

# Step into the Closing Meeting: Navigating an FDA Closeout and Beyond

**FDA Small Business Regulatory Education for Industry (REdI) Annual Conference**

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**How will  
you step  
into your  
next  
FDA  
closeout?**



# Learning Objectives

- Identify typical activities conducted at the closing meeting
- Describe Agency's approach to classifying inspections and explain how written responses can affect final classification
- List most common 483 citations issued to medical device industry
- Describe common pitfalls with CAPA effectiveness checks and how these deficiencies can lead to 483 observations

**CAPA = corrective and preventive actions**

# The Closeout

# Potential Activities at the Closing Meeting

- **Issuance of Form FDA 483, Inspectional Observations**
  - Investigator's observations do not represent a final Agency determination regarding compliance
- **Discussion Items**
  - Additional issues of concern not included in 483
- **Issuance of Affidavit**
  - Statements to identify the interstate movement of product

# Responding to the 483

- **Annotation**

- Acknowledges management's response to an observation
  - Promise to Correct (optional timeframes)
  - Reported Corrected / Corrected and Verified
  - Under Consideration
  - Annotation Intentionally Left Blank

- **Written response**

- Encouraged but not required to respond in writing
- May affect the final classification of the inspection

# Classifying Inspections

# Classification of the Inspection

- **NAI (no action indicated)**
  - No objectionable conditions identified
- **VAI (voluntary action indicated)**
  - Objectionable conditions identified but agency not prepared to take administrative or regulatory action
- **OAI (official action indicated)**
  - Objectionable conditions identified + regulatory/administrative actions recommended

# Post-inspectional Notification

## FMD-145

- Correspondence sent to inspected firm within 45 calendar days after inspection is deemed closed/finalized
  - EIR released for OAI inspections when finalized and after confirmation that no further action is planned
- Receive redacted copy of narrative EIR

EIR = establishment inspection report

# The Next FDA Inspection

- Investigator will verify corrections if a 483 was issued during the previous inspection
- Timing depends on previous inspection's classification, product risk, and signals received by the Agency



FY 2023

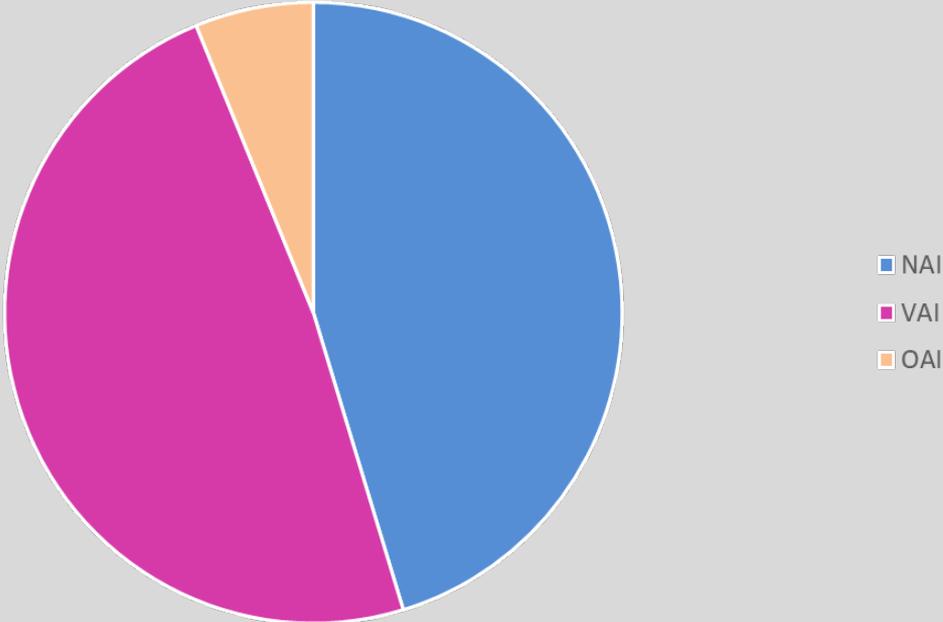


# **Most Common Citations Issued by Medical Device Investigators**

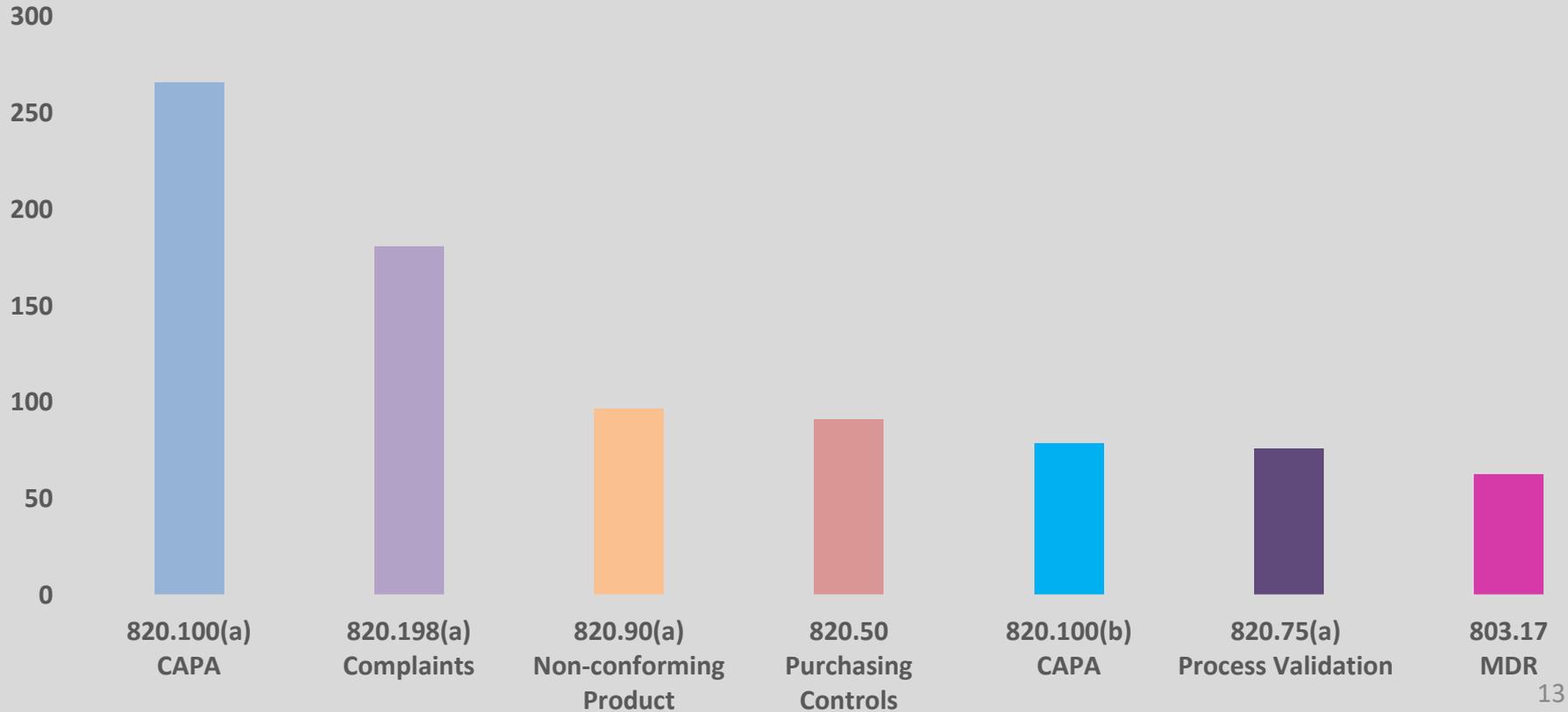
# Office of Medical Devices and Radiological Health Operations, FY2023

	<b>1,396</b> Medical Device Inspections
	<b>836</b> Mammography Inspections
	<b>70</b> Rad Health Inspections
	<b>1,819</b> Domestic Inspections
	<b>442</b> Foreign Inspections
	<b>81</b> Unannounced Inspections

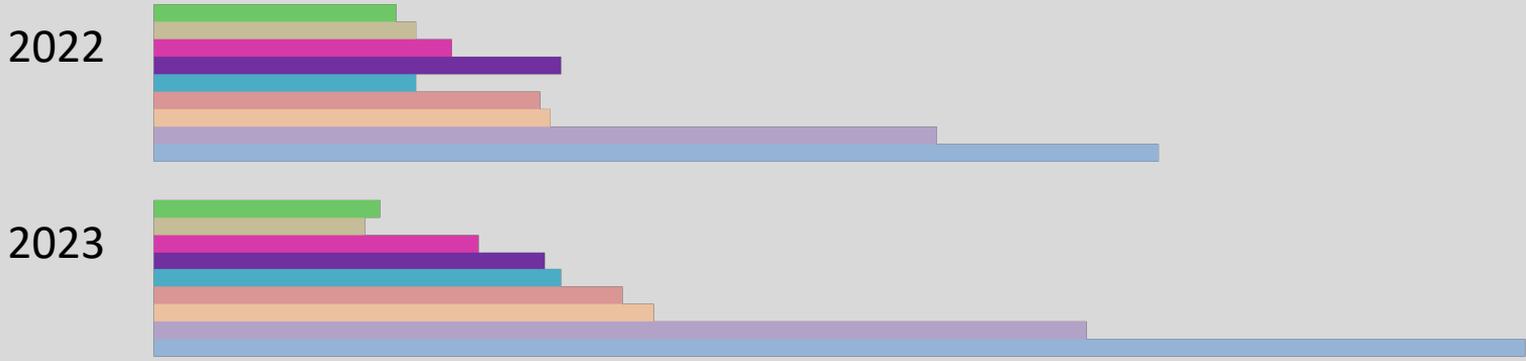
Domestic Medical Device Inspections by Classification



# Most Frequent Citations Issued by Medical Device Investigators 2023



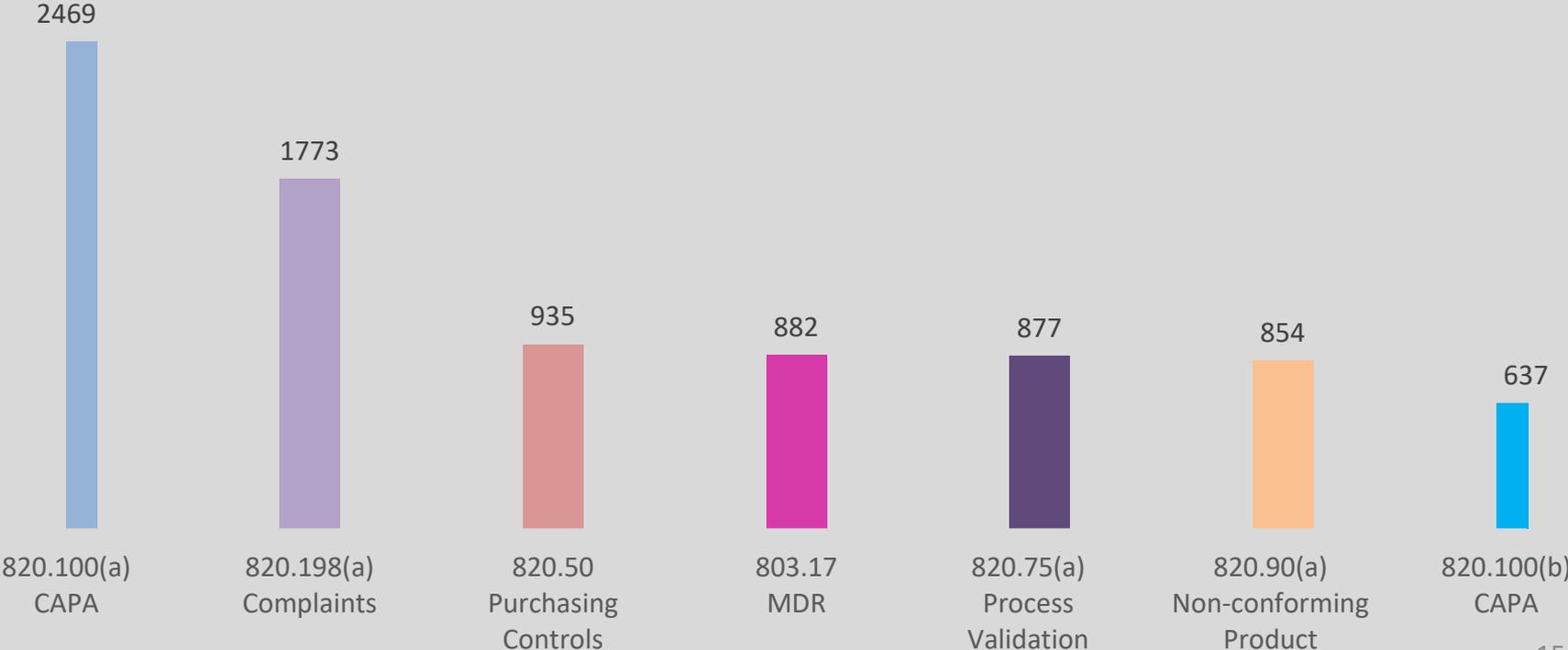
## Comparison Between Selected Citations, Years 2022-2023



	2023	2022
■ Training	44	47
■ Design Change	41	51
■ MDR	63	58
■ Process Validation	76	79
■ CAPA Documentation	79	51
■ Purchasing Controls	91	75
■ Nonconforming Product	97	77
■ Complaints	181	152
■ CAPA	266	195



# Most Frequent Citations Issued by Medical Device Investigators 2015 - 2023



# Common Pitfalls with CAPA

# Verification of Effectiveness

- Verify or validate corrective/preventive action
  - to ensure that it is **effective** and
  - to ensure it does not adversely affect finished device

# Investigator's Record Review

(Based on true events)

- A firm opens a CAPA after receiving an observation for inadequate complaint investigations
  - Corrective actions include SOP revision and employee training
  - At next inspection, the Investigator reviews this CAPA's effectiveness check...

# Documenting Effectiveness Checks

No plan or acceptance criteria

This firm is verifying implementation but not effectiveness of the corrective action

The Complaint Procedure has been revised to include information on investigating complaints. Training records attached. Therefore, this CAPA is effective and can be closed.

# Observation for Inadequate Effectiveness Checks

(Also based on true events)

**Procedures for corrective and preventive action have not been adequately established.**

Specifically, the effectiveness check plan for CAPA-27, initiated to address lack of established acceptance criteria in validation plans and protocols, did not include clearly defined acceptance or sampling criteria, and only reviewed one design change without further justification for the sample size selected.

**820.100(a)**

# Documenting Effectiveness Checks

Timeframe

Sample based on statistical rationale.

**Plan:** X months following implementation of the revised SOP, review n number of complaint records. This CAPA will be deemed effective if all records include A, B, and C.

Acceptance criteria

**Objective Evidence:** On (date), Employee X reviewed n out of X complaint records and all included A, B, and C. See Attachment 1 for complaint records.

Evidence

# Knowledge Check

Which subsystem is most often cited by medical device investigators?

A. Production and Process Controls

B. CAPA

C. Design Controls

D. Management Controls

# Knowledge Check

My firm will always receive a copy of the establishment inspection report (EIR) within 45 calendar days from the closeout meeting?

A. True

B. False

# Resources

Slide Number	Cited Resource	URL
7	Inspectional Classifications	<a href="http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/inspection-classifications">www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/inspection-classifications</a>
12-14	Code of Federal Regulations, Title 21, Subchapter H (Medical Devices)	<a href="http://www.ecfr.gov/current/title-21/chapter-I/subchapter-H">www.ecfr.gov/current/title-21/chapter-I/subchapter-H</a>
8	Field Management Directive (FMD-145): Release of the Establishment Inspection Report (EIR)	<a href="http://www.fda.gov/media/83055/download">www.fda.gov/media/83055/download</a>
15-19	Quality System Inspection Technique	<a href="http://www.fda.gov/files/Guide-to-Inspections-of-Quality-Systems.pdf">www.fda.gov/files/Guide-to-Inspections-of-Quality-Systems.pdf</a>
11	FDA Data Dashboard	<a href="http://datadashboard.fda.gov/ora/index.htm">datadashboard.fda.gov/ora/index.htm</a>

# Summary

- Medical device firms are most frequently cited for:
  - Lack of/inadequate CAPA procedures
  - Lack of/inadequate complaint handling procedures
- Annotating the 483 and/or responding in writing:
  - Acknowledges your promise to correct deficiencies
  - May affect the classification of the inspection

# Questions



# Your Call to Action

- Invite senior management, ask questions, and provide clarification at end-of-day summaries/wrap-ups so there are no surprises.
- Discuss your plans for correction with the Investigator during the closing and/or provide a written response.
- When completing CAPA effectiveness checks, ensure there is a plan with acceptance criteria based on statistical rationale and objective evidence.