematic audit of all activities to ensure adequacy and compliance with all elements and subsystems of the Quality System regulation on a regular and *ad hoc* basis. (Even though FDA may perform an inspection of selected subsystems under the QSIT approach, manufacturers must audit **all** subsystems.)
- ❑ Comprehensive follow-up from previous audits and documentation of the follow-up action, i.e. linkage to the corrective/preventive action process.
- ❑ Position descriptions of the auditors and a statement that they are:
 - ❑ qualified by training and experience,
 - ❑ independent of the areas being audited, and
 - ❑ able to be objective in their assessments.
- ❑ The requirement to document the dates when audits occur.
- ❑ The requirement to ensure that audit reports are accurate and contain appropriate language.
- ❑ The procedure for the distribution of audit reports, limited to specified individuals.
- ❑ The procedure or requirement that the results from audits are to be stamped confidential, are not required to be, and should not be disclosed during a routine FDA inspection.

Audit reports should be maintained in accordance with the company's document retention program.

Q.16 What evidence might be shown to an investigator to demonstrate that audits are being conducted?

A.16 Evidence to show that audits have been conducted might include:

- ❑ Audit procedures.
- ❑ A list of the audits conducted, the dates they were conducted, and their scope.

- List of audit team members.
- Corrective actions that resulted from quality audits*.
- Schedule of upcoming audits.

For an explanation of FDA's access to the information in quality audit reports, see answer to question 14.

* N O T E: In the course of a follow-up investigation for a recall, safety alert, or other corrections, an FDA investigator may seek information on how a nonconformity was detected. Under some circumstances, this could lead to requests for information relating to internal audits. Firms should develop an internal policy and/or procedure on how to handle these requests.

To view the FDA “Guide To Inspections of Quality Systems,” go to www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm