Overview of Nonconforming Product

FDA Small Business
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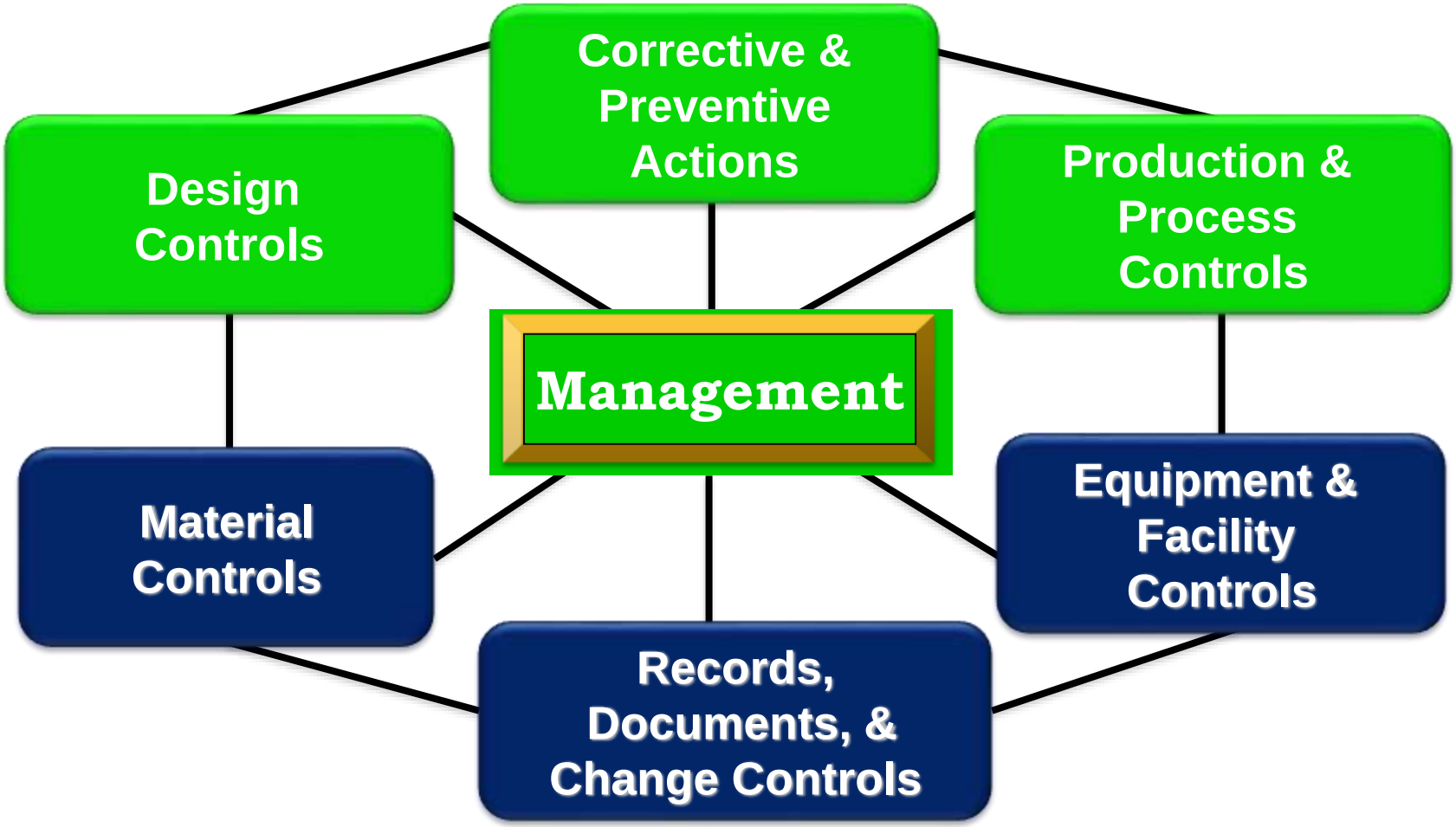
Learning Objectives

- ***Define*** nonconforming product
- **Understanding** the Process Flow
- Know the **Importance** of disposition with regards to nonconforming product

The 7 Subsystems of a Quality System

Guide to Inspections of QS: Quality System Inspection Technique

The 4 Major Subsystems

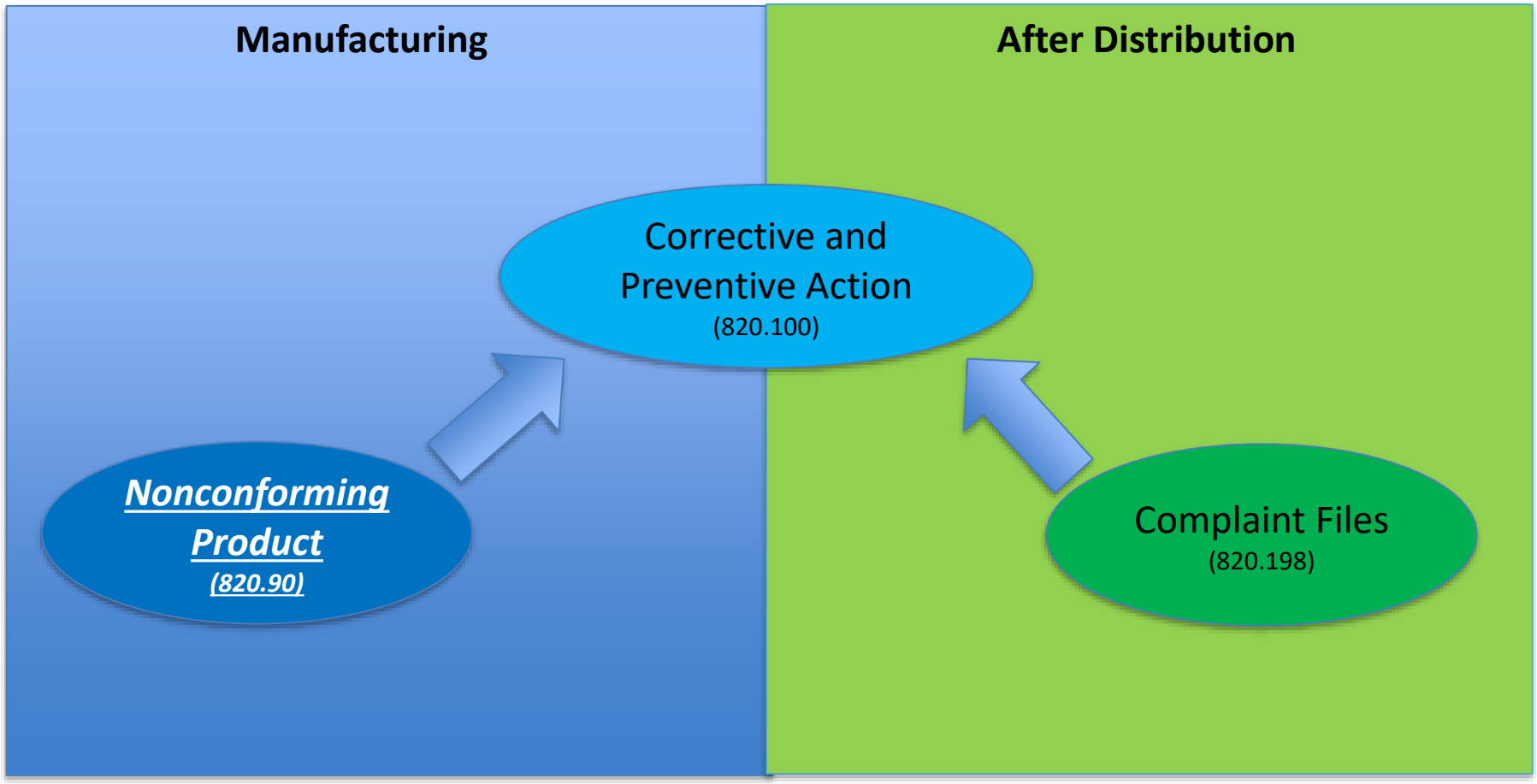


Guide to Inspections of QS: Quality System Inspection Technique

What is the CAPA Subsystem?

- One of the 4 major Quality System subystems
- 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)

The CAPA Subsystem



Frequent CAPA Subsystem Citations

- **483 Observations**
  - 1,131 of 3,525 (32%)
  - most frequent, along with Production & Process Controls Subsystem
  - 20% were Nonconforming Product
- **Warning Letters**
  - 111 of 121 (91.7%)
  - CAPA Subsystem most common citation
  - 16.2% were Nonconforming Product

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)

Control of Nonconforming Product 21 CFR 820.90(a)

"Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product…"

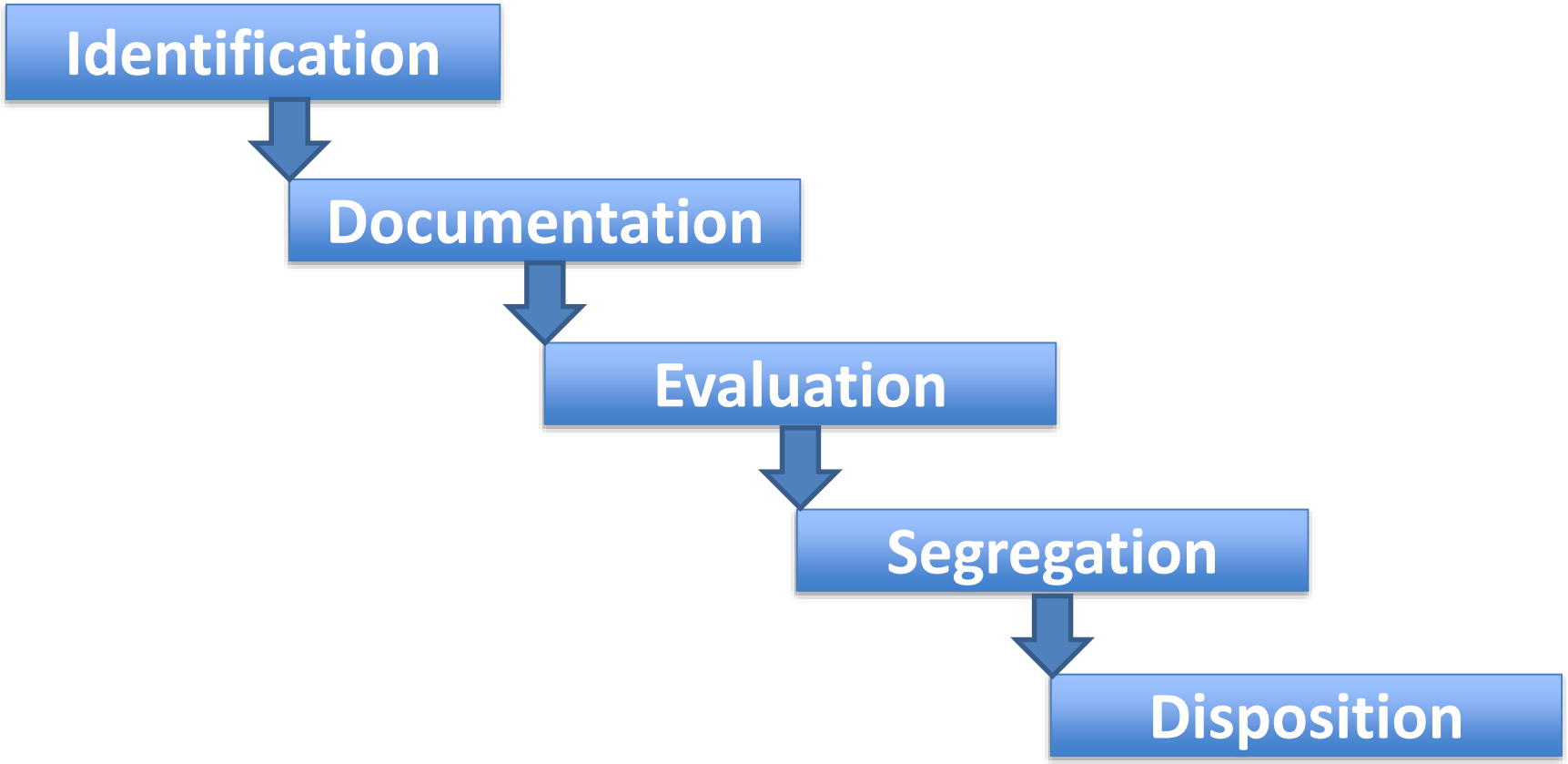
What is Nonconforming Product?

- **Specification** = 21 CFR 820.3(y) any requirement with which a product, process, service, or other activity must conform
- **Nonconformity** = the nonfulfillment of a specified requirement. **[21CFR820.3(q)]**
- **Product** = components, manufacturing materials, in-process devices, finished devices, and returned devices. **[21CFR820.3(r)]**

What is Nonconforming Product?

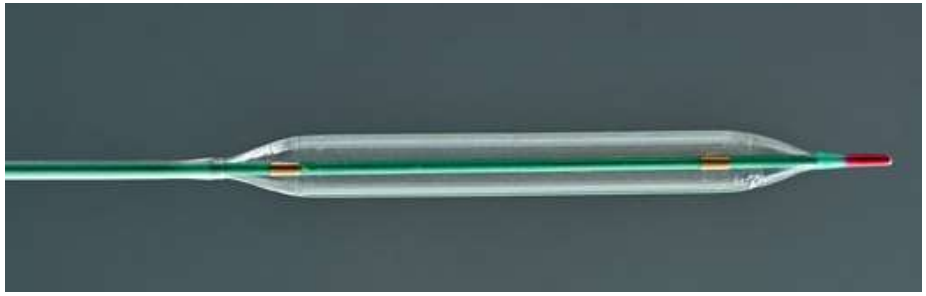
- Product that does not fulfill its specified requirements
- Nonconformance can occur in both product and process
- Nonconforming processes can lead to nonconforming product.

Process Flow

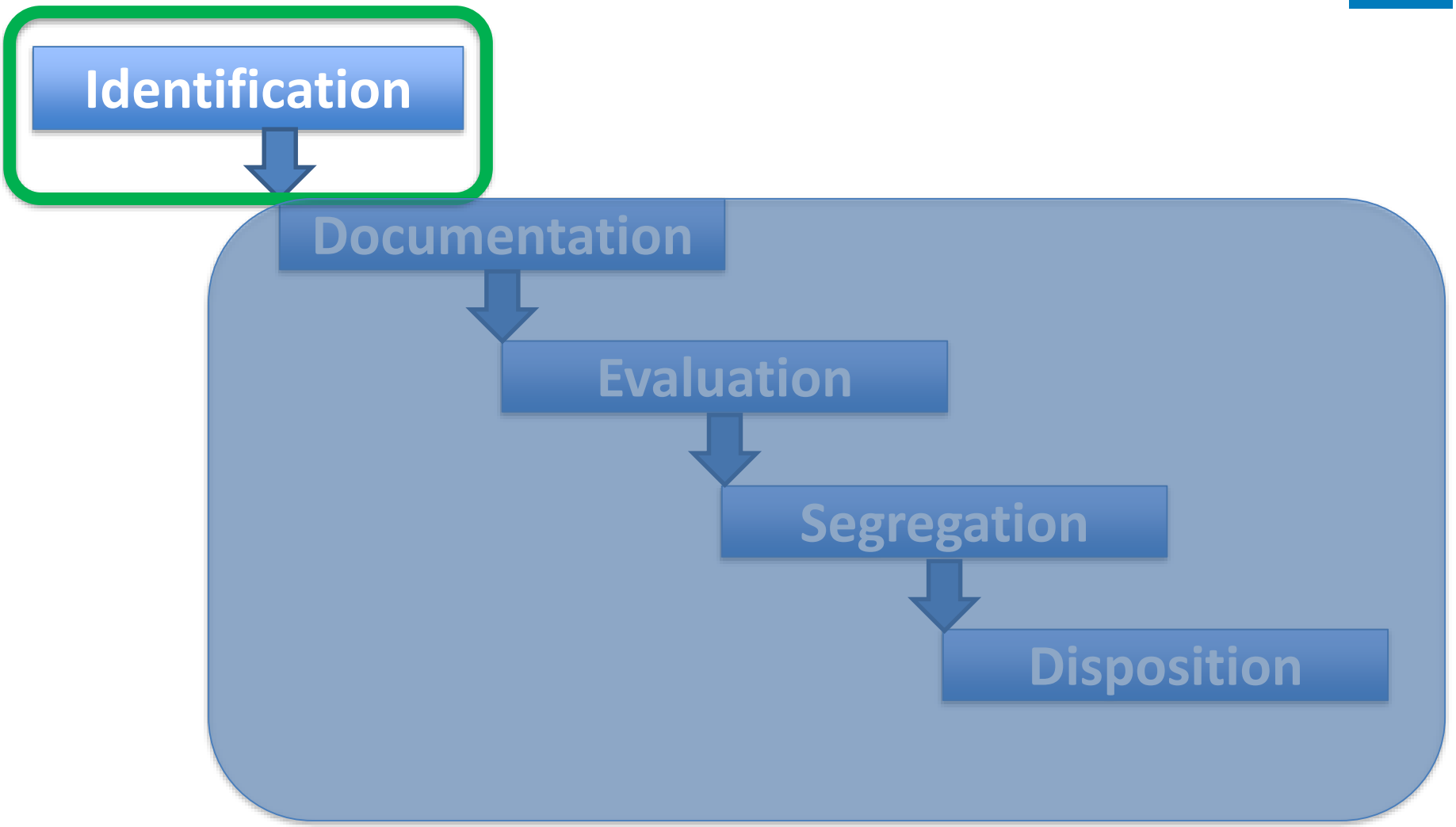


Case Study

Company A purchases all the extruded tubing for the catheter from Supplier B.



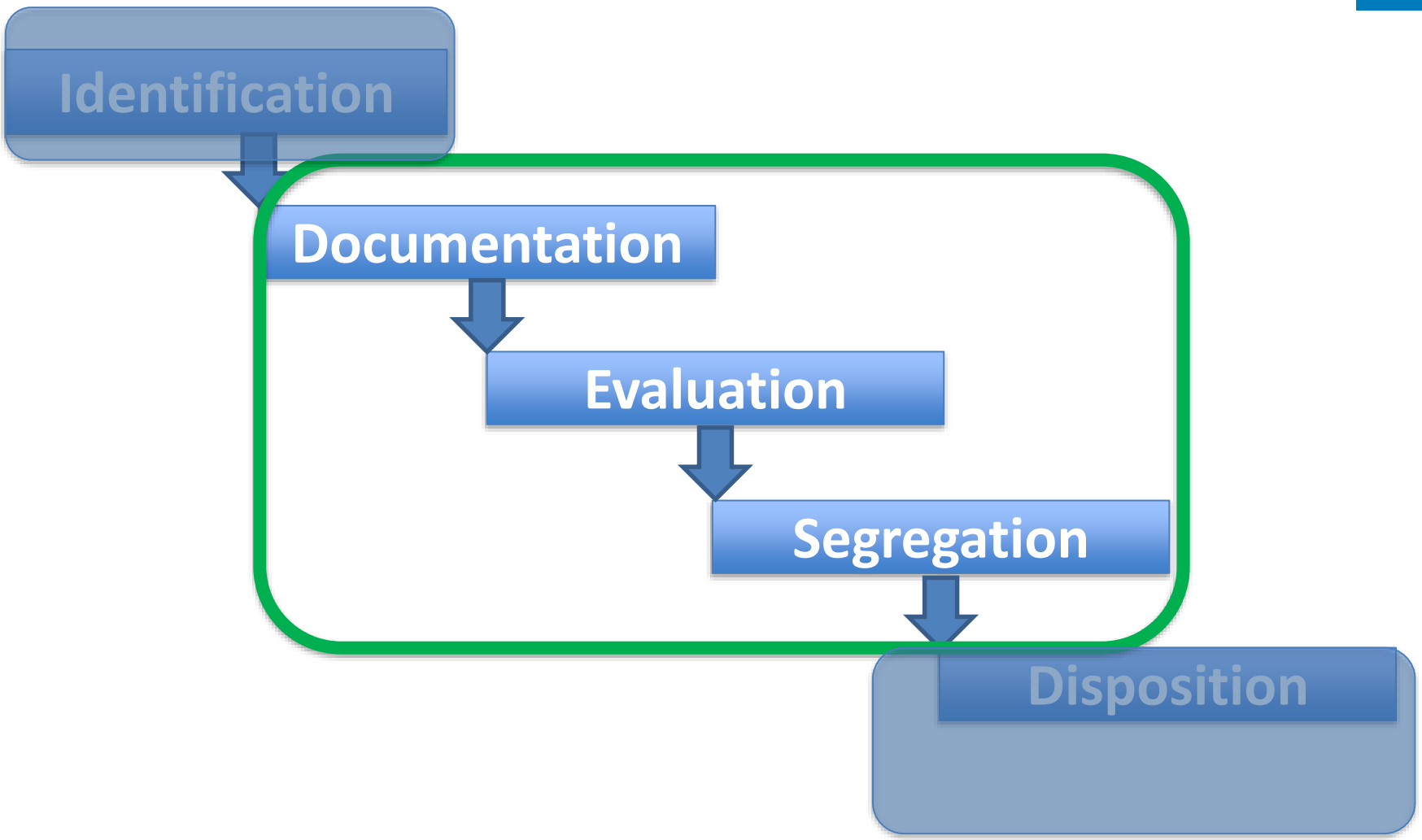
Process Flow



Sources of Nonconforming Product

- Received components/material that fail incoming inspection
- Products/components that fail inspection or test steps during manufacturing
- Product returned to manufacturer with defects through complaint handling and segregation

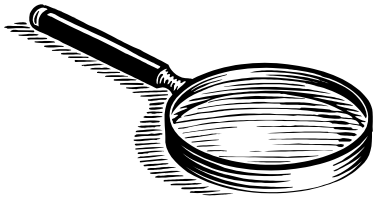
Process Flow



Control of Nonconforming Product
21 CFR 820.90(a)

... The evaluation of nonconformance shall include a **determination of the need for an investigation and notification of the persons or organizations responsible** for the nonconformance. The evaluation and any investigation shall be documented.

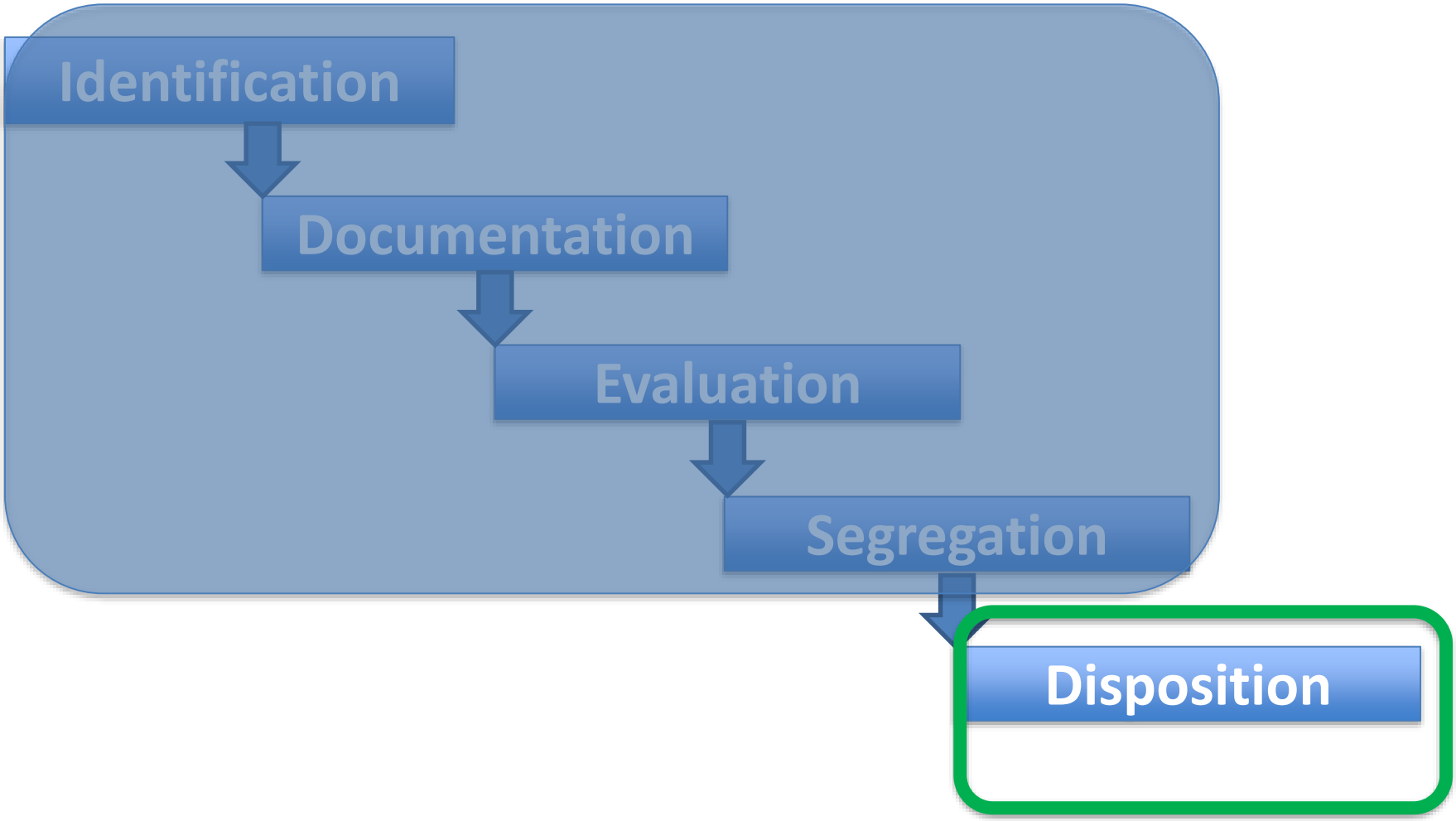
*Investigation is **Not Always** required*



Common Industry Practice

- Material Review Board/Material Review Committee (MRB/MRC),
  - Not ad hoc, but in an approved procedure
  - Issue if see same nonconformity over and over
  - May need CAPA
- Typically a form that identifies the material, the problem, evaluation, segregation, the investigation (if any), disposition and signatures

Process Flow



Disposition of Nonconforming Product 21 CFR 820.90(b)(1)

Each manufacturer shall establish and maintain procedures that **define the responsibility for review and the authority for the disposition of nonconforming product**. The procedures shall set forth the review and disposition process.

Disposition of Nonconforming Product 21 CFR 820.90(b)(1)

Disposition of nonconforming product shall be documented. **Documentation shall include the justification for use of nonconforming product** and the signature of the individual authorizing the use.

Typical Nonconforming Product Dispositions

- Scrap
- Return to Supplier
- Use As-Is
- Rework
- Downgrade

"... FDA believes that the justification should be based on scientific evidence, which a manufacturer should be prepared to provide upon request. Concessions should be closely monitored and not become accepted practice"

Per preamble comment #156

Rework Procedures
21 CFR 820.90(b)(2)

Each manufacturer shall **establish and maintain procedures for rework**, to include retesting and reevaluation of the nonconforming product after rework, **to ensure that the product meets its current approved specifications**.

Rework Procedures
21 CFR 820.90(b)(2)

Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR [Device History Record].

Summary

- Identification and monitoring of nonconforming product often “triggers” CAPA activities.
- Nonconforming product investigations can also be leveraged during CAPA investigations.
- Not every nonconformance is a CAPA.

References

- **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
- **CDRH Learn Module on CAPA**
  fda.yorkcast.com/webcast/Play/c78cfebf72774163a59f8f6f197435451d
- **Inspection Guide - Complaint Handling System**
  www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114934.htm#Control
- **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
- **Global Harmonization Task Force (GHTF) document: Quality Management System-Medical Devices- Guidance on corrective action and preventive action and related QMS processes**

Questions

Please complete the session survey:
surveymonkey.com/r/DEV-D2S04

Call to Action

- Control your nonconformance
- Nonconformances are inputs for CAPA
- Information from the disposition of nonconforming product leads to continuous improvement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