

# Complaint Files

**FDA Small Business  
Regulatory Education for Industry (REdI)  
Rockville, MD  
September 28, 2017**

**Stanley Liu**  
Consumer Safety Officer  
Premarket Programs Branch  
Division of Industry and Consumer Education  
Office of Communication and Education  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# 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](#)

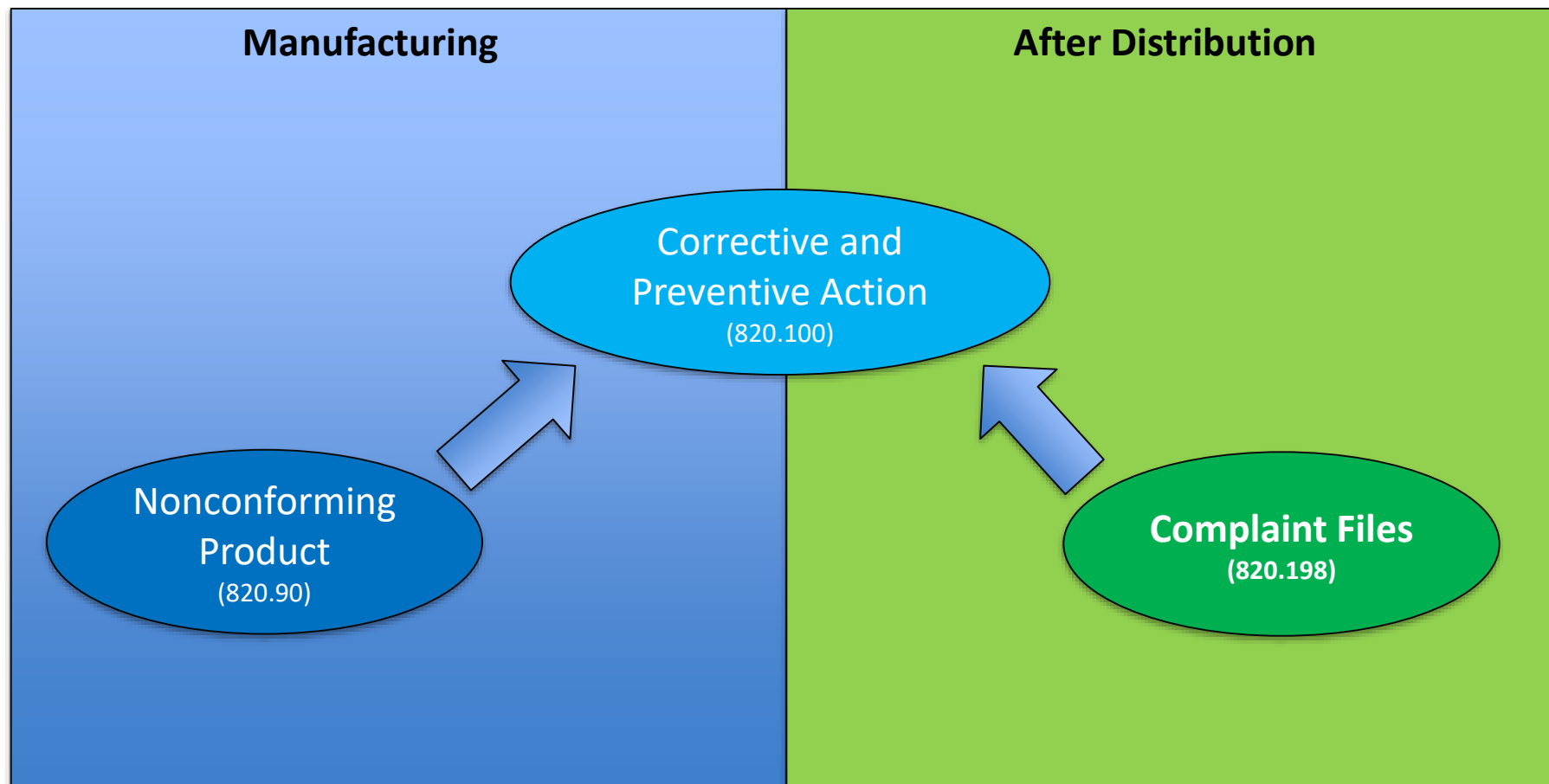
# What is the CAPA Subsystem?

- 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** Warning Letters

had CAPA Subsystem-related issues, including  
Complaint Files

Source: “2016 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**
  - 1,017 of 3,027 (34%)
  - Most frequent observation
  - ~38% of CAPA were Complaint Files
- **Warning Letters**
  - 189 of 594 (32%)
  - CAPA Subsystem second most common citation
  - ~32% of CAPA citations were Complaint Files

Source: "2016 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

# Complaints and Servicing

- Complaints may appear during Servicing\*
- What then? Options:
  - Train Servicers to **identify** complaints
  - Have Formally Designated Unit review Servicing reports/records

*\* 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 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)

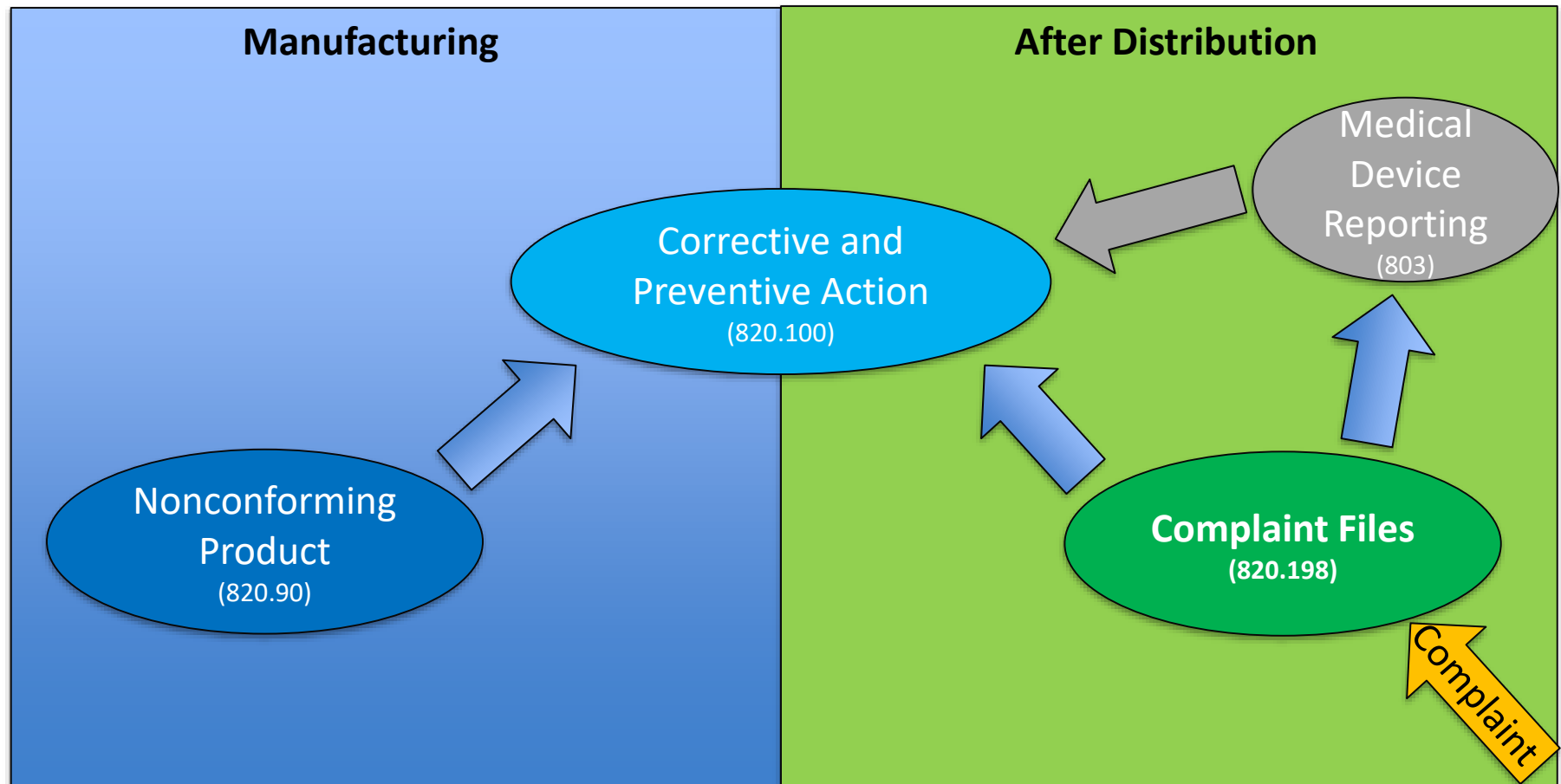
## 21 CFR 820.198(d)

- 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)

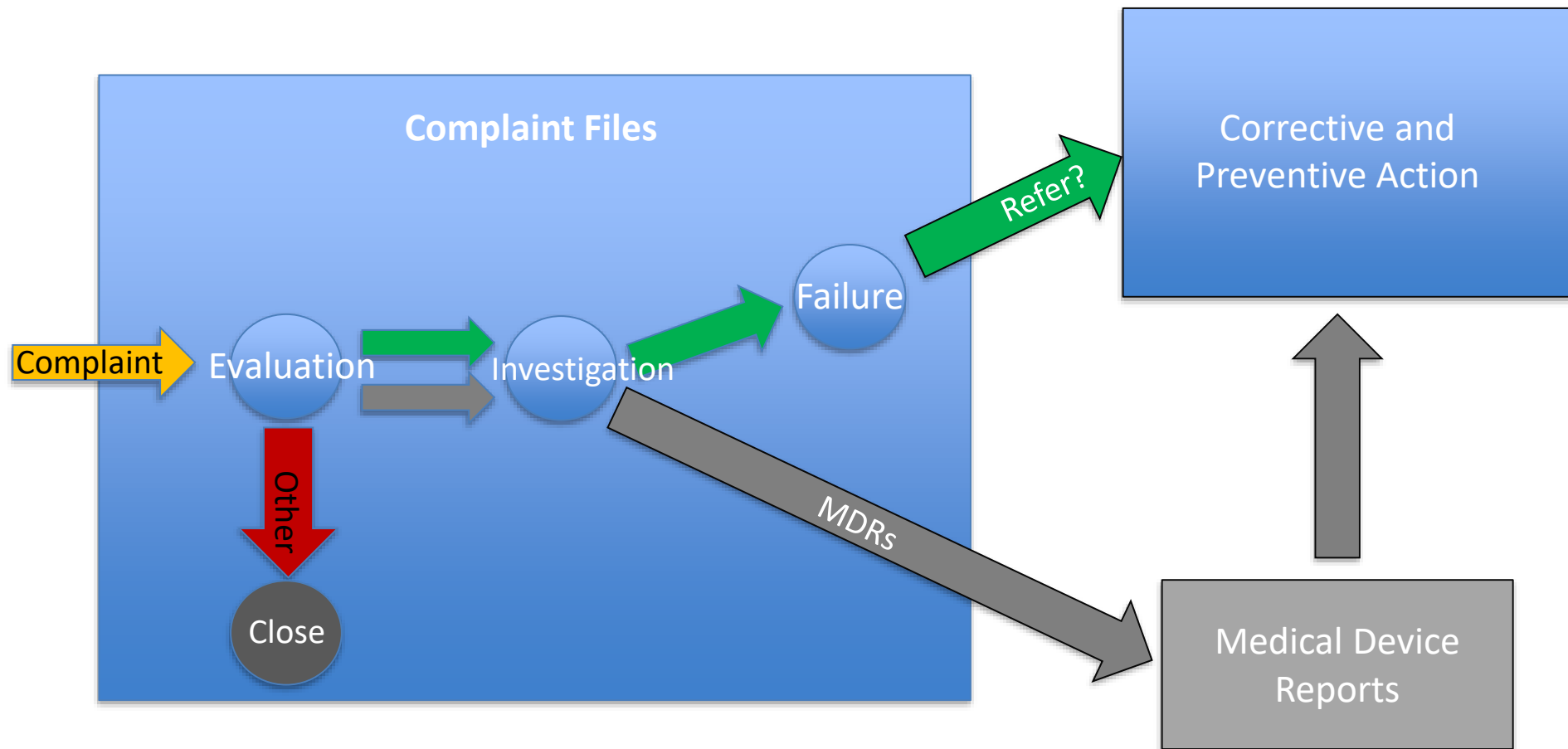
Refer to CAPA:

- 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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1)

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm)

- **Inspection Guide - Complaint Handling System**

[www.fda.gov/iceci/inspections/inspectionguides/ucm114876.htm](http://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](http://www.fda.gov/iceci/inspections/inspectionguides/ucm074883.htm)

- **CY 2016 Annual FDA Medical Device Quality System Data**

<https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm554548.pdf>

# Questions?

Please complete the session survey:  
[surveymonkey.com/r/DEV-D2S05](https://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

