ROOK QUALITY SYSTEMS

Presented By Sarah Lacey Robbins, RAC

Developing & Maintaining An FDA-Compliant Complaint Handling Process

MEDMARC® LIFE SCIENCES INSURANCE

ROOK QUALITY SYSTEMS

NICE TO MEET YOU!

Sarah Lacey Robbins

RQS | SENIOR QUALITY MANAGER

- Bachelor Degree in Chemistry, Winthrop University
- 10+ years of Quality Management, Regulatory Affairs & Project Management experience within medical device industry
- Provides consulting for compliance with FDA, EU MDR, MDSAP, ISO, IEC, & more!
- Achieved multiple “0 Finding” FDA inspections
- Expert in managing post-market quality activities including, CAPA, audit responses, & process improvements

Rook Quality Systems provides a seamless way to outsource your quality management needs while saving you money & improving compliance.

Tailored Services To Meet Your Specific Business Needs

- → COMPLAINT HANDLING & INVESTIGATION SUPPORT
- → CAPA MANAGEMENT
- → DOCUMENT CONTROL & NCR
- → ADVERSE EVENTS & MDR FILINGS
- → INTERNAL/EXTERNAL/SUPPLIER AUDITS
- → POST-MARKET SURVEILLANCE

Session Agenda

→ FDA Complaint Handling Requirements

→ Complaint Handling Process

→ Complaint Trending & Management Review

→ Best Practices

→ Q/A

FDA Requirements
For Medical Device Complaints

FDA DEFINITION

Complaint

☆ 21 CFR 820.20

Complaint means 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.

FDA DEFINITIONS

Complaint Files

☆ 21 CFR 820.198(a)

Establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure:

→ Processing in uniform & timely manner

→ Documentation of oral complaints upon receipt

→ Evaluation to determine if failure investigation and/or MDR is required

☆ 21 CFR 820.198(b)

Review & evaluate complaints to determine whether an investigation is necessary. If determined that no investigation is needed, document:

→ Reason

→ Name of responsible individual

FDA DEFINITIONS

Complaint Files

☆ 21 CFR 820.198(c)

Any alleged complaint involving possible failure of a device or labeling/packaging to meet any of its specification must be reviewed, evaluated, & investigated.

EXCEPTION

When an investigation has already been performed on a similar complaint; recurring complaints require CAPAs.

☆ 21 CFR 820.198(d)

Any complaint that represents an event which must be reported to FDA shall be promptly reviewed, evaluated, & investigated by a designated individuals & shall be maintained in a separate portion of the complaint files or otherwise clearly identified.

Records of investigation shall include a determination of:

1. WHETHER DEVICE FAILED TO MEET SPECIFICATIONS
2. WHETHER DEVICE WAS BEING USED FOR TREATMENT OR DIAGNOSIS
3. RELATIONSHIP, IF ANY, OF DEVICE TO REPORTED INCIDENT

FDA DEFINITION

Complaint Files

☆ 21 CFR 820.198 (e)

When an investigation is made, a record of the investigation shall be maintained by the formally designated unit.

RECORD OF INVESTIGATION SHALL INCLUDE:

- Name of device
- Date that complaint was received
- UDI, UPC, or other device identification & control numbers used
- Name, address, & phone number of complainant
- Nature & details of the complaint
- Dates & results of investigation
- Any corrective actions taken
- Any reply to the complaint

FDA DEFINITIONS

Complaint Files

☆ 21 CFR 820.198(f)

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

☆ 21 CFR 820.198(g)

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

→ A location in the U.S. where manufacturer's records are regularly kept

→ Location of initial distributor

Complaint Handling **Process**

FDA DEFINITION

What Is A Complaint?

Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.

NON-COMPLAINT FEEDBACK

- Opinion/comment on device that does not involve the information on the left

COMPLAINT FEEDBACK

- Customers, patients, end users
- Healthcare professionals
- Distributors, vendors, & retailers
- Social media (LinkedIn, Instagram, ect.)
- Indirect sources, such as passing conversation

All Complaints Should Be Immediately Documented.

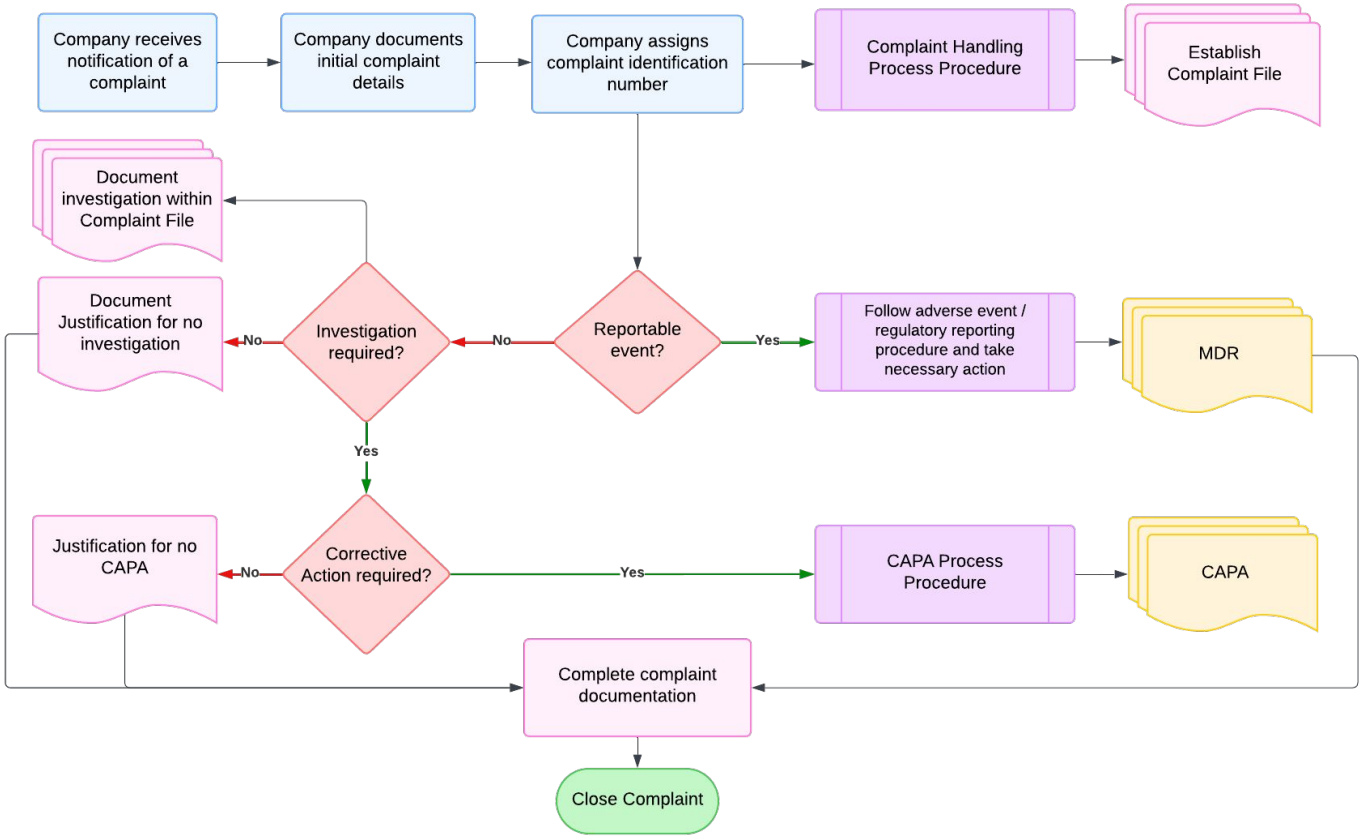
COMPLAINT HANDLING PROCESS

What Should I Ask?

BE SURE TO REQUEST:

- Name & contact info of customer/patient allegedly affected by complaint
- Date of alleged event
- Device name, product number, SKU
- Device lot number
- Device quantity
- Date you were made aware of complaint
- How customer/patient was allegedly affected & is doing now
- Type & severity of injury
- Was medical treatment received to address or prevent injury?
- Are images available of the defect, malfunction, or injury?

I Received a Complaint, Now What?



FDA REQUIREMENTS

Medical Device Reporting (MDR)

SERIOUS ADVERSE EVENT (SAE)

- Injuries that involve permanent bodily damage or impairment; or
- Requires medical intervention to prevent above
- Death

If adverse event suggests a risk to public health

MDR must occur within 5 calendar days of becoming aware

For all other adverse events

MDR must occur within 30 calendar days of becoming aware

☆ Rationale to report or to not report must be documented within the complaint file!

Complaint Investigation

Internal Review

- Manufacturing, batch, inspection records, test reports
- Installation/servicing records
- Complaint/feedback logs (similar complaints)
- Risk documentation (FMEA, Risk Analysis)
- Current inventory
- Devices in the field

Reaching Out to Customer/Patient

- Additional information
- Requesting return of device or images
- Requesting patient records

Trend Analysis

- Review previous complaints for occurrence rates
- Review nonconformances & CAPAs (related events)

COMPLAINT HANDLING PROCESS

Complaint Investigation

If the investigation is determined not required, a justification of why the investigation was not performed must be documented.

When reaching out to customers/patients/end users, **document the date & time of contact attempt & method**

- If contacted individual does not respond after 3 attempts, the contact attempt details must be noted within investigation & attached to complaint, then complaint handling process may continue.

Identify Root Cause – Where Issue Originated

- 5 Why Analysis, Fishbone Diagram, Fault Tree Analysis

Conduct a **Risk Assessment** For All Complaints

- Determination of potential harm

COMPLAINT HANDLING PROCESS

Corrective Actions & Preventive Action (CAPA)

Complaints Will Require CAPAs For:

Correct or prevent systemic issues within processes and/or devices affecting product quality, safety, or performance

Previous complaints with the same or similar issues indicating a trending issue

☆ If CAPA is opened in relation to a complaint, the **complaint & CAPA records shall reference each other**

COMPLAINT HANDLING PROCESS

Corrective Action & Preventive Action (CAPA)

TYPICAL ACTIONS FOR A COMPLAINT:

- Reaching out to customers for more information
- Requesting devices to be returned for inspection & providing replacement
- Consulting clinical SME for risk evaluation

All actions require evidence that demonstrates their implementation

- After evidence of implementation & verification of effectiveness has been provided, the complaint may be closed.

Complaints can be closed before an associated CAPA

- Only if actions or investigations required for completion have been transferred & established within the CAPA itself.

COMPLAINT HANDLING PROCESS

Complaint Closure

Complaints May Close Upon Completion Of:

→ **Documented source information**

→ **Investigation is complete**

- Or justified as not required

→ **MDR determination has been made**

→ **CAPA has been established**

- Or justified as not required

→ **Final resolution** (May include complaint response)

☆ Quality Review & Signature of Responsible Personnel is Required

COMPLAINT HANDLING PROCESS

Complaint Trending & Management Review

Complaint trending should be conducted at minimum, once per year and documented within Management Review, however it is recommended to monitor complaint trends frequently through established metrics.

- Product / Product Family
- Customer / Region
- Issue Type
- Root Cause Categories
- Severity & Risk Levels
- Associated CAPAs
- Closure Rate

Best Practices

1. Establish Clear & Adequate Process for Handling Customer Complaints
2. Conduct Personnel Training on Complaint Handling Awareness, Procedures, & Assessment
3. Establish Complaint Files – Adequately Document All Complaints From Receipt to Closure
4. Monitor & Trend Customer Complaints, Establishing Metrics on Complaint Trends
5. Ensure Management is Aware of Received Complaints by Conducting Management Review
6. Perform Internal Audits

Do You Have Any Questions?

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LET'S CONNECT!

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