U.S. FOOD & DRUG ADMINISTRATION

Handling Medical Device Complaint Files with Quality

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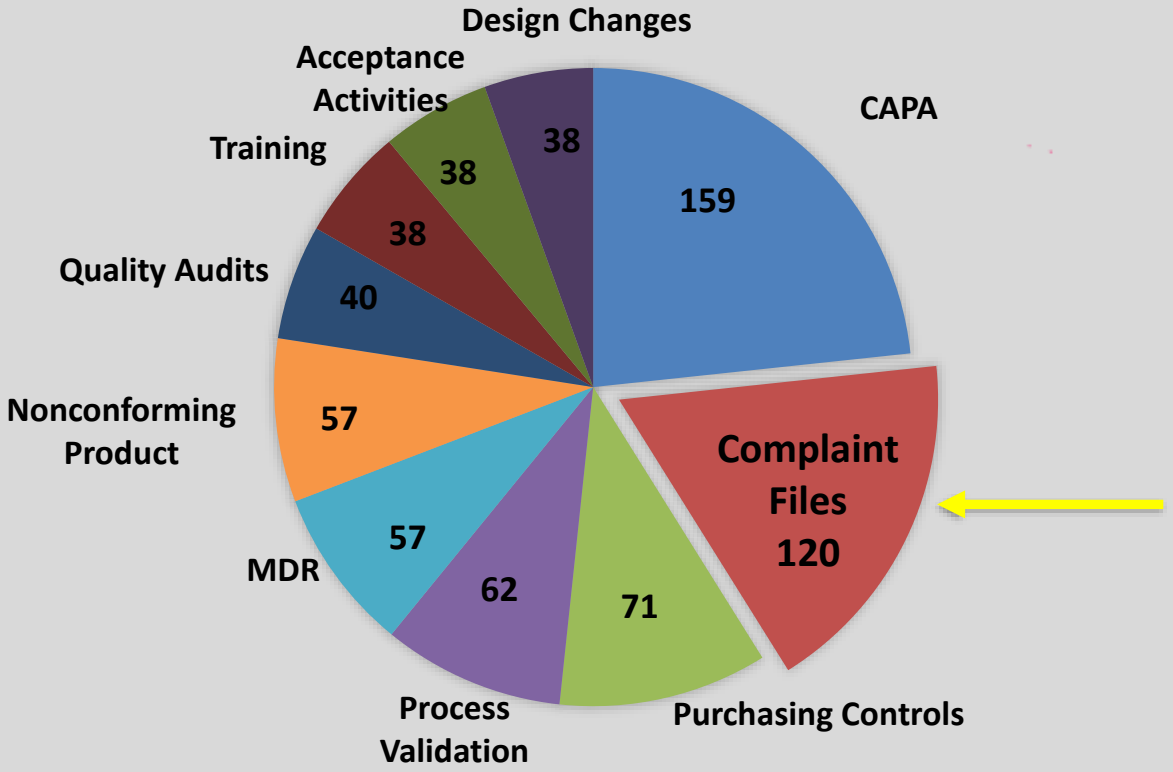
Complaint Files

FDA Datadashboard

Medical Device Inspection Citations

FISCAL YEAR 2022



FDA Datadashboard

Learning Objectives

- Discuss Importance of Complaint Files
- Review a key definition
- Identify requirements within the Quality System Regulation and ISO 13485:2016
- Identify challenges associated with handling medical device complaint files
- Discuss strategies for handling medical device complaint files

Importance of Complaint Files

Importance of Complaint Files

Provide	Serve	Ensure	Maintain	Ensure
Provide valuable information to improve the medical device quality	**Serve as a critical source of information during inspections and audits**	Ensure patient safety	Maintain detail records of complaints or adverse events related to a medical device	Ensure compliance with regulatory requirements

Key Definitions

Key Definition: Complaint

- **Title 21 Code of Federal Regulations (21 CFR) 820.3(b)**
  - Any written, electronic, or oral communication that alleges deficiencies of a device **after** it is released for distribution
- **ISO 13485: 2016 Clause 3.4**
  - Written, electronic or oral communication that alleges deficiencies
    - of a medical device **released from** organizations' control
    - of a service that affects the performance of such medical devices

Quality System Regulation, 21 CFR 820.3

Examples

Patient reports that insulin pump is not delivering the correct amount of insulin as prescribed

- resulting in high blood glucose levels

Consumer reports that blood glucose test kit did not contain the test strips as indicated on kit label

- resulting in inability to perform test

Requirements for Complaint Files

Requirements

21 CFR 820	ISO 13485: 2016
Complaint files: 21 CFR 820.198(a)-(g)	**Complaint handling:** Clause 8.2.2 **Reporting to regulatory authorities:** Clause 8.2.3 **Control of Records** Clause 4.2.5

Complaint Files

21 CFR 820.198(a)

- Complaint files must be maintained by each manufacturer
- Procedures for receiving, reviewing, and evaluating complaints must be established and maintained by a formally designated unit
- Complaints must be processed uniformly and timely
- Oral complaints must be documented upon receipt
- Complaints must be evaluated to determine if they require reporting to FDA

Complaint Files

21 CFR 820.198(b) and (c)

- Complaints must be reviewed and evaluated to determine if investigation is necessary

- Record must be maintained when no investigation is made
  - include reason no investigation was made
  - name of individual to make decision not to investigate

- Complaints must be reviewed, evaluated, and investigated if involving possible failure of a device, labeling, or packaging
  - unless such investigation has already been performed for similar complaint

Complaint Files

21 CFR 820.198 (d)-(g)

- Complaints representing an event required to be reported to FDA must be promptly reviewed, evaluated, and investigated
  - by designated individual
  - maintained in separate complaint files or clearly designated
- Records of investigation must be maintained and include specific information
- Investigated complaint and the records must be reasonably accessible to manufacturing establishment
- Records required by this section must be reasonably accessible in the United States if complaint unit is located outside of the United States

Complaint Files

ISO 13485:2016 Clause 8.2.2

- The organization must document procedures for timely complaint handling
  - must comply with regulatory requirements

- The procedures must include requirements and responsibilities for:
  - receiving and recording information
  - evaluating feedback to determine if it constitutes a complaint
  - investigating complaints
  - reporting information to regulatory authorities as necessary
  - handling complaint-related product
  - initiating corrections or corrective actions as needed

Complaint Files

ISO 13485:2016 Clause 8.2.2

- Document justification of any complaint not investigated
- Document any correction or corrective action
- Relevant information must be exchanged between the organization and the external party involved
  - if investigation determines outside activities contributed to the complaint
- Complaint handling records must be maintained

Complaint Files

ISO 13485:2016 Clause 8.2.3

- The organization must document procedures for notifying the appropriate regulatory authorities
  - notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices
- Maintain records of reporting to regulatory authorities

Complaint Files

Similarities

- Document procedures for handling complaints
- Complaints to be handled in a timely manner
- Document procedures and maintain records for notifying the appropriate regulatory authorities
- Document the justification when no investigation is made

Complaint Files

Differences

- ISO standard does not describe specific types of complaints to be investigated
- The QS regulation includes specific record keeping requirements for the investigation and the standard does not
- The ISO standard requires notification of issuance of advisory notices to be reported

Knowledge Check

What is the importance of complaint files?

1. Provide valuable information to improve the medical device quality
2. Ensure patient safety
3. Maintain detail records of complaints or adverse events related to a medical device
4. All of the above

Challenges Handling Complaint Files

Challenges Handling Complaint Files

Challenges

- Ensuring compliance with regulatory requirements
- Managing a high volume of complaints
- Conducting thorough investigations

Challenges Handling Complaint Files

Challenges
• Managing communication with stakeholders • Ensuring consistency • Ensuring timely resolution

Common Strategies for Handling Complaint Files

Strategies for Handling Complaint Files

Strategies
• Implementing robust complaint handling procedures • Investing in complaint management software • Utilizing outside expertise

Strategies for Handling Complaint Files

Strategies
• Maintaining open communication with stakeholders • Providing training and resources for complaint handling • Establish clear and specific time frames for investigations and escalation procedures for complex cases

Knowledge Check

What is one strategy for handling complaint files with quality?

1. Managing a high volume of complaints
2. Implement a robust complaint handling procedure
3. None of the above

Resources

Slide Number	Cited Resource	URL
1	Quality System Regulation	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-M/section-820.198
	CDRH Learn Module: Postmarket Activities; Complaint Files	www.fda.gov/media/109411/download
11	AAMI Quality Systems White Paper Comparison of 21 CFR 820 to ISO 13485:2016-2018	www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf
11	AAMI Technical Information Report 102 (TIR 102)	

Summary

- The Quality System Regulation and ISO 13485:2016 standard have similar requirements for handling medical device complaint files.
- Handling complaint files for medical devices with quality can be quite complex and present many challenges.
- There are strategies available to alleviate most, if not all, of the challenges presented in handling complaint files.

Questions