THE QUALITY SYSTEM REGULATIONS

SUBPART B – QUALITY SYSTEM REQUIREMENTS

21 CFR 820.20
MANAGEMENT RESPONSIBILITY

21 CFR 820.20
Management Responsibility

(a) Quality policy

Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality.

Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

21 CFR 820.20
Quality Policy and Objectives

Documented Quality Policy that describes the overall intentions, directions and commitment of management and the organization to Quality.

COMPANY X is dedicated to improving patient outcomes through the development of technical and clinical innovations that provide solutions to significant unmet clinical needs.
We will remain firmly focused on the patient and our customers in our effort to provide products and services of the highest quality.

In order to meet this commitment, we will comply with customer and regulatory requirements and maintain the effectiveness of the Quality Management System, continually look for opportunities to improve our operations, processes and procedures and establish COMPANY X as a premier company in the medical device field.

21 CFR 820.20
Quality Policy and Objectives

- Defined Quality Objectives that support the Quality Policy.
  - Clear and Easy to Understand
  - Achievable
  - Measurable (defined criteria)
  - Time-bound
  - Reported
  - Reviewed

21 CFR 820.20
Quality Policy and Objectives

- Quality Policy is understood, implemented, and maintained at all levels of the organization.
  - Quality Policy and Quality Objectives are:
    - Written
    - Posted
    - Incorporated into employee training
    - Provide guidance in making decisions
    - Incorporated into the quality system

ISO 13485:2016 – refer to 5.3 for Quality Policy

21 CFR 820.20
Management Responsibility

- *(b) Organization. Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.*
- *(1) Responsibility and authority. Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.*
- *(2) Resources. Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.*

21 CFR 820.20
Management Responsibility

- *3) Management representative. Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:*
  - *(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and*
  - *(ii) Reporting on the performance of the quality system to management with executive responsibility for review.*

21 CFR 820.20
Management Responsibility

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

21 CFR 820.20
Management Review Procedure

- Written procedure that defines:
  - Frequency
    - dependent on needs and size of the organization
    - typically 2 to 4 times per year
  - Required attendees (with explicit delegation as appropriate)
    - Management with Executive Responsibility
    - Management Representative
    - Other company managers (optional)

21 CFR 820.20

Management Review Agenda

- **Agenda Items**
  - Actions from previous management review
  - Performance to Quality Objectives
  - Performance to other Quality Metrics
  - Changes/Improvements to the Quality System
  - Performance of the Quality Systems*
    - Customer Complaints and MDR/ reportable events
    - Non-Conforming Materials
    - Purchasing Controls / Supplier Quality
    - Corrective and Preventive Actions / Field Corrective Actions
    - Internal and External Audits
    - New or revised regulatory requirements or other regulatory issues.
    - Compliance, suitability and effectiveness of the Quality Management System, including Risk Management, Quality Policy and Quality Objectives.
    - Decisions/Actions
    - Conclusions

*Example only, not a complete list of items

21 CFR 820.20
Examples of Management Review Records

- **Records of Management Review**
  - Attendance Sheet*
  - Agenda*
  - Data Presented
  - Meeting Minutes
  - Actions
    - Timelines and method for tracking to completion
  - Certification Statement*
    - Date
    - Attendees
    - Agenda
    - A statement that any required corrective actions have been taken.

* Items may be requested by FDA.

21 CFR 820.180
Records (c) Exceptions

This section does not apply to the reports required by 820.20(c) Management review, 820.22 Quality audits, and supplier audit reports used to meet the requirements of 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

21 CFR 820.20 (d)
Quality Planning

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

21 CFR 820.20 (d) Quality Planning

- Typically this is a roadmap / chart that defines the overall quality system. Much of what is required to be part of the plan is found in:
  - Quality Objectives
  - Quality Manual
  - Quality Plans for significant quality system or facility projects.
    - Implementing an electronic document control system
    - Moving a product line to a new facility

ISO 13485:2016 – refer to section 5.4 for Planning (including 5.4.1 Quality objectives and 5.4.2 for Quality management system planning)

21 CFR 820.20 (e)
Quality System Procedures

- *(e) Quality system procedures. Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.*

21 CFR 820.20 Management Responsibility

Excerpt from Warning Letter

"…Failure to implement your management review procedure, as required by 21 CFR 820.20(c). Specifically, your management review procedure states that management review meetings are held quarterly. Your firm has not documented a management review meeting since December 2004*…"

*Warning letter dated 2010.

21 CFR 820.20 Management Responsibility

483 Observation (Jan 2018)

The quality policy and quality objectives was/were not established by management with executive responsibility. Specifically, Your documented quality policy has the following deficiencies:

a. The policy is titled, "Quality Policy for FY2016" (a policy for one year);
b. The quality policy is signed by an management executive who has left your facility as of March of 2017;
c. The policy has no document control references (i.e. quality control number)

Management Review Poll Question

Is the following statement a true QSR deficiency?

Failure to implement your management review procedure, as required by 21 CFR 820.20(c).

Specifically, your management review procedure states that management review meetings are only conducted annually.

Summary
Management Responsibility

- Quality policy and Quality Objectives must describe the overall intentions and directions of the company with regards to quality.
  - Management must assure the policy and objectives are understood and implemented throughout the organization
- Organization chart; management representative defined.
- Management Review
  - Procedure
  - Documented evidence
  - To be effective, Management Review must be meaningful to the organization.
  - Actions which result from Management Review must be appropriately resourced, completed in a timely manner, and reported back to Management.
- Quality Plans
- Quality System is documented by Quality Procedures.

21 CFR 820.22
QUALITY AUDITS

21 CFR 820.22
Quality Audit

- *Each manufacturer shall*
  - *establish procedures for quality audits*
  - *conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.*
  - *Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited.*
  - *Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary.*
  - *A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited.*
  - *The dates and results of quality audits and re-audits shall be documented.*

21 CFR 820.22
Quality Audit

- Monitor and sustain compliance with the QSR
- Identify areas of non-compliance with QSR or your own internal procedures.
- Complete corrective actions to bring back into compliance.

21 CFR 820.22
Quality Audit Procedure

- **Internal Audit Procedure that defines:**
  - **Audit Schedule requirements**
    - Each element of the QSR should be audited at least annually.
    - More frequent audits for areas with previous audit findings, or other areas of concern (e.g. recent changes) may be advised.
  - **Auditor Requirements**
    - Must not be responsible for areas they are auditing
    - Define auditor qualification and training requirements
    - You may use qualified 3rd party auditors to complete your internal audits if you do not have personnel who are qualified and/or have sufficient independence.
  - **Audit Process**
  - The audit process needs to address:
    - Re-audit requirements
    - Method for assigning, documenting and tracking audit corrective actions to completion and determining effectiveness

ISO 19011:2011 Guidelines for auditing management systems can provide some guidance when creating the audit process.

21 CFR 820.22

Quality Audit
Excerpt from Warning Letter

"…Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system …. For example, no procedures for quality audits were available for review by the investigator..."

21 CFR 820.22

Quality Audit Excerpt from Warning Letter

- Failure to establish and maintain procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.
- These quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited, as required by 21 CFR 820.22. For example, your firm's Quality System Manual, Version 2.0, dated July 19, 2013, Section 9.2, "Internal Auditing," describes performance of audits conducted across all functional business groups. However, the procedure does not specify that audits cannot be conducted by individuals who have direct responsibility for the area being audited. Specifically, the chart, included in the procedure, states that audits should be conducted by managers or supervisors from each audited area.

21 CFR 820.22
Quality Audit Records

- **Audit Schedule***
- **Proof of Audit***
  - Audit date
  - Auditor name and signature
  - Elements of the QSR audited
  - Statement that any required corrective action has been undertaken
- **Audit Report**
  - Audit date
  - Auditor name and signature
  - Auditee(s)
  - Elements of the QSR audited
  - Audit Findings
  - Need for re-audit

**Documents that may be requested by a FDA Investigator.*

21 CFR 820.22
Quality Audit Records

- Other Audit Documentation
  - Completed audit checklist
  - Auditor notes
- Corrective Actions/ Effectiveness Verifications*

**Documents that may be requested by a FDA Investigator.*

21 CFR 820.22

Internal Auditing Is Good Business Practice

- Proactively measure the health (state of effectiveness) of your quality system.
- Identify and correct areas of actual or potential non-conformance with the quality system requirements.
- Continuous improvement - demonstrate that you are constantly evaluating, correcting and improving your quality system.

21 CFR 820.25
PERSONNEL

21 CFR 820.25 Personnel

- *(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.*
- *(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.*
  - *(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.*
  - *(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.*

21 CFR 820.25
Personnel and Training

- Training Procedure shall be established.
  - ISO standard 10015:1999 Quality management – Guidelines for training is a useful guideline for training

- Define education and experience requirements for each job.
  - Job description
  - Resume
  - Certifications

21 CFR 820.25 Personnel and Training

- Recommended best practices:
- Define internal training requirements for each job.
  - Training matrix that defines jobs vs. requirements
  - All employees should be trained to the QSR, Quality Policy, Quality Manual, procedures specific to their job duties.

21 CFR 820.25
Personnel and Training

- **Recommended Training Methods**
  - Classroom, on the job, notification/read & understand, eLearning's
  - Measurement of training effectiveness
  - Include awareness of defects and errors that can occur

21 CFR 820.25
Personnel and Training

- **Training Records**
  - Date, name/signatures of trainer and trainees
  - Training content (procedures/revision)
  - Certification (if required)
  - Effectiveness measurements (e.g. quiz or performance review)
  - Records are available to verify personnel qualifications to perform specified operations.

21 CFR 820.25
Personnel and Training

- **Link Training to Document Control system**
  - Document changes often trigger training activities
  - Training is completed prior to implementation of changes

21 CFR 820.25 Training

Excerpt from Warning Letter

*'…Failure to adequately establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities….. For example, there is **no** documentation of employee training to your firm's numerous procedures and work instructions that are necessary for your employees to perform their assigned duties…"*

21 CFR 820.25 Training

483 Observation (April 2018)

Procedures for training and identifying training needs have not been established.
Specifically, the firm does not have any training procedures in place for training on SOPs and the quality system regulations.
In addition, there are no training records in place for individuals associated with the firm that manufacture [X] kits and process orders.

QUESTIONS?