Corrections and Removals – Is 21 CFR 806 the Forgotten Regulation?

Robert Titkemeyer and *Diane Mandell* explain the importance of this regulation and suggest ways for implementing it.

Consultants have an opportunity to visit numerous facilities and observe a large number of quality systems. These visits show that the majority of companies in the medical devices sector do an excellent job in implementing the FDA 21 CFR 820 Quality System Requirements (QSR) and 21 CFR 803, Medical Device Reporting (MDR). On the other hand, the opposite is true of regulation 21 CFR 806, Corrections and Removals. Time and time again it appears that implemented quality systems lack any reference to 21 CFR 806, Corrections and Removals. Has this regulation been overlooked?

The following paper looks at the importance of this requirement, evaluates the possible reasons why corrections and removals have been overlooked, and suggests ways that companies may implement the requirement.

Manufacturers often overlook the regulation on corrections and removals

21 CFR Part 806 Requirements

Reports of Corrections and Removals – 21 CFR 806.10

Each device manufacturer and importer shall submit a written report to the FDA of any correction or removal of a device, *if* the correction or removal was initiated to:

- reduce a risk to health posed by the device; *or*
- remedy a violation of the act caused by the device, which may present a risk to health.

Reports in the items above are not required if:

- the information has already been reported to the FDA under the Medical Device Reporting regulation, 21 CFR 803 or under 21 CFR 1004.
- the correction or removal meets the following criteria:
  - when the action is taken to improve the performance or quality of a device but does not reduce a risk to health posed by the device or remedy a violation of the act caused by the device;
  - market withdrawals, 21 CFR 806.2(h) and 21 CFR 7.3(j) – a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by the FDA or that involves no violation of the act, e.g. normal stock rotation practices;
  - routine servicing, 21 CFR 806.2(k) – any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g. calibration, replacement batteries, and responses to normal wear and tear. However, repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy or identical repairs or replacement of multiple units of a device are not routine servicing. Such serving should be 'trended' to determine if a problem exists;
  - stock recoveries, 21 CFR 806.2(l) and 21 CFR 7.3(k) – the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e. the device is located on the premises owned, or under the control of, the manufacturer and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

There is a long list of exemptions to the reporting rule

The key to the correction and removal regulation is determining when an event is reportable. The definition of risk to health is found in 21 CFR 806.2(j):

- a reasonable probability that use of, or exposure to the product will cause serious adverse health consequences or death (Class I Recalls); *or*
- that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote (Class II Recall).

The key is knowing when an event is reportable

Manufacturers and distributors are required to submit a corrections and removals (CAR) report to the appropriate FDA district office within 10 working days of the decision to initiate a correction or removal. A list of the information required in the report is listed in 21 CFR 806.10(c)(1-13).

A foreign manufacturer or owner or operator of devices should submit reports of corrections and removals. It should be noted that foreign device manufacturers should submit correction and removal reports to the district office where the product is being imported.

Records of corrections and removals required to be maintained but not required to be

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reported to the FDA, 21 CFR 806.20:

- Each device manufacturer and distributor that initiates a correction or removal of a device that is NOT required to be reported to the FDA under 806.10 shall keep a record of each correction or removal;
- Records of corrections and removals NOT reported to the FDA must contain the following information:
  - the brand name, common or usual name, classification, name, product code (if known), and the intended use of the device;
  - the model, catalogue or code number of the device and the manufacturing lot or serial number of the device or other identification number;
  - a description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken;
  - justification for NOT reporting the correction or removal action to the FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person; *and*
  - a copy of all communications regarding the correction or removal; *and*
  - Manufacturers shall retain all records required under this section for a period of two years beyond the expected life of the device, even if the respective firm has ceased to manufacture or import the devices.

Records of corrections and removals not reported to the FDA must contain specific information

In addition, correction and removal files/records must be transferred to any new/subsequent manufacturer or importer of the device and maintained for the required period of time.

Records of corrections and removals must be transferred to any new manufacturer

Why are CAR so poorly implemented?

A consultant has an opportunity to observe specific practices and from these, draw some general conclusions. Here are some common reasons why companies may be overlooking correction and removal requirements.

A. Lack of audit attention from the FDA

The FDA's Quality System Inspection Technique (QSIT) focuses on seven main elements of the quality system: facilities and equipment controls; management controls*; material controls; records documents change control; production and process controls*; design controls*; and corrective and preventative actions (CAPA)*.

It is noteworthy that the correction and removal element is missing from the above list. This is because, technically, it is a satellite programme of corrective and preventative actions, along with medical device reporting and medical device tracking.

The QSIT inspection guidance[1] designates four of the seven elements as major subsystems that are the basic foundation of a firm's quality system (designated above with an asterisk). Those four major subsystems are management controls; corrective and preventative actions (with satellites medical device tracking, corrections and removals and medical device tracking); design controls; and production and process controls (with satellite sterilization process controls). A typical FDA inspection for a moderately-sized company will generally last five days. Assuming that each of the four major subsystems requires one day to review, then at most there is only one day to review any satellite systems (which is left to the inspector's discretion). Due to the potential for risk, the sterilization process controls are much more likely to be included if satellite systems are inspected, leaving at most half a day to review any additional areas. Most inspectors are comfortable with medical device reporting because of the previous bottom-up techniques, and may gravitate to this area. It appears that corrections and removals and medical device tracking are the least FDA audited sections of most quality systems. In addition, if the corrective and preventative action system has not produced any major issues then the likelihood of the inspector drilling down further is limited.

A typical FDA inspection of a medium-size company will last about five days

B. No equivalent ISO standard

ISO 9001 and related standards do not include a requirement for documenting corrections and removals. When a regulatory professional is faced with a multitude of regulatory requirements, the most common-sense approach is to complete those items that are harmonized in order to get the most thorough review for the time spent. The lack of an equivalent ISO standard means that the inspector places a low priority on requirements that are specific to one regulatory agency and focuses on the more important harmonized standards. If a company's corporate office is international, it may have a minimal understanding of the corrections and removals requirement and as a result, the requirement can be overlooked.

C. The field support/field service function tends to run autonomously from the more regulated manufacturing and engineering functions

The most important function of the field support/field service organisation is the maintenance of distributed product and resulting customer satisfaction. They are by definition customer-focused and generally do not associate their activities with imposed regulatory requirements. The majority of corrections and removals are identified by, implemented, and tracked through the field support/field service function. The FDA initiated its regulatory principle relating to the manufacturing sector with the promulgation of Good Manufacturing Practices (GMP) and then added design controls and harmonisation with international regulations under the current Good Manufacturing Practices (cGMP). Limited attention has been placed on distributed inventory and maintenance practices.

The majority of corrections and removals are identified by field support staff

D. MDR and associated recalls handle product failure

Corrections and removals get minimal attention as a subset of the larger critical concern of medical device reporting and possible recalls.

How to properly implement the CAR regulations

What should a company do if its system does not address CAR?

First, do not panic because, as stated above, the likelihood of this oversight being discovered is low, particularly if a strong corrective and preventative action system has been implemented. Second, the implementation is relatively simple and in most cases there will be company documents available for assembling the required corrections and removals file.

Introduction of a corrections and removals policy is relatively simple if one has not been started before

What's the easiest way to implement a compliant CAR policy?

First, if a company has been in operation for a long period of time without a correction and removal policy, it needs to assess all previous change-control documentation and field service/field upgrades to determine whether there were any instances that caused a correction and removal to be initiated. Specifically, it must determine if any of the changes were initiated to eliminate a potential risk to health, or remedy a violation of the act caused by the device which may present a risk to health. This assessment should be documented and used to initiate the corrections and removals file.

If change control or field service/field upgrade documents are found that initiated a correction and removal, the best policy is to organise these past issues and contact the FDA to determine how to proceed. Companies should be candid and make sure they can provide adequate back-up that none of the issues led to injuries to patients or care-givers. Companies should remember to reference the definition of risk to health found in 21 CFR 806.2(j) during the assessment. They should be prepared for a visit by the local FDA inspector if they find multiple incidents of unreported corrections and removals. Companies should remember that a correction and removal is initiated to reduce the risk to health posed by a medical device. If a device has caused an injury, then it should have been reported through the medical device reporting process and initiation of corrections and removals notice to the FDA is not necessary. If the company finds instances where correction or removal of a device was initiated that is *not* required to be reported to the FDA under 806.10, it should create a record of each correction or removal per FDA 21 CFR 806.20. The company should place a note in the file indicating how the corrections and removals file was created.

Second, going forward, companies should implement a process to capture corrections and removals. The most effective and easily documented way to review and capture corrections and removals is to do an assessment of each change control to determine if it meets the requirement for corrections and removal. This can be accomplished by adding a check box on the change control document that asks the question *Was this change initiated to eliminate a potential risk to health or remedy a violation of the act caused by the device which may present a risk to health?* Documenting evidence that every change was reviewed, to determine if it meets the requirements for FDA reporting or if it needs to be documented per 21 CFR 806.20, will satisfy the FDA's requirement.

Companies can capture corrections and removals information by adding a check box on change control documents

Conclusion

For a variety of reasons, many medical device manufacturers have neglected the requirement for implementing a quality policy to assure conformity with FDA 21 CFR 806, corrections and removals. Recognising this fault requires immediate attention to assess previous changes and implement ongoing assessment of changes to assure compliance with this regulation. If a company's policy is lacking, it should take corrective action and not incur additional FDA scrutiny. It should review its current quality policy and determine its compliance with 21 CFR 806, corrections and removals today.

References

1. www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm