Complaint Files

FDA Small Business
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Learning Objectives

- Understand the Complaint File Handling System:
  - ***Context*** within the overall Quality System and CAPA subsystem
  - ***Mechanisms*** and continual Postmarket role
  - ***Contribution*** to Quality and Safety

Poll Question

How would you rate your knowledge about Complaint Files?

a) Expert

b) Good

c) Basic

d) None/Little – that's why I'm here!

The 7 Subsystems of a Quality System

Guide to Inspections of QS: Quality System Inspection Technique

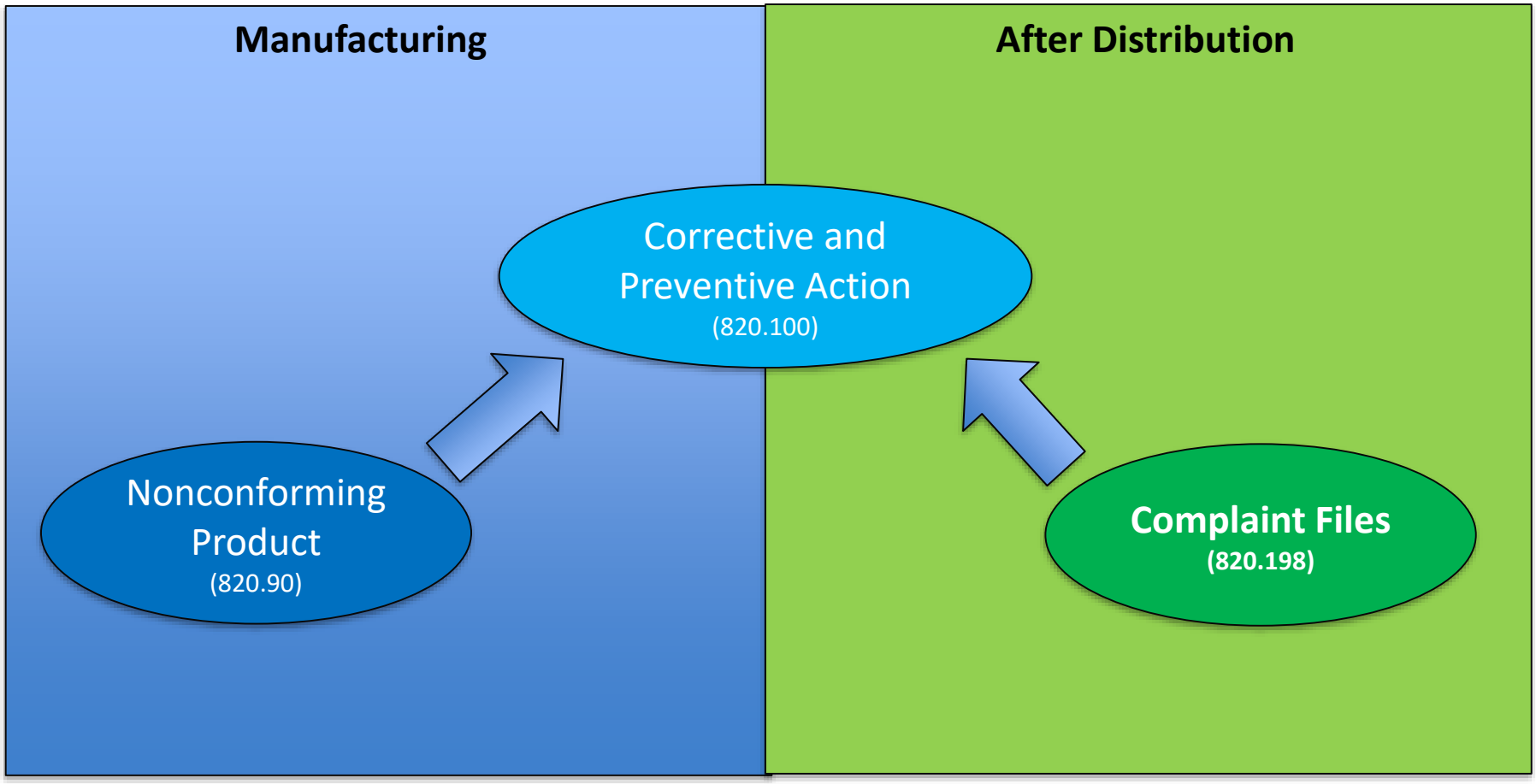
What is the CAPA Subsystem?

- One of the 7 Quality System subsystems
- Corrective and Preventive Action (CAPA) Subsystem
  - Nonconforming Product (21 CFR 820.90)
  - Corrective and Preventive Action (21 CFR 820.100)
  - **Complaint Files (21 CFR 820.198)**

CAPA Subsystem Roles

- Manufacturing
  - Nonconforming Product (820.90)
- Manufacturing and “After Distribution”
  - Corrective And Preventive Action (21 CFR 820.100)
- **“After Distribution”**
  - **Complaint Files (21 CFR 820.198)**

The CAPA Subsystem



Complaint Files – Why Do They Matter?

1/3 of all 483 Observations

AND

most Warning Letters

had CAPA Subsystem-related issues, including Complaint Files

Source: "*2015 Annual FDA Medical Device Quality System Data: Inspections, FDA Form 483 Observations, and Warning Letter Citations*" (CDRH Office of Compliance, Division of Analysis and Program Operations, Registration & Risk Branch)

Frequent CAPA Subsystem Citations

- **483 Observations**
  - 1,131 of 3,525 (32%)
  - most frequent, along with Production & Process Controls Subsystem
  - 33% were Complaint Files
- **Warning Letters**
  - 111 of 121 (91.7%)
  - CAPA Subsystem most common citation
  - 25.8% were Complaint Files

Source: "*2015 Annual FDA Medical Device Quality System Data: Inspections, FDA Form 483 Observations, and Warning Letter Citations*" (CDRH Office of Compliance, Division of Analysis and Program Operations, Registration & Risk Branch)

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 an MDR is required

Initial Review and Evaluation

21 CFR 820.198(b)

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

Investigation of Failures

21 CFR 820.198(c)

- Any 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

*Similar complaints may not require investigation, but may require Corrective and Preventive Action due to *recurrence*.

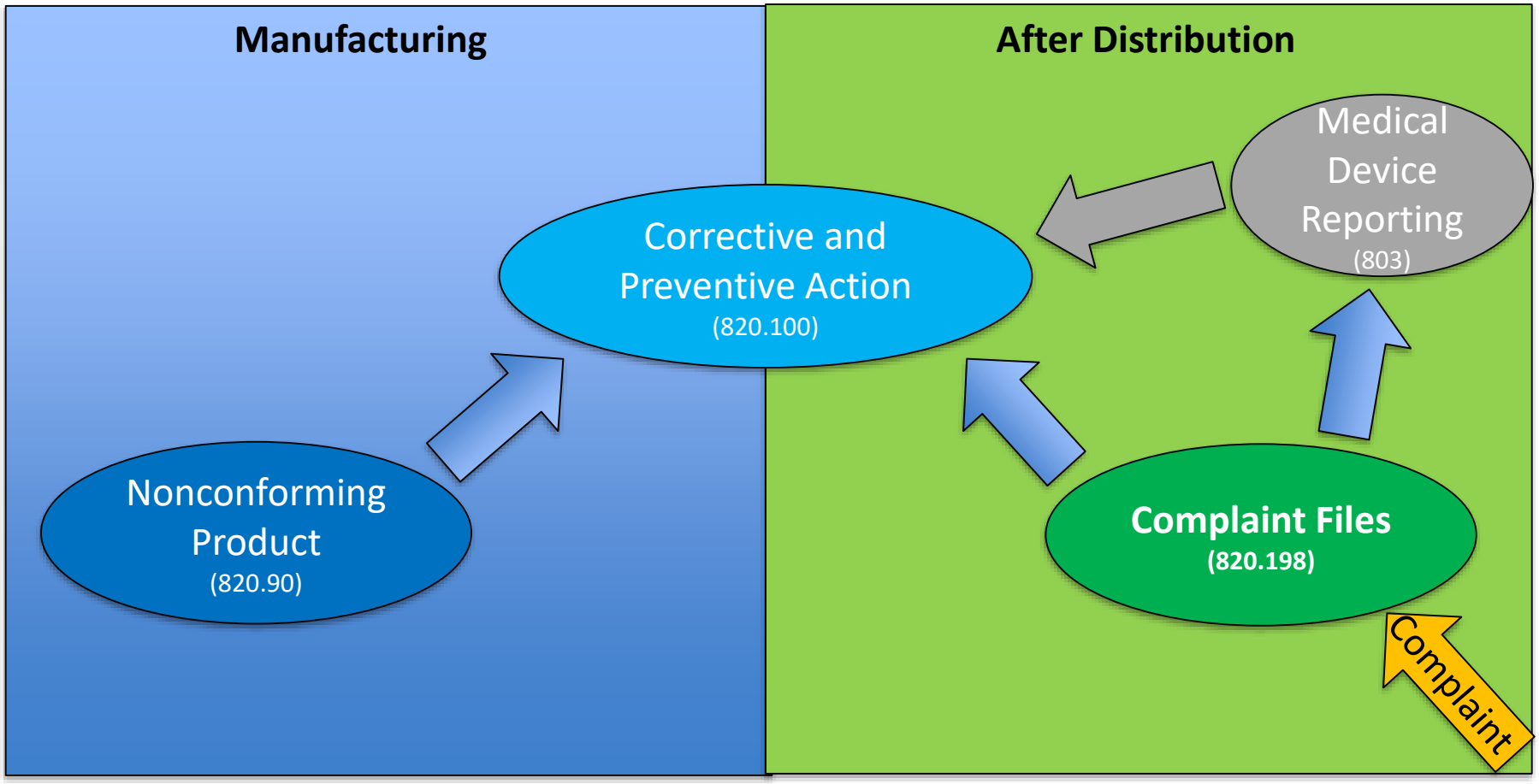
Medical Device Reporting (MDR)

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 manufacturing to design.
- 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., context, conditions, etc.)
- A prescriptive regulation 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)
- **Investigations and Thresholds**
  - Handle within Complaint Files System
  - Refer to Corrective and Prevent Action Subsystem

Thresholds

When should complaints be handled under Complaints or referred to Corrective and Preventive Action?

Thresholds – Complaint Files

Handle corrections under Complaint Files if:

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

Thresholds – Complaint Files (Examples)

Potentially could handle under Complaints:

- Device was mishandled during shipping and dented or scratched
- Minor malfunction occurred when used outside intended/indicated uses in an unanticipated way
- A part became loose or unattached, but was undamaged
- Device plastic casing cracked when dropped
- Instruction Manual stuck to device and was lost during unpacking

Thresholds – CAPA

Refer to CAPA if:

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

Thresholds – CAPA (Examples)

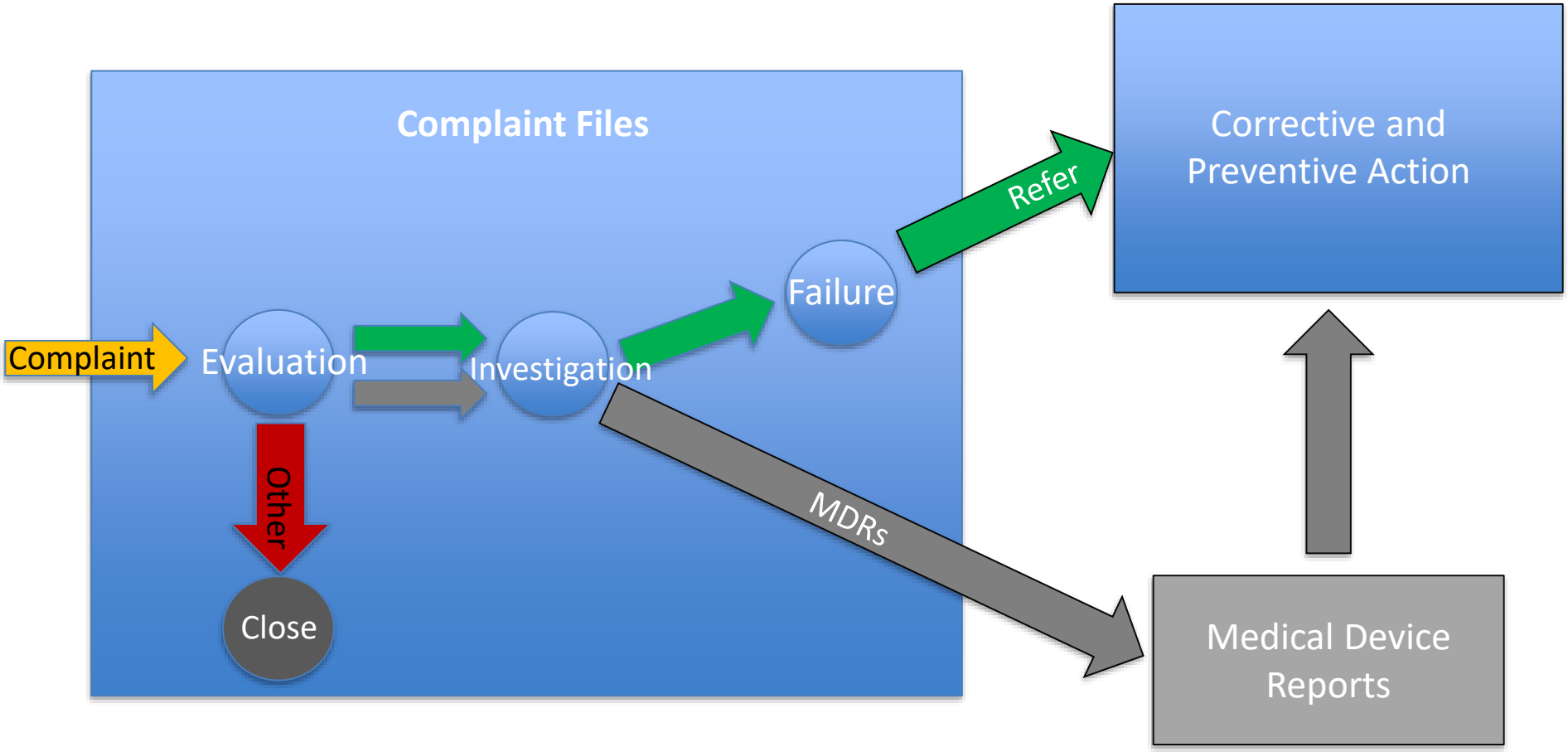
Refer to CAPA:

- Device has a report of a short battery life
- A large number of devices were dented or scratched
- Device caught on fire or exploded
- Use in a high electromagnetic area caused frequent, specific malfunctions
- 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 referrals 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 Accessibility

21 CFR 820.198(f)

- When a designated complaint unit is located *off-site*, records must be reasonably accessible to the manufacturing establishment (and FDA).
- Must comply with all other Quality System requirements (especially Records, 21 CFR 820 Subpart M).

Outside U.S. Accessibility

21 CFR 820.198(g)

- When designated complaint unit is located *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).

Complaint Files - Summary

- Complaint Files are a component of the CAPA ***subsystem*** of the ***Quality System***
- **"*After* Distribution"**
- **Goal** – to ensure manufacturer:
  - Processes complaints in uniform, timely manner
  - Documents oral complaints upon receipt
  - Evaluates complaints to determine if a failure investigation and/or an MDR is required

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

- **2015 Annual FDA Medical Device Quality System Data**
  www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM490768.pdf

Questions?

Please complete the session survey:
surveymonkey.com/r/DEV-D2S05

Call to Action

- “Learn from mistakes” – Complaint File system can impact:
  - Quality
  - Design
  - Manufacturing
- Complaint Files are a gateway mechanism for CAPA and Postmarket activities
- Robust Complaint File system can improve Quality and Safety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