Complaint Files

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Complaint Files – Why Are They Important?

- Premarket
  - Often the focus
- Postmarket
  - Often neglected
  - Opportunity for improvement – Complaint Files
    - “Learn from Mistakes”
    - Product longevity
    - Increased market share
    - Better, safer, more effective product

Learning Objectives

1. Understand context of complaint files within:
   - Overall Quality System and
   - Corrective and Preventive Action (CAPA) subsystem
2. Learn about the mechanisms of complaint files and continual postmarket role
3. Understand the contribution that complaint files have toward product quality and safety

What is the CAPA Subsystem?

- One of the 7 Quality System subsystems

- Corrective and Preventive Action (CAPA) Subsystem

Parts of CAPA Subsystem	Regulation Number (21 CFR)	General Applicability
Nonconforming Product	820.90	Manufacturing
Corrective and Preventive Action	829.100	Manufacturing and After Distribution
Complaint Files	**820.198**	**After Distribution**

Complaint Files - Overview

21 CFR 820.198

a) General Requirement

b) Initial Review and Evaluation

c) Investigation of Failures

d) Medical Device Reporting

e) Records

f) Off-Site Accessibility

g) Outside U.S. Accessibility

Complaint – Definition

21 CFR 820.3(b)

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

General Requirement

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 and timely manner
- Documentation of oral complaints *upon receipt*
- Evaluation to determine if failure investigation and/or a medical device report (MDR) is required

What to do With Servicing* Reports

- Train Servicers to **identify** possible complaints
  - Formally designated unit then reviews these possible complaints

- Have Formally Designated Unit **review** all Servicing reports/records for complaints

** Servicing (21 CFR 820.200) not discussed in this presentation beyond potential impact upon Complaint Files*

Initial Review and Evaluation

21 CFR 820.198(b)

- **Review** and **Evaluate** complaints to determine whether an investigation is necessary.
- If determine that **no** Investigation is needed, document:
  - Reason
  - Name of responsible individual

Investigation of Failures

21 CFR 820.198(c)

- Any alleged complaint involving possible failure of a *device* or *labeling/packaging* to meet any of its specifications must be Reviewed, Evaluated, and Investigated.

Exception – when an investigation has **already** been performed on a similar complaint

- Recurring similar complaints may not require investigation under complaint file handling but may require CAPA.

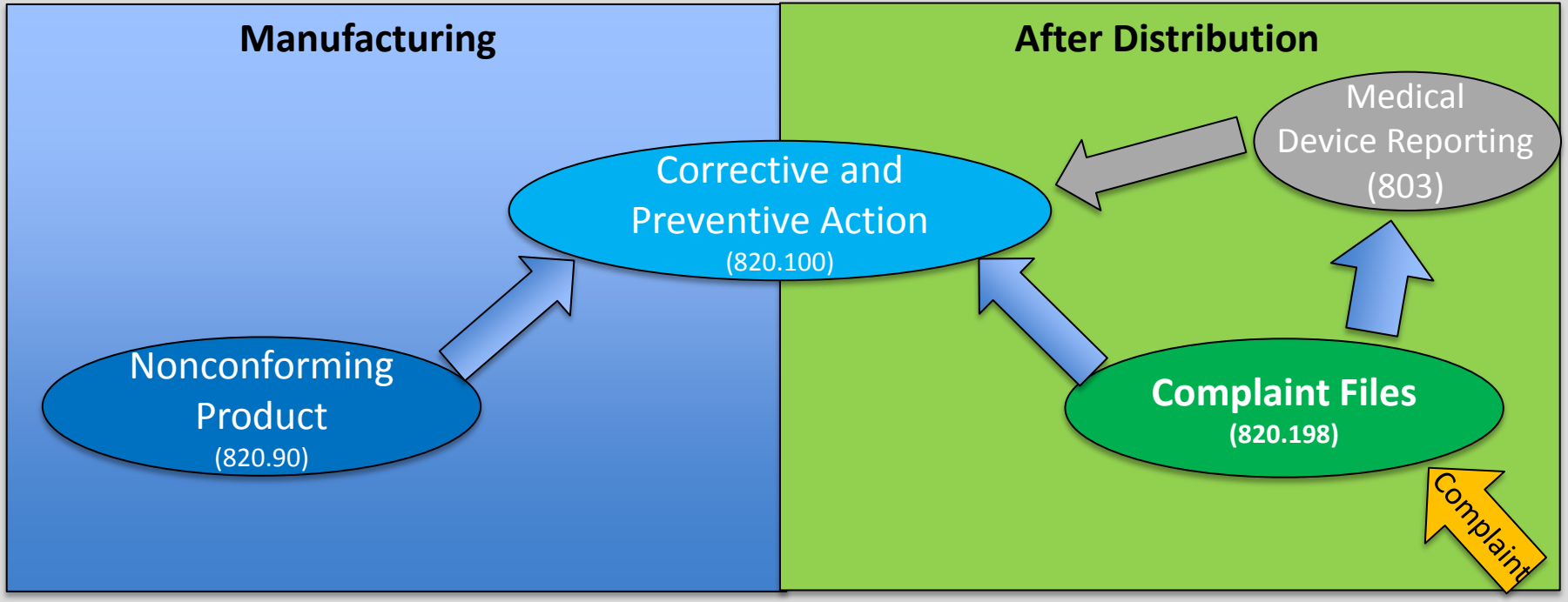
Medical Device Reporting (MDR)

21 CFR 820.198(d)

- Complaints that are also Medical Device Reports* (MDRs) must be promptly reviewed, evaluated, and investigated by designated individual(s).
- Maintain in a **separate** portion of the complaint files or be otherwise **clearly** identified.
- Keep additional records of investigation:
  - Whether device failed to meet specifications
  - Whether device was used for treatment/diagnosis
  - Relationship, if any, of device to reported incident/adverse event

**See 21 CFR 803 for details on MDRs*

How Does It All Fit Together?



Investigation – Why?

- All medical devices will eventually have a failure or MDR-reportable event.
- May impact everything from design to manufacturing.
- Robust system ensures responses/reactions are:
  - Accurate
  - Appropriate
  - Timely
- Result is a better, safer and more effective product.

Investigation – Why No Specifics?

- Multitude of variables:
  - Heterogeneous nature of devices and complaints
  - Risk
  - Severity
  - Frequency
  - Other factors (e.g., conditions, context, etc.)
- A set of prescriptive requirements governing all possible variables and situations is not feasible
- Regulation is **flexible**

Investigation – Details

(Think of It This Way)

- Regulation is **not vague** – FDA has given manufacturers freedom to define their **own** circumstances

- Manufacturers must **understand** their own product, risks, conditions and context for its use, and **apply** the Regulatory Requirements to make **their** Complaint Files System work

- Result: Manufacturers must decide upon their own **details**

Manufacturer Responsibilities - Details

- **Definitions**
  - Failure (device, labeling/packaging)
  - Medical Device Report
  - Other (“non complaints”)
- **Actions**
  - Investigate (“investigable”)
  - Other (“non complaints,” “similar” complaint)
- **Investigation Thresholds**
  - Handle within Complaint Files System
  - Refer to Corrective and Prevent Action Subsystem

Thresholds – Complaint Files

Handle corrections under Complaint Files if they meet some general criteria (with corresponding examples):

- Easy/specific correction
- Isolated incident
- Minor issue
- Not design issue/does not impact design
- Not Manufacturing issue/does not impact Manufacturing

Complaint Files – Easy/Specific Correction

- Device was mishandled during shipping and is dented or scratched.

Complaint Files – Isolated Incident

- Minor malfunction occurred when it was used once outside the intended/indicated uses in an unanticipated way.

Complaint Files – Minor Issue

- A part became loose or unattached, but was not damaged.

Complaint Files – Not Design Issue

- Device plastic casing cracked when accidently dropped.

Complaint Files – Not Manufacturing Issue

- Instruction Manual stuck to device and was lost during unpacking.

Thresholds – CAPA

Complaints should be referred to CAPA if they meet some general criteria (with corresponding examples):

- No easy/specific correction
- Recurring (based on valid analytical method)
- Severe
- Design issue/may impact design
- Manufacturing issue/may impact Manufacturing

CAPA – No easy/specific correction

- Device has a report of a short battery life.

CAPA – Recurring

- A large number of devices were dented or scratched over time.

CAPA – Severe

- Device caught on fire or exploded.

CAPA – Design Issue

- Use in a high electromagnetic (EM) area caused frequent, specific malfunctions

CAPA – Manufacturing Issue

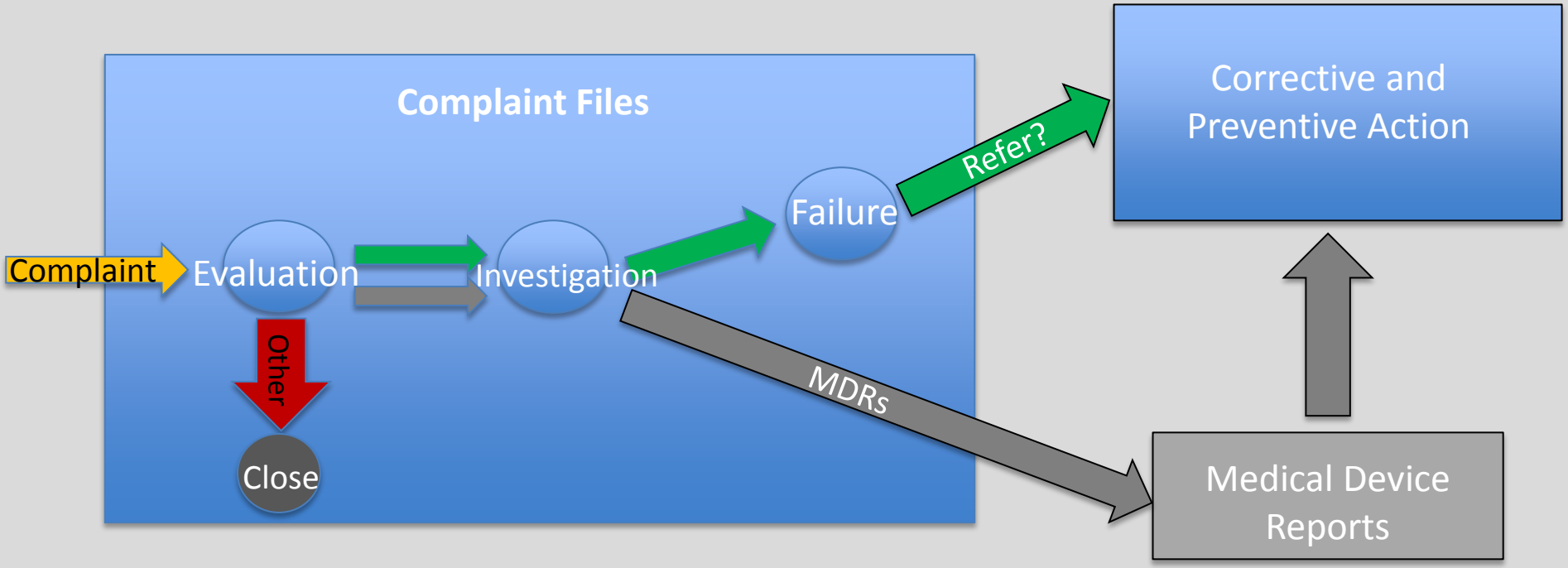
- Mold was found inside packaging

Thresholds – Balance is Key

- Too many failures handled under Complaints may **fail** to address **systemic** issues.
  - Generally simple, specific, contained issues

- Too many complaints referred to CAPA will **overwhelm** the system.
  - Generally more complex, ambiguous, systemic issues

Investigations – How Do They Work?



Records

21 CFR 820.198(e)

Records of investigations must be maintained:

- Device name
- Date complaint received
- Unique Device Identifier (UDI), Universal Product Code (UPC), and other device identification(s) (e.g., control/batch/lot number(s))
- Name, address, and phone number of complainant
- Nature/details of the complaint
- Results and dates of investigation
- Corrective action taken
- Reply/response to complainant

Off-Site and Outside U.S. Accessibility

21 CFR 820.198(f) and (g)

- When designated complaint unit is located *off-site* and/or *outside of the U.S.*, records must be *reasonably accessible* in the U.S. at:
  - Location in U.S. where the records are regularly maintained
  - Location of the initial distributor (e.g., Importer)
- Must comply with all other Quality System requirements (e.g., Records, 21 CFR 820 Subpart M).

QS Regulation and Guidance

- **Quality System Regulation and Preamble**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm

- **Inspection Guide - Complaint Handling System**
  www.fda.gov/iceci/inspections/inspectionguides/ucm114876.htm

- **Guide to Inspections of Quality Systems [Quality System Inspection Technique (QSIT)]**
  www.fda.gov/iceci/inspections/inspectionguides/ucm074883.htm

Call to Action

1. Use your Complaint File system to “Learn from mistakes” – they can impact:
    - Quality
    - Design
    - Manufacturing
2. Complaint Files are a gateway mechanism for CAPA and Postmarket activities
3. A robust complaint file system can improve Quality and Safety

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE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