TRANSFORMING COMPLAINTS: A GUIDE TO MODERNIZING YOUR APPROACH

Honeywell

Sparta Systems

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SHIFTING THE BURDEN OF COMPLAINTS

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The U.S. Food & Drug Administration (FDA) has consistently regulated medical devices since 1976. Yet, management of complaint files remain among the top 483 observations given.

"YOUR MOST UNHAPPY CUSTOMERS ARE YOUR GREATEST SOURCE OF LEARNING"

– Bill Gates

Industry leaders are urged to stop viewing complaints as a burden and transform their current mindset on company culture, core values, strategic goals and objectives. Why? Because manufacturers are undertaking, at a rapid pace, digital transformation–the fourth revolution, Industry 4.0.

Therese Costich, president and managing partner of the Costich Group, states "4.0 is the process that surrounds an organization as it creates its digital platforms linking all sources of data, thereby capitalizing on the sea of information that is engulfing it". If industry leaders want to survive the digital transformation, one of their initiatives must be a successful movement to Quality 4.0. Quality 4.0 enhancements allow for employees to be efficient, connect intelligent automated processes, shorten time-to-value and improve data-based decision making.

Industry leaders who take an in-depth look and rethink critical components of their quality management system (QMS), such as complaint management, will:

- Reduce variations
- Prevent defects
- Reduce rework
- Improve productivity
- Improve efficiency
- Improve compliance
- Improve resources
- Achieve transformation goals
- Reduce risk
- Improve safety
- Exceed customer expectations

This white paper is written to provide an overview of complaint file regulations and standards and aid manufacturers with rethinking their complaint process.

WHAT IS A 483?

A 483 is an Inspectional Observation Form used by the FDA to list the conditions or practices observed during the inspection that indicate that an FDA-regulated product may be in violation of the Federal Food, Drug and Cosmetic Act (FDCA). [1]

OVERVIEW OF REQUIREMENTS AND STANDARDS

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WHAT IS THE DIFFERENCE BETWEEN A REQUIREMENT AND A STANDARD?

The International Standards Organization, or ISO, develops standards for businesses worldwide to operate using a uniform set of best practices. These standards are not enforceable U.S. laws. However, the Government Code of Federal Regulations, or CFR, is passed by the U.S. Congress and published in the United States Code and is enforceable as a law.

In this document, ISO 13485 refers to ISO 13485:2016/(R)2019 medical devices—quality management systems—requirements for regulatory purposes. ISO 13485 is a stand-alone QMS standard written to support medical device manufacturers.

"SAY WHAT YOU DO AND DO WHAT YOU SAY."

– unknown

WHAT IS A COMPLAINT?

In 21 CFR §820.3(b), a complaint is defined as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution." [2]

WHAT ARE THE COMPLAINT REQUIREMENTS?

In 21 CFR §820.198, complaint files, the FDA states that as a manufacturer, you must have straightforward, uniform procedure(s) describing the process to receive, review and, when appropriate, investigate complaints within a timely manner. In addition, the person(s) who reviews complaints shall be trained.
The complaint file regulation is listed in the below table, per the CFR - Code of Federal Regulations Title 21. [3]

§820.198 COMPLAINT FILES

A

Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that:

(1) All complaints are processed in a uniform and timely manner;
(2) Oral complaints are documented upon receipt; and
(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the FDA under part 803 of this chapter, Medical Device Reporting.

B

Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacture shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

C

Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such an investigation has already been performed for a similar complaint another investigation is not necessary.

D

Any complaint that represents an event which must be reported to the FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by Keep additional records of §820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;
(2) Whether the device was being used for treatment or diagnosis; and
(3) The relationship, if any, of the device to the reported incident or adverse event.

E

When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;
(2) The date the complaint was received;
(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification and control number(s) used;
(4) The name, address, and phone number of the complaint;
(5) The nature and details of the complaint;
(6) The dates and results of the investigation;
(7) Any corrective action taken; and
(8) Any reply to the complainant.

F

When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

G

If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

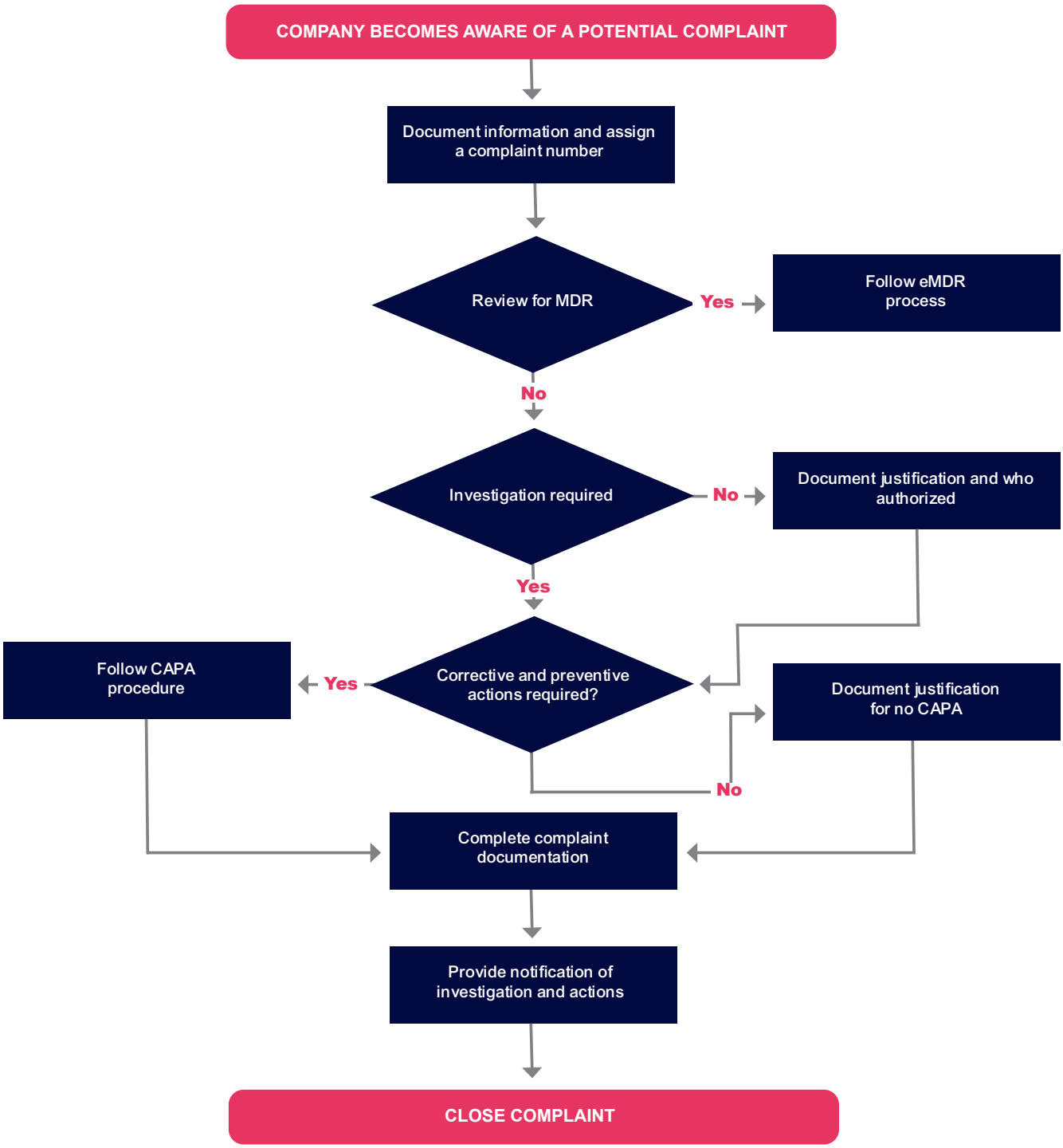
(1) A location in the United States where records are regularly kept; or
(2) The location of the initial distributor.

WHAT ARE THE MAIN DIFFERENCES BETWEEN ISO 13485:2016 AND §820.198?

21 CFR PART 820 ISO 13485:2016	DIFFERENCE
CFR §820.198: Complaint files **ISO 8.2.2: Complaint handling**	CFR: Recordkeeping more stringent ISO: Procedure for complaint handling needs to include responsibilities and requirements for: • Determining reportable events • Handling of complaint-related products • Determining initiation of corrections or corrective actions
CFR: N/A **ISO 8.2: Monitoring and measurement** **ISO 8.2.1: Feedback** **ISO 8.2.5: Monitoring and measurement of processes**	ISO: Method(s) documented how the organization gathers and monitors information to meet customer requirements. ISO: Documented process(es) on how and what data is used for feedback, and the data must be part of risk management. In addition, any regulatory requirements for gaining specific experience from post-production activities must be part of the feedback process(es). ISO: Documented process(es) for methods and measuring the QMS processes and achieving planned results.

OVERVIEW OF THE COMPLAINT PROCESS

The below flowchart provides a high-level overview of the complaint process.



RETHINKING COMMON COMPLAINT OBSERVATIONS 3

Manufacturers seem to struggle with post-market surveillance (PMS). Choosing to stick with a manual process or a wrong-fit system can lead to incomplete complaint information, delays in investigations and adverse event reporting and data integrity.

COMPLAINT INTAKE

Complaint handling is a crucial component of a successful QMS. A robust complaint handling system that receives sufficient information, triage, prioritize, assess, resolve and communicates the complaints promptly will benefit the company by customer loyalty, patient safety and total cost of quality.

There are several methods to report a product complaint to the manufacturer, such as:

- The customer sent a credit memo request with or without the returned product
- Phone call
- Email
- Online notification
- Social media
- Oral
- Voluntary MedWatch report
- Manufacturer's representative

One of the roadblocks to a robust and beneficial complaint system is the complexity of a complaint intake system. Using a homegrown database with a time-consuming manual paper process to receive and categorize complaints becomes overcomplicated, which can lead to the following issues:

- Increased risk of data integrity
- Backlogs of complaints
- Poor use of employee time
- Exposure to risk due to an inability to properly report the scope of the problem to regulatory bodies
- The disconnect between other quality processes leading to difficulty in trending and corrective and preventive actions
- No connectivity to foundational solutions creating limitations in informing enterprise resource planning (ERP), product lifecycle management (PLM) and laboratory information management system (LIMS) of a broad issue
- Lack of a timely review, reporting to the regulatory authority and disposition
- Extended time for complaint handling
- Poor customer satisfaction

Utilizing a closed-loop Enterprise Quality Management System (EQMS) that can seamlessly integrate critical processes will provide consistency and ensure a complete and adequate intake process, thus facilitating the process and product improvement. In addition, an EQMS offers the ability for automated complaint categorization and initial complaint review and risk assessment using precise supporting data. Along with an EQMS, companies must provide vital training to field personal and complaint handling and the importance of meaningful information.

INVESTIGATIONS

Part of an effective complaint system is understanding and completing a complaint investigation and if no investigation is required, then an authorized person will document the reason. Using a systematic process to gather and establish the facts behind a complaint and document all parts of the investigation tells a complete story and is easy to follow. When an investigation is thorough, there should be a known root cause and necessary actions. An EQMS can provide a simple, straightforward process coordinated among multiple departments, with action items and target dates, providing an automated connection with Corrective and Preventive Actions (CAPA), remedial actions and Failure Modes and Effects Analysis (FMEA). Many companies struggle with the complexity of risk management and, therefore, lose the value of the process. An EQMS takes the complexity of risk management and makes it obtainable for standard users.

The FDA has taken steps to provide transparency, to the public, on adverse event reporting. By law under §803.20, manufacturers, importers and device user facilities must investigate and report certain device-related adverse events and product malfunctions to the FDA through an electronic format that can be process, review and archive. [4]

Using complaint management systems that provide intelligent decision trees to standardize the reportability process and efficiently automate the electronic medical device reporting (eMDR) process will help companies identify and resolve product issues.

HOW CAN I INVESTIGATE COMPLAINTS WITHOUT RECEIVING THE PRODUCT BACK?

Test products manufactured around the time of the device in question

Review the DHR, DHF and DMR

Review any related services records

Analyze any CAPAs or nonconformance data related to device

Test the family type

DATA INTEGRITY

The FDA requires that medical device companies retrieve, track and trend all complaints, claims, recalls and failures through the effectiveness of the resolution. Relying on a paper-based system often forces companies to operate in silos. As a result, they miss the ability to review complaints system-wide, leaving it difficult and time-consuming to provide reliable data.

Trending complaints offer insight into customer satisfaction and product performance, allowing deficiencies to be adequately corrected.

Integration of a digital system will allow for trending across one or all sites, providing companies with the ability to cross-collaborate and proactively monitor real-time data. The benefit of real-time visibility is the data enables manufacturers' framework to include:

- Tangible productivity gains
- Customer loyalty
- No duplicate investigations
- Company growth
- Fast and appropriate reactions to obstacles

MEDICAL DEVICE REPORTING FOR MANUFACTURERS GUIDANCE

DOWNLOAD

BENEFITS OF TRANSFORMING THE COMPLAINT PROCESS

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When manufacturers do not have a vital resource or processes, they will find themselves dealing with a backlog of complaints. How many times have you heard “It’s not in the budget” or “too much volume and not enough people”? It is time to consider the “do more with less” mentality and improve efficiency without overworking employees. Stop wasting time on broken processes and invest in understanding how to provide valuable data to enhance the complaint process. Implementation of Quality 4.0 technologies will help reduce product risk. Providing the ability to recognize if a product issue is widespread or preventing additional future problems is significant. When companies stop looking at a complaint as a burden, but as a vital part of providing a proactive quality system that prioritizes the voice of the customer, it will aid in the following:

- A strong QMS performance
- Positive customer relationship
- Reducing cost
- Improving product design, manufacturing and safety of devices
- Lowering a chance of a recall and regulatory fines
- A streamlined compliant system with device regulations and consensus standards
- Positive employee morale

“WE CAN’T SOLVE PROBLEMS BY USING THE SAME KIND OF THINKING WE USED WHEN WE CREATED THEM.”

– Albert Einstein

WHY PARTNER WITH SPARTA SYSTEMS, A HONEYWELL COMPANY

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Pharmaceuticals and medical device companies are moving away from their legacy paper-based complaint processes and towards an electronic system built for compliance. The TrackWise Digital® Complaint Management solution is an integrated quality and risk system that centralizes the complaint handling process, maximizing control, minimizing risk and improving quality. Unlock data that will drive timely and informed decision-making using TrackWise Digital Complaint Management software, powered by AI technology. TrackWise Digital is a cloud and SaaS-based QMS that enables organizations to manage complaint intake efficiently, conduct investigation, perform risk assessment, review reportability, complete corrective actions and trend complaint categories.

SOURCES

1. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

2. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.3

3. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.198

4. https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

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