Contents

Corrective and Preventive Actions (CAPA)

Overview

Introduction

This Standard Operating Procedure (SOP) covers FDA's regulations that govern

- Corrective and Preventive Actions (CAPA) raised by a firm for product and quality problems
- reporting of medical devices
- Corrections and Removals (CAR) of nonconformances, and
- tracking of medical devices.

Contents

The table below lists the contents of this SOP.

1. Corrective and Preventive Actions

Overview

Contents

The table below lists the topics in this section.

1.1. Inspectional Objectives

Purpose

The purpose of the corrective and preventive action subsystem is the following:

- collect and analyze information
- identify and investigate product and quality problems
- verify or validating corrective and preventive actions
- communicate corrective and preventive action activities to responsible people, providing relevant information for management review
- document these activities to deal effectively with product and quality problems
- take appropriate and effective corrective and/ or preventive action to prevent their recurrence, and
- prevent or minimize device failures.

One of the most important elements of the quality system is the corrective and preventive action subsystem.

Stages in CAPA inspection

The table below describes the stages in conducting CAPA inspection:

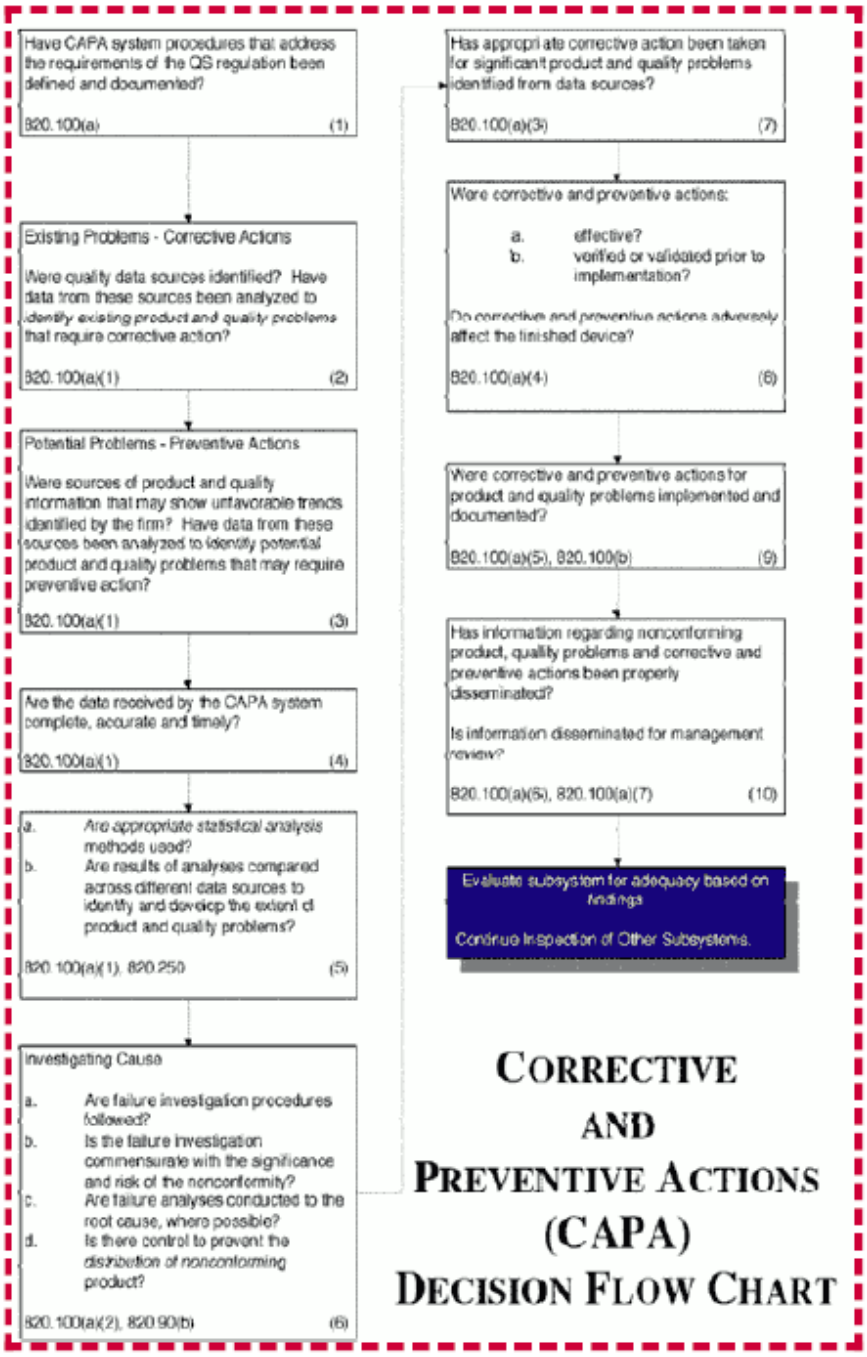
Stage	Description
1	Evaluation of the Firm's CAPA System Procedures
2	Analysis of quality and product problems requiring CAPA
3	Data verification and adherence to effective statistical techniques
4	Analysis of failure investigation procedures
5	Analysis of Preventive Action for Product and Quality Problems
6	Verification if the problems and corrective action were documented and submitted for management review

Continued on next page

1.1. Inspectional Objectives, Continued

Decision flowchart

The flowchart below describes the stages in conducting CAPA inspection.



1.2. Evaluation of the Firm's CAPA System Procedures

Efficient CAPA system procedures

For the CAPA system procedures to be efficient, the procedures must include the following:

- definitions and interpretation of words or terms such as
  - non-conforming product
  - quality audit
  - correction
  - prevention, and
  - timely, to name a few
- how the firm will meet the requirements for all elements of the CAPA subsystem
- implemented procedures

Firm's analysis to identify the problem source

The firm must have the established the following in identifying their problem source:

- methods and procedures to input product or quality problems built into the CAPA subsystem
- routine analysis of quality data regarding product and quality problems.
- analysis of
  - data and information of from all acceptance activities
  - complaints
  - service, and
  - returned product records.

Records relevant for review

The following records are relevant for review:

- raw data that is used by the firm when conducting their quality audits, management reviews, etc.
- trending information and results of analyses that are generally part of evaluations under the corrective and preventive action requirements
- information utilized in internal audits and management reviews

***Note**: Information or data utilized in internal audits and management reviews are considered raw data and hence relevant for routine review.*

Continued on next page

1.2. Evaluation of the Firm's CAPA System Procedures, Continued

Records irrelevant for review

As per Agency policy (CPG 7151.02), do not request records regarding the results of any of the following:

- internal quality audits
- management reviews
- third party audits (including ISO audits), or
- supplier audits

Verifying the efficiency of the firm's CAPA system procedures

The table below describes the steps in verifying the efficiency of the firm's CAPA system procedures.

Step	Action
1	Check if the firm has efficient CAPA system procedures that address the requirements of the quality system regulation. ***Reference**: For more information about efficient CAPA system procedures of a firm, refer to Efficient CAPA system procedures.*
2	Gain a working knowledge of the firm's corrective and preventative action.
3	Determine if the firm has a system for the identification and input of quality data into the CAPA subsystem. ***Note**: Such data includes information regarding product and quality problems (and potential problems) that may require corrective and/or preventive action.*

Continued on next page

1.2. Evaluation of the Firm's CAPA System Procedures, Continued

Determining if sources of problems identified are appropriate

The table below describes the steps in determining if the sources of the product and quality problems identified are appropriate.

Step	Action
1	Confirm that the firm has analyzed the data from sources of product and quality problems requiring corrective action. ***Reference**: For more information about the firm's analysis about the source of the problem, refer to Firm's analysis to identify problem source.*
2	Analyze the product and quality problems that require corrective action.
3	Determine if the firm is capturing and analyzing data from acceptance activities relating to • component • in-process, and • finished device testing.
4	Capture and analyze information obtained from distribution that includes • complaints • service activities • returned products • information relating to concessions (quality and nonconforming products) • quality records, and • other sources of quality data such as – quality audits – installation reports, and – lawsuits, to name a few.

1.3. Product and Quality Information Showing Unfavorable Trends

Statistical Process Control: definition

Statistical Process Control (SPC) is an example of a statistical control technique for process controls. SPC is utilized to monitor a process and initiate process correction when a process is drifting toward a specification limit.

Indicators of Preventive Actions

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 non-conforming product) are also positive indicators of preventive actions.

In-conformance product data: firm's analysis

A firm captures and analyzes in-conformance product data to detect a shift in test results. This shift may indicate changes in the

- vendor processes
- component design, or
- acceptance procedures.

Preventive Action

Identification of the above indicators may necessitate a vendor investigation as a preventive action.

Devices with stability issues: Firm's monitoring routine

For devices where stability is an issue, the firm continually monitors test results of reserve samples. These monitoring activities may trigger

- process changes
- additional training activities, and
- other changes required to maintain the process within its tolerances and limits.

Continued on next page

1.3. Product and Quality Information Showing Unfavorable Trends, Continued

Evaluating unfavorable trends identified by the firm

The table below describes the steps in evaluating unfavorable trends identified by the firm as the problem source.

Step	Action
1	Confirm that the firm has analyzed and identified potential product and quality problems by doing the following: • Review the 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 the firm has taken preventive actions regarding unfavorable trends recognized from the analysis of product and quality information.
2	Monitor in-process and finished device test results to identify additional indicators of potential quality problems. ***Reference**: For more information about the firm's analysis and monitoring, refer to In-conformance product data: firm's analysis and Devices with stability issues: Firm's monitoring routine.*
3	Determine if the firm is using statistical control techniques for process controls where statistical techniques are applicable. ***Reference**: For more information about statistical control techniques, refer to Statistical Process Control.*

***Reference:** For more information about these activities, refer to the linkages in 820.70 Production and Process Controls and 820.250 Statistical Techniques.*

1.4. Statistical Techniques and Data Verification

Statistical techniques

Statistical techniques include the following:

- Pareto analysis
- Spreadsheets, and
- Pie charts

Non-statistical techniques

Non-statistical techniques include the following:

- Quality review boards
- Quality review committees, and
- Other methods

Product and quality problems: firm's analysis

The analysis of product and quality problems must include the comparison of problems and trends across different data sources to establish a global, and not an isolated view, of a problem.

Example

Problems noted in service records are comparable with similar problem trends noted in complaints and acceptance activity information.

Verify data accuracy

The list below describes the guidelines for data accuracy verification:

- Challenge the quality data information system by doing the following:
  - Select one or two quality sources.
  - Using the sampling tables, review records from the chosen data sources to determine if the firm had entered the data into the CAPA system.
- Determine if
  - the data is complete and accurate, and
  - the firm had entered it in the CAPA system a timely manner.

***Reference**: For more information about this activity, refer to linkages 820.80 Acceptance Activities, 820.90 Nonconforming Product, 820.170 Installation, 820.198 Complaint Files and 820.200 Servicing.*

Continued on next page

1.4. Statistical Techniques and Data Verification, Continued

Verify the firm's mode of detecting problems

Follow the guidelines below to verify the firm's mode of detecting problems:

- Analysis of the product and quality problems using appropriate statistical and non-statistical techniques. (**Reference**: For more information about statistical and non-statistical techniques, refer to Statistical and non-statistical techniques and Product and quality problems: Firm's analysis)
- Determination of the proper course of preventive action upon capturing the full extent of the problem before the probability of occurrence and risk analysis

1.5. Failure Investigation Procedures

Determining if the firm follows failure investigative procedures

The table below describes the steps in determining if the firm follows failure investigative procedures in root cause analysis of nonconformity.

***Reference**: For more information about management responsibility and nonconforming products, refer to linkages 820.20 Management Responsibility and 820.90 Nonconforming Product.*

Step	Action
1	Determine provisions to the CAPA procedures.
2	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. ***Note**: The decision process may be linked to the results of a risk analysis and essential device outputs.*
3	Select and confirm all failure modes using the sampling tables.
4	Determine the depth of investigation.
5	Using the sampling tables, review the number of incomplete failure investigations for potential • unresolved product non-conformances, and • distribution of nonconforming product. ***Note**: If you are unable to resolve the problem, exercise product recall to avoid significant risks to the patient or user.*
6	Review the records using the sampling tables.
7	Using the sampling tables, review the following: • Nonconforming product and quality concessions • Controls for preventing distribution of nonconforming products • Product and quality concessions ***Note**: Reviewing product and quality concessions is a means to verify that the firm exercised concessions appropriate to product risk, within the requirements of the quality system and not solely to fulfill marketing needs.*

Continued on next page

1.5. Failure Investigation Procedures, Continued

Determining provisions to the CAPA procedures

Do as follows to determine the provisions to the CAPA procedures:

Step	Action
1	Review the firm's CAPA procedures that it uses to conduct failure investigations.
2	Determine if these procedures include provisions for • identifying the failure modes • determining – the significance of the failure modes (using tools such as risk analysis), – if a failure analysis should be conducted as part of the investigation, and – the depth of the failure analysis.

Selecting and confirming all failure modes

Do as follows to select and confirm all failure modes:

Step	Action
1	Using the sampling tables, do the following: • Select failure investigation records pertaining to more than one failure mode (if possible). • Determine if the firm is following their failure investigation procedures.
2	Confirm that all failure modes from your selected sample of failure investigations are captured within data summaries such as • reports • pie charts • spreadsheets, and • Pareto charts, to name a few.

Continued on next page

1.5. Failure Investigation Procedures, Continued

Determining the investigation depth

Determine whether the depth of the investigation (where possible) is sufficient (root cause) to determine the corrective action necessary to correct the problem.

Step	Action
1	Select one significant failure investigation that resulted in a corrective action.
2	Determine if the firm had identified the root cause to accomplish verification or validation of the corrective action.

Reviewing the records

Using the sampling tables, do the following to review the records:

Step	Action
1	Review the records regarding nonconforming product where the firm concluded corrective or preventive action was not necessary.
2	Is the firm continuing to distribute a nonconforming product? • If *yes*, note this as an important deficiency based on the class of, and the risk associated with, the product. • If *no*, proceed to step 7.

***Reference**: For more information about nonconforming products, refer to linkages 820.20 Management Responsibility, 820.25 Training, 820.30 Design Controls, 820.90 Nonconforming Product and possibly 820.250 Statistical Techniques.*

1.6. Preventive Action for Product and Quality Problems

Product and quality problems: effective actions

Effective actions to name a few, include the following:

- recall actions
- changes in acceptance activities for
  - components
  - in-process, and
  - finished devices, and
- a product or process change to correct a reliability problem or to bring the product into conformance with product specifications

Effective engineering principles

Effective engineering principles of a firm must include the following:

- a verification or validation protocol
- verification of product output against documented product requirements and specifications
- maintenance and calibration of test instruments, and
- test results that are made available and readable

Continued on next page

1.6. Preventive Action for Product and Quality Problems, Continued

Determining if the firm has taken effective actions

The table below describes the steps in determining if the firm has taken effective actions to product and quality problems.

Step	Action
1	Using the sampling tables, do the following: • Select and review significant corrective actions. • Determine if the change or changes could have extended beyond the action taken. ***Reference**: For more information about signification correct actions, refer to Product and quality problems: appropriate action.*
2	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. ***Note**: Investigators must discuss and evaluate these issues but not say anything that could be construed as requesting a product recall.*

Determining if the preventive action was verified before implementation

The table below describes the steps in determining if the preventive action was verified before implementation.

Step	Action
1	Review the product and quality trend results.
2	• From the trend results, select a sample of significant corrective and preventive actions. • Determine the effectiveness of these preventive actions.
3	• Determine if the firm has verified or validated the corrective or preventive actions. • Verify if these actions are effective and do not adversely affect the finished device.

Continued on next page

1.6. Preventive Action for Product and Quality Problems, Continued

Determining if the preventive action was verified before implementation, continued

Step	Action
4	• Validate the corrective actions, if needed. • Verify if the corrective actions include – design controls, if appropriate, and – effective engineering principles. ***Reference**: For more information about effective engineering principles, refer to Effective engineering principles.*

***Reference**: For more information regarding this CAPA element, refer to linkages 820.30 Design Control and 820.70(b) Production and Process Control.*

1.7. Effective Action: Documentation and Management Review

Dissemination mechanism: Quality Assurance

Dissemination mechanism is a mechanism to disseminate relevant CAPA information to those individuals (Quality Assurance) directly responsible for assuring product quality and the prevention of quality problems.

Verifying firm's preventive action implementation and documentation

The table below describes the steps in verifying the firm's preventive action implementation and documentation.

Step	Action
1	Using the sampling tables, select and review records of the most recent corrective or preventive actions. ***Note**: This sample may consist of or include records from the previously selected sample of significant corrective actions.*
2	To ensure implementation and documentation of the firm's preventive action, view the following: • Actual processes • Equipment, and • Facilities, or • Documentation

Continued on next page

1.7. Effective Action: Documentation and Management Review, Continued

Verifying the firm's management review

The table below describes the steps in verifying if the firm has disseminated and submitted the problems and corrective action for management review.

***Reference**: For more information about this CAPA element, refer to the linkages 820.20 Management Responsibility.*

Step	Action
1	Find the records that were submitted for management review during a recent CAPA event.
2	From these records, determine if the information (quality problems with preventive action) submitted for management review was relevant. ***Note**: Review the raw data as opposed to the results of the management review.*
3	• Review the CAPA (and other procedures if necessary). • Confirm that there is dissemination mechanism. • Review relevant CAPA information disseminated to Quality Assurance.
4	Using the sample of records from the procedure Verifying firm's preventive action implementation and documentation, confirm that information related to product and quality problems is disseminated to Quality Assurance.

2. Medical Device Reporting (MDR)

Overview

Contents

The table below lists the topics in this section.

2.1. Inspectional Objectives

Purpose

The Medical Device Reporting (MDR) Regulation requires medical device manufacturers, device user facilities and importers to establish a system that ensures

- prompt identification
- timely investigation
- reporting
- documentation, and
- filing of device-related death, serious injury, and malfunction information.

Verification of Compliance with MDR

The events described in MDR may require the FDA to initiate corrective actions to protect the public health.

Therefore, compliance with MDR must be verified to ensure that CDRH's Surveillance Program receives both timely and accurate information.

Stages in MDR

The table below describes the stages in Medical Device Reporting (MDR)

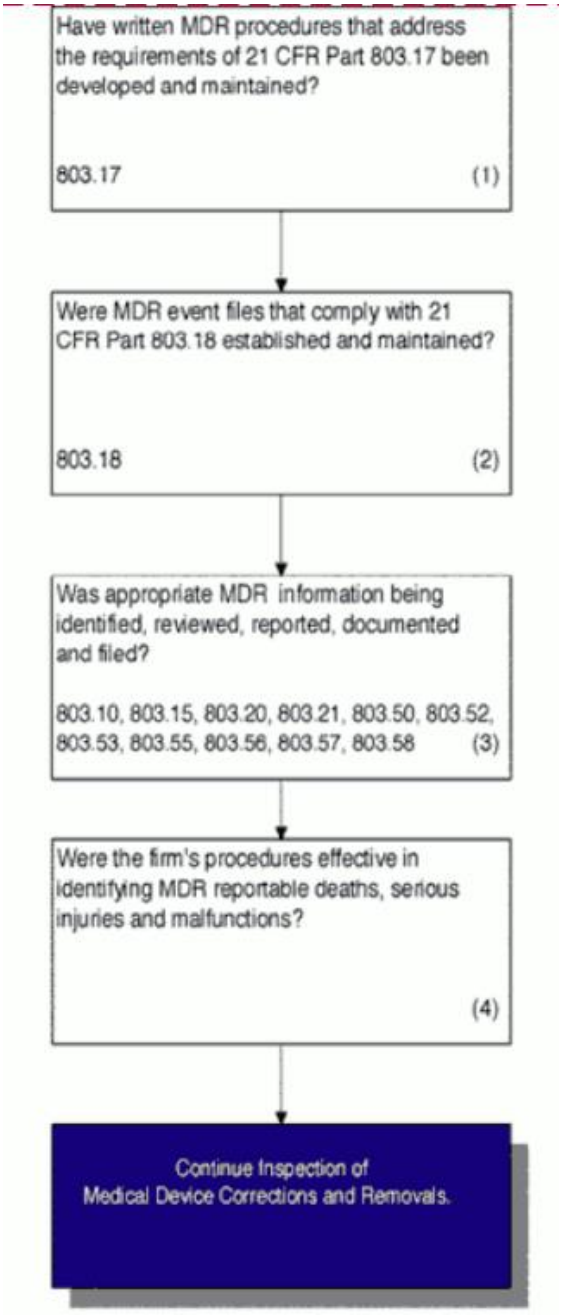
Stage	Description
1	Verification of MDR procedures
2	Verification of maintenance of MDR event files
3	Confirmation of MDR information
4	Confirmation of adherence to procedures

Continued on next page

2.1. Inspectional Objectives, Continued

Decision flowchart

The flowchart below depicts the stages of MDR.



2.2. MDR Procedures and Maintenance

Compliance: MDR procedures

The MDR procedures of the firm must address the requirements in 21 CFR Part 803.17.

Guidelines: verifying adherence to MDR procedures

To verify adherence to MDR Procedures, review and confirm that the firm's *written* MDR procedures have the following:

- **Internal Systems**: To provide for the
  - timely and effective identification
  - communication, and
  - evaluation subjecting to medical device reporting.
- **A standard review process:** To
  - determine when an event meets the criteria for MDR reporting, and
  - ensure the timely transmission of complete device reports to FDA.
- **Documentation and Recordkeeping**: To evaluate if
  - an event is reportable
  - all MDR reports and other information are submitted to the FDA, and
  - systems ensure access to information to facilitate timely follow-up and inspection by FDA.

Compliance: MDR event files

The firm must maintain MDR event files that comply with **21 CFR Part 803.18**.

Continued on next page

2.2. MDR Procedures and Maintenance, Continued

Verifying maintenance of MDR event files

The table below describes the steps in verifying the maintenance of MDR event files.

Step	Action
1	Using the sampling tables, select the number of MDR files
2	Review and verify that the MDR event files (hard copy or electronic) are • prominently identified, and • easy to access.
3	Are the event files prominently identified and easy to access? • If *yes*, allow the MDR files to be maintained as part of the 820.198 complaint file. • If *no*, do nothing.
4	Confirm that the MDR event files contain the following: • information from any source that describes a – device-related death – serious injury, or – malfunction • the firm's evaluation of the above 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.) • documentation about decisions on not submitting an MDR report for a – device-related death – serious injury, or – malfunction

Continued on next page

2.2. MDR Procedures and Maintenance, Continued

Verifying maintenance of MDR event files, continued

Step	Action
5	Confirm that the MDR event files contain the following *when applicable*: • copies of – device-related death – serious injury, and – malfunction • five-day reports submitted on – FDA form 3500A – Supplemental Reports (3500A), and – Baseline Reports (3417) • MDR-related correspondence

Confirming the appropriate MDR information

The list below describes the guidelines for confirming that the MDR information is handled appropriately.

- Using the sampling tables, select the number of MDR reports that were submitted to the FDA.
- Compare the firm's written procedures with the way it was
  - identified
  - processed
  - evaluated
  - reported, and
  - applied for filing reports.
- Document the following:
  - any discrepancies between the firm's practice with the written procedures
  - any failure to follow or obtain information required by the regulation and form 3500A (e.g., timely reporting, complete investigation, consistency, etc.)

Firm's effective procedures

Procedures of a firm are effective when it is possible to identify the following:

- device-related deaths
- serious injuries
- malfunctions

Continued on next page

2.2. MDR Procedures and Maintenance, Continued

Confirming effectiveness of the firm's procedures

The table below describes the steps in confirming effectiveness of the firm's procedures.

Step	Action
1	Using the sampling tables, select the number of unreported complaints and records from one additional source of quality data such as • service reports • repair reports, and • returned goods files to name a few.
2	• Review the firm's records. • Confirm that they do not contain information relating to MDR reportable events such as – device-related deaths – serious injuries, or – malfunctions.
3	Do you identify unreported events? • If *yes*, – determine the firm's rationale for not submitting MDR reports, and – go to step 4. • If *no*, do nothing.
4	Has the firm failed to identify these events, or provide an adequate rationale for not submitting an MDR report? • If *yes*, consider this as a significant MDR-related observation. • If *no*, do nothing. ***Note**: If the firm's investigation determines that a manufacturer's device caused the event and hence the firm did not submit an MDR report, this counts as adequate rationale for not submitting the report.*

3. Corrections and Removals

Overview

Contents

The table below lists the topics in this section.

3.1. Inspectional Objectives

Purpose

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 to protect the public health.

Stages in making corrections and removals

The table below describes the stages in making corrections and removals.

Stage	Description
1	Determining if corrections were initiated by the manufacturer
2	Confirming implementation of reporting requirements
3	Verification of compliance

3.2. Analysis: Corrections and Removals

Corrections and removals: initiated by manufacturer

Check if the manufacturer initiated the corrections or removals of a device:

- If *yes*, proceed to Confirming implementation of the reporting requirements.
- If *no*, do as follows:
  - Inspection under Reports of Corrections and Removals is *not* necessary.
  - Proceed to the inspection of Medical Device Tracking.
  - Mention in the EIR that you considered Reports of Corrections and Removals for inspection.

Confirming implementation of the reporting requirements

The table below describes the steps in confirming implementation of the reporting requirements.

Note**: The reporting requirements must be as per **21 CFR Part 806.

Step	Action
1	Using the sampling tables, select the number of files relating to corrections or removals that have been reported to the FDA.
2	• Review the files. • Verify that the firm – is submitting written correction and removal reports to the appropriate FDA District Office within 10 days of initiating the actions, and – has provided all the information required in the written report per 806.10.
3	• Using the sampling tables, select the number of corrective action files in general. (**Example:** CAPA files) • Review the files.
4	Do you identify any apparent Class I or Class II recalls that have not been reported to the appropriate FDA District Office? • If *yes*, – discuss the discrepancy with the firm. – list the unresolved discrepancies on your FDA 483 if necessary. • If *no*, do nothing.

***Note**: All observations must be consistent with current FDA policies and procedures.*

3.3. Analysis: Firm's Documentation and Compliance

Firm's compliance as per CFR

As per compliance requirements, the firm must

- establish and maintain a file for all non-reportable corrections and removals per 21 CFR Part 806.20, and
- comply with the other file-related requirements of 21 CFR Part 806.

Documentation of reported corrections

Documentation of reported corrective actions is required by the Quality System Regulation (21 CFR 820.100, Corrective and Preventive Action and 21 CFR 820.198, Complaint Files).

***Note**: Part 806 does not require firms to establish and maintain files for corrections and removals reported to the FDA.*

Confirming the firm's adherence to documentation and compliance

The table below describes the steps in confirming the firm's adherence to documentation and compliance.

***Reference**: For more information about a firm's compliance requirements, refer to Firm's compliance as per CFR.*

Step	Action
1	Using the sampling tables, select the number of files relating to non-reportable corrections or removals (806.20 files). ***Reference**: For information about documentation of reported corrections, refer to Documentation of reported corrections.*
2	• Review the 806.20 files. • Verify that the records contain the following: – All the information required in 806.20. – Confirmation that the files are retained for the appropriate period of time (2 years beyond the expected life of the device).
3	Do these files contain evidence of Class I or Class II recalls, and/ or Class III voluntary recalls under 21 CFR Part 7? • If *yes*, do the following: – Discuss the discrepancy with the firm. – List the unresolved discrepancies on your FDA 483 if necessary. • If *no*, proceed to step 4.

Continued on next page

3.3. Analysis: Firm's Documentation and Compliance, Continued

Confirming the firm's adherence to documentation and compliance, continued

Step	Action
4	Does the firm comply with the other file-related requirements of 21 CFR Part 806? • If *yes*, proceed to step 5. • If *no*, do the following: – Discuss the discrepancy with the firm. – List the unresolved discrepancies on your FDA 483 if necessary.
5	Are any claims for exemption from 806 a result of submission under either the MDR regulation or Radiological Health Requirements? • If *yes*, proceed to step 6. • If *no*, do the following: – Discuss the discrepancy with the firm. – List the unresolved discrepancies on your FDA 483 if necessary. ***Note**: For assistance regarding this, contact the District Recall Coordinator.*

***Note**: All observations must be consistent with the current FDA policies and procedures.*

When the device has been sold to another firm: guidelines

Use the guidelines below when the device has been sold to another firm.

If the firm that has bought the device is ...	Then ...
in your district	verify that the 806.20 files have been transferred to the new manufacturer or importer.
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.

4. Medical Device Tracking

Overview

Contents

The table below lists the topics in this section.

4.1. Inspectional Objectives

Purpose

The purpose of the Medical Device Tracking Regulation is to ensure that the manufacturers and importers of certain medical devices can

- expeditiously locate and remove these devices from the market, and/ or
- notify patients of the significant device problems.

Stages in medical device tracking

The table below describes the stages in medical device tracking.

Stage	Description
1	Determining if the firm manufactures a tracking device
2	Verification of the firm's SOP for tracking
3	Verification of the firm's QA program for an audit tracking system

4.2. Analysis: Firm's MDT System and Policies

Review of quality audit: agency's policy

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's access to a firm's quality audit results.

FDA Inspection

The audit procedures and documents that demonstrate that the audits have been conducted at the appropriate time intervals are subject to FDA inspection.

Determining if the firm manufactures/ imports a tracking device

The table below describes the steps in determining if the firm manufactures/ imports a tracking device.

Step	Action
1	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 subject to the tracking regulation does ...	Then ...
not manufacture or import a device	terminate your tracking inspection.
manufacture or import a device	verify that the firm is aware of its tracking obligations through • discussions with the Management Representative (or designee), or • the review of established procedures. ***Note**: This verification makes the firm aware of its obligation.* ***Reference**: For more information about a firm's obligation if it manufactures or imports a tracking device, refer to Firm's obligation if it manufactures or imports a tracking device.*

Continued on next page

4.2. Analysis: Firm's MDT System and Policies, Continued

Determining if the firm manufactures/ imports a tracking device, continued

Step	Action
2	Has the firm purchased its tracking device from another firm? • If *yes*, confirm (where applicable) that the firm has obtained and maintains the prior manufacturer's tracking records or equivalent information. • If *no*, do nothing.

Firm's obligation: manufactures or imports a tracking device

If a firm manufactures or imports a tracking device, it is obligated to

- notify FDA if it goes out of business and provide copies of its tracking records to its FDA District Office
- transfer tracking records to a firm purchasing its tracked device(s), and
- continue tracking the device if the firm stops manufacturing or importing when the firm remains in business.

Verifying the firm's SOP for tracking

The table below describes the steps in verifying that the firm has an established SOP for tracking.

***Note**: This SOP must comply with the requirements of in 21 CFR Part 821.25(c).*

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

Continued on next page

4.2. Analysis: Firm's MDT System and Policies, Continued

Verifying the firm's SOP for tracking, continued

Step	Action
3	• Select one or two files (if applicable) containing tracking information requested by the FDA. • Confirm that the appropriate information required by 821.25(a)(1) _ 821.25(a)(3) was provided within the appropriate time-frame(s).
4	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.

Verify the firm's QA program for an audit tracking system

The list below describes the guidelines for verifying the firm's QA program for an audit tracking system. Confirm that the

- audit procedure addresses both
  - functioning of the tracking system, and
  - accuracy and completeness of the data within the system, and
- firm has conducted audits of its tracking system at the appropriate time intervals that amounts to
  - no less than every six months for the first three years of tracking, and
  - annually thereafter.

***Note**: The firm's QA program must include audits of its tracking system within the timeframes specified in 21 CFR Part 821.25(c)(3).*

5. References

Overview

Contents

The table below lists the topic in this section.

5.1. Abbreviations

List of terms and their full forms

The table below provides the full forms of the abbreviated terms used within this SOP.

Term	Full Form
CAR	Corrections and Removals
CAPA	Corrective and Preventative Actions
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CPG	Compliance Policy Guidelines
EIR	Establishment Inspection Report
ISO	International Standards Organization
MDR	Medical Device Reporting
QA	Quality Assurance
SOP	Standard Operating Procedure
SPC	Statistical Process Control