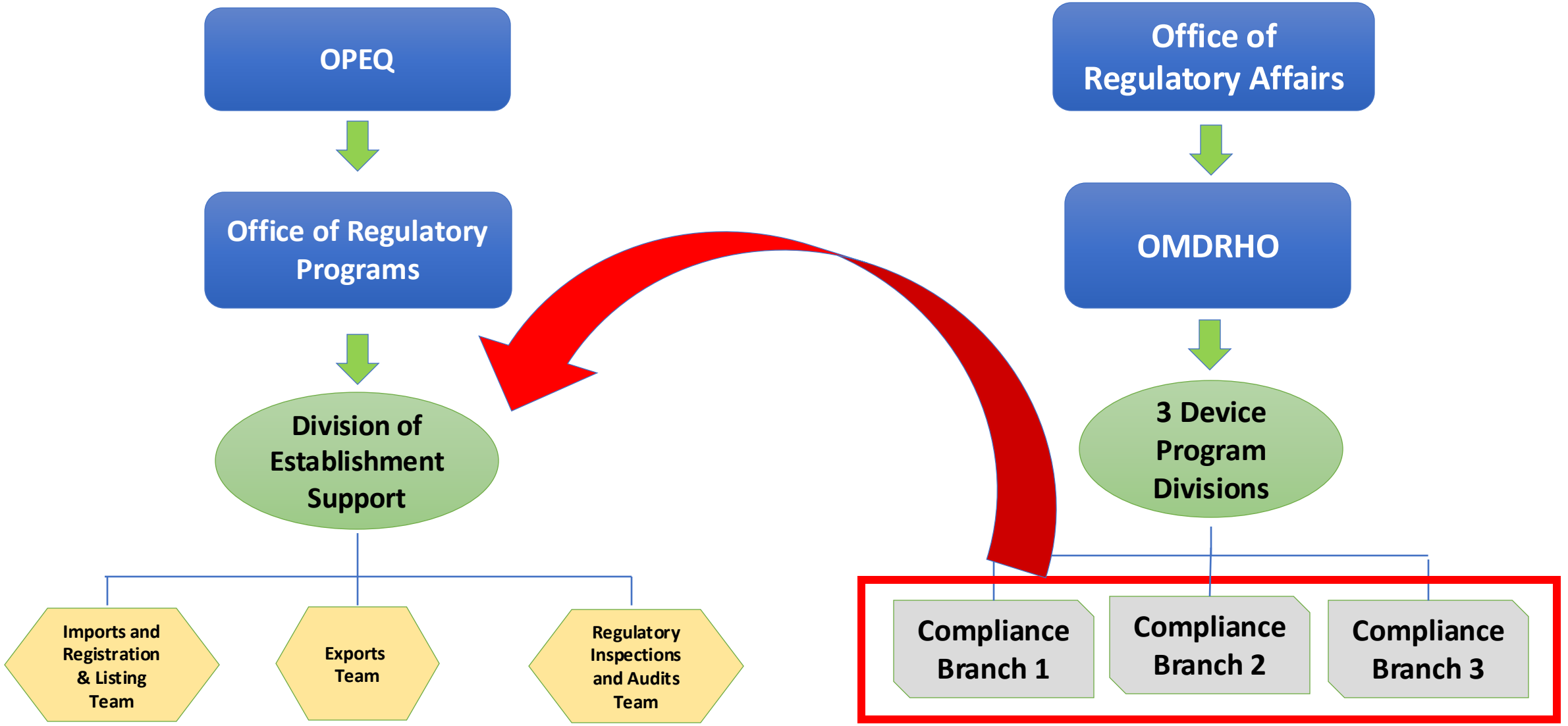
FDA Updates: Inspections and Compliance

Keisha Thomas, MS, MHS, RAC, CQA
Associate Director, Compliance and Quality
CDRH, Office of Product Evaluation and Quality

FDA Reorganization and Compliance Unification

- FDA reimagining the Human Foods Program, making additional changes to promote efficiencies across the Agency
- Former Office of Regulatory Affairs (ORA) has transitioned to the Office of Inspections and Investigations (OII): core mission to now focus on investigations, inspections and import operations
- Realigning most ORA compliance functions and staff to the Centers to simplify operations and speed decision-making
  - *no changes to Recall process*
- Reorganization implementation date: 10/1/2024

Where will the compliance branches move?



Reorganization Impact

- Nothing changing related to the inspection process and engagement
  - inspections continue to be conducted by OII

- Engagement with the FDA device program on compliance matters will be unified within CDRH (both domestic and foreign sites)
  - Medical device compliance decision making unified within Center

- Device review work will continue to follow the TPLC review model and work across CDRH review offices

What do we expect from this compliance transition?

Expand compliance expertise within the Center

Opportunity to create one medical device compliance program

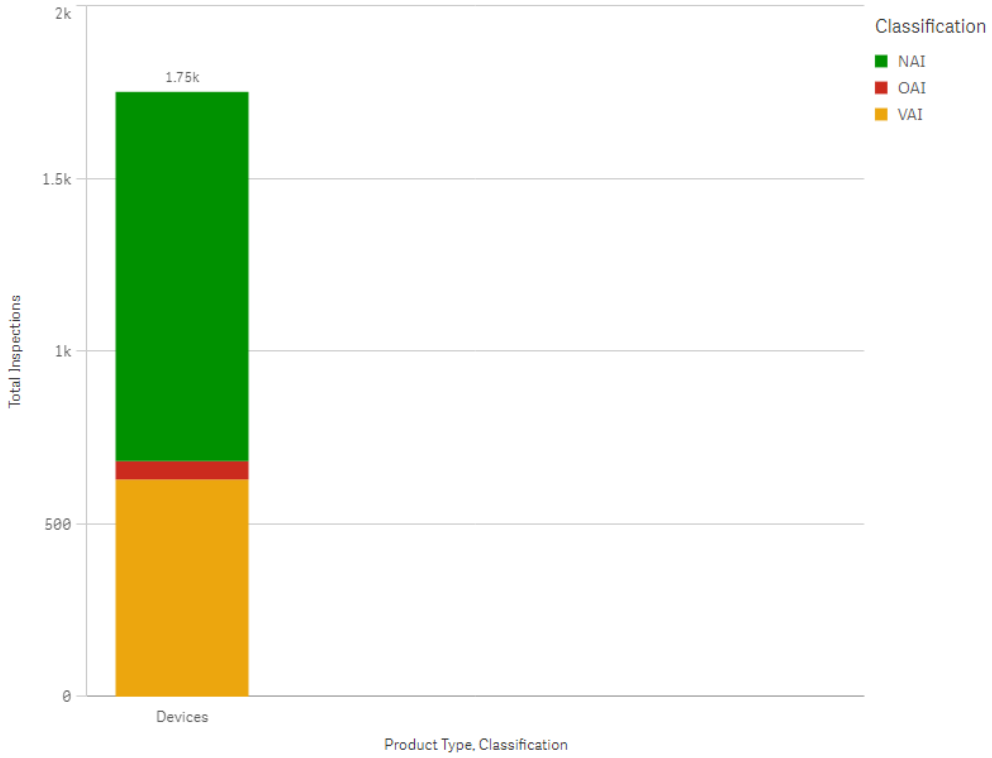
Leverage expertise to support and improve other programs

Improve communication and faster decision making

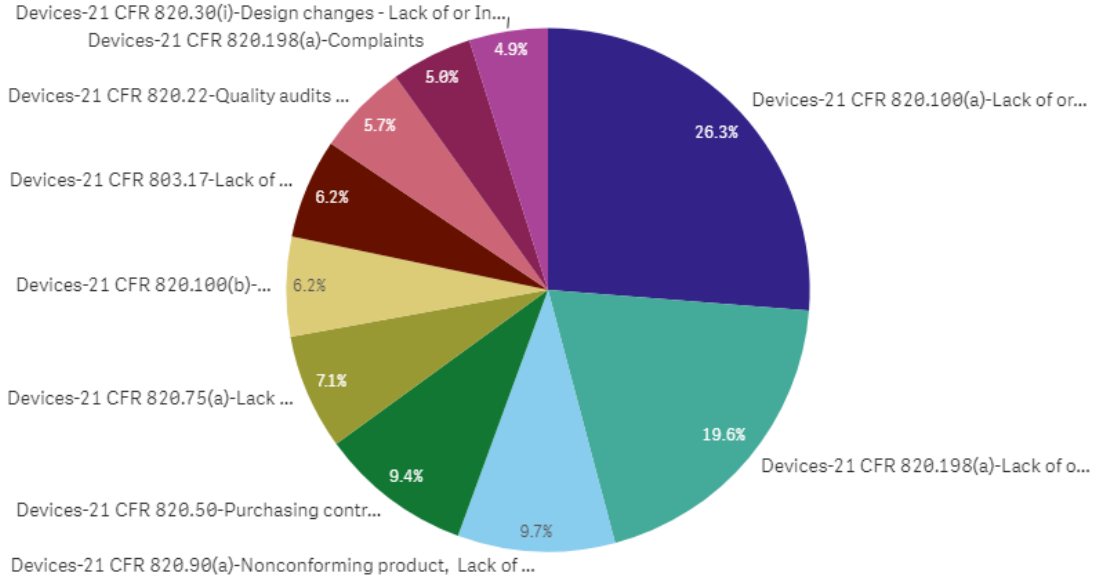
Inspection and Compliance Data

FY 2024 Inspection Data

Device Inspections



Top 10 Inspectional Citations



FY 2024 Compliance Data

53 OAI Inspections

- Top 4 Observations
  - CAPA (820.100): remains the most cited inspectional observation
  - Complaint Handling (820.198): second highest observation
  - Process Validation (820.75)
  - Medical Device Reporting (803.17)

41 Device Warning Letters issued

- ~70% included unapproved device charges
  - 501(f)(1)(b)/ 502(o)-- lack of 510k/ PMA
  - new intended uses/ off label claims
  - 26 domestic; 15 foreign

Recalls

- **1017** device recall events
  - 3285 recalled products

FY 2024 Recall Data

1017 Device Recalls

- Recall Classifications
  - Class I: 113
  - Class II: 889
  - Class III: 15

Recall Root Causes

- Top 5 Recall Root Causes
  - Device Design
  - Process Controls
  - Software design
  - Nonconforming material/component
  - Lack of marketing application

Orthopedic Recalls

- 80 Recalls
  - Class I: 2
  - Class II: 78

Compliance and Quality Priorities

Compliance and Enforcement

- Risk-based enforcement
- Repeat OAI firms
- Counterfeit devices
- Data Integrity/ Fraud
- Unique Device Identifier
- Post Approval Studies

Compliance and Quality Integration

- Balancing use of traditional compliance and enforcement tools with innovative tools/initiatives
- Advancing Quality
  - Case for Quality (CfQ)
  - Voluntary Improvement Program(VIP)
  - Advanced Manufacturing

VMSR

VMSR – Voluntary Malfunction Summary Reporting

- FDA receives >3 mill MDRs every year
  - Majority of MDRs submitted to FDA are malfunctions
- Bundling "like events" into a single summary has benefits for manufacturers, the public, and FDA
  - For manufacturers: can significantly reduce the volume of reports to submit to FDA
  - For the public: may make malfunction event trends for a particular device more readily transparent
  - For FDA: streamlined review that facilitates more efficient understanding of malfunction issues

5,386 eligible procodes (78%)

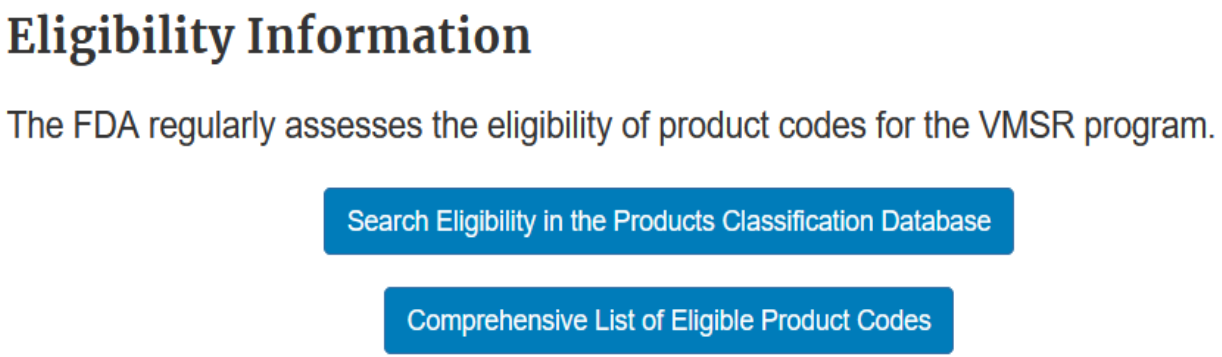
1,515 ineligible

6,901 total product codes

VMSR – Voluntary Malfunction Summary Reporting

- VMSR Final guidance published August 2024
  - Explains product eligibility and conditions where individual reporting is necessary
  - Clarifies how to submit summary reports

- VMSR Eligibility Status published on FDA's VMSR Program webpage



QMSR

Quality Management System Regulation (QMSR)

FDA published the final amendment to 21 CFR Part 820: **Quality Management System Regulation (QMSR)** on February 2, 2024; harmonizing the current Quality System regulation for medical devices by converging its requirements with international quality management system requirements

Revisions to Part 820 replace most of the existing regulation with an incorporation by reference (IBR) to the 2016 edition of International Organization for Standardization (ISO) 13485 - *Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*

There is a 2-year transition period from the Quality System Regulation to the Quality Management System Regulation. QMSR effective date is: February 2, 2026.

Overview of the Quality Management System Regulation

- Withdraws most of the requirements in the previous part 820
  - Retains the scope and some definitions from the Quality System Regulation
- Incorporates by reference ISO 13485:2016
  - Minimal called out provisions to ensure consistency with other applicable FDA requirements
    - Includes definitions and requirements
- Incorporates by reference Clause 3 if ISO 9000:2015, Quality management systems--Fundamentals and vocabulary*
  - Terms and definitions necessary for the application of ISO 13485
- Includes conforming edits to Part 4 (cGMPs for combination products)
  - Does not impact the CGMP requirements for combination products

Structure of the QMSR

820.1 Scope.

820.3 Definitions.

820.7 Incorporation by reference.

820.10 Requirements for a quality management system.

- Links additional FDA requirements such as MDR, UDI, Corrections & Removals, and Tracking; applicability of Design and Development activities

820.35 Control of records.

- Supplements record keeping activities, complaint/servicing records, UDI, and confidentiality

820.45 Device labeling and packaging controls.

QMSR Regulatory Text Outline

PART 820—QUALITY MANAGEMENT SYSTEM REGULATION

Subpart A—General Provisions

Sec.
820.1 Scope.
820.3 Definitions.
820.5 [Reserved]
820.7 Incorporation by reference.
820.10 Requirements for a quality management system.

Subpart B—Supplemental Provisions

820.20–820.30 [Reserved]
820.35 Control of records.
820.40 [Reserved]
820.45 Device labeling and packaging controls.

Subparts C–O [Reserved]

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* Current good manufacturing practice (CGMP) requirements are set forth in this quality management system regulation (QMSR). The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to assure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act and that the use of other terminology, such as "safety and performance," in this part does not change this statutory standard or the requirements of this part. Any manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, or servicing of a finished device must establish and maintain a quality management system that is appropriate for its specific device(s). Manufacturers subject to this part include, but are not limited to, manufacturers that perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, as well as initial distributors of foreign entities that perform these functions. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

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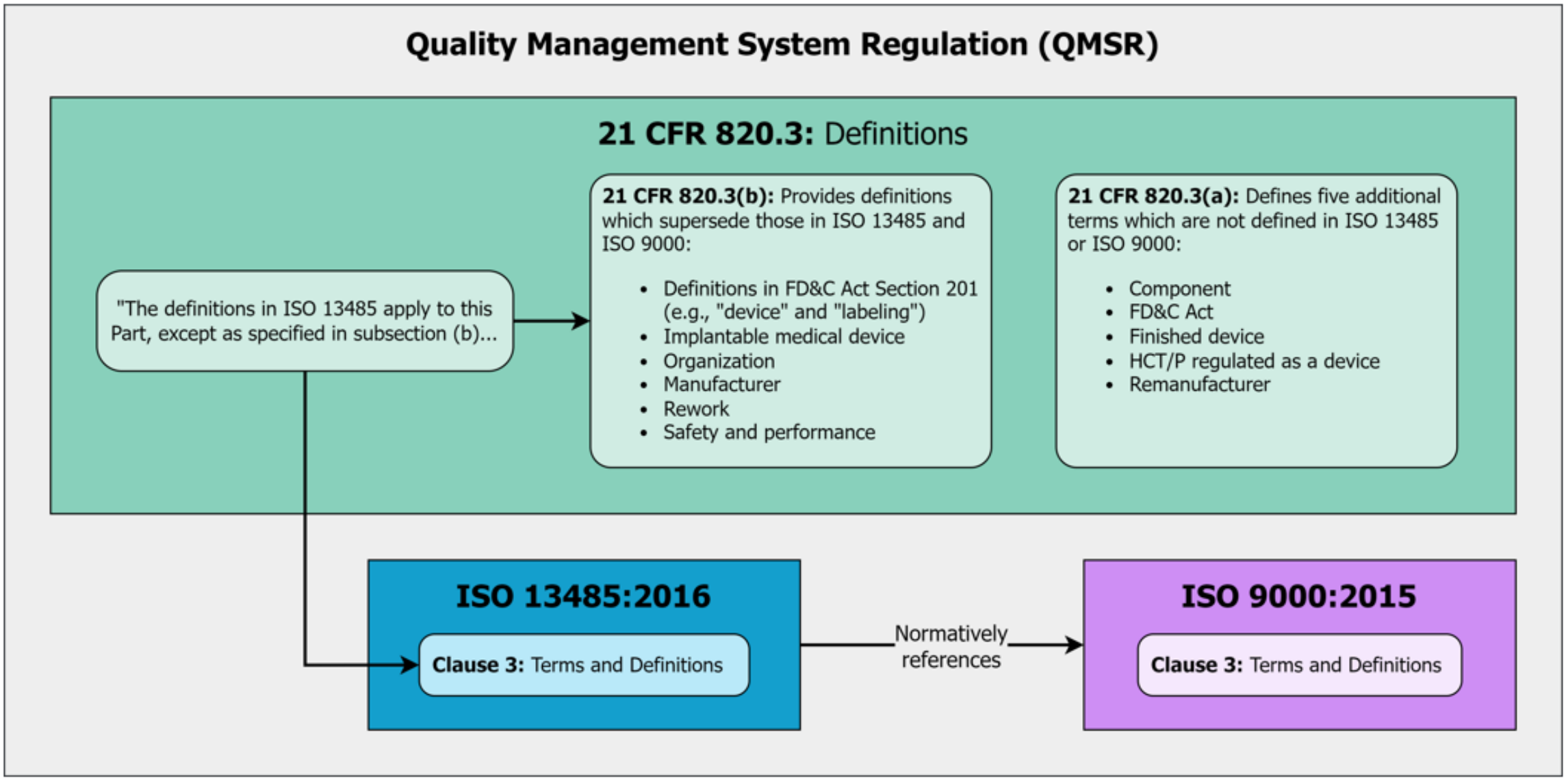
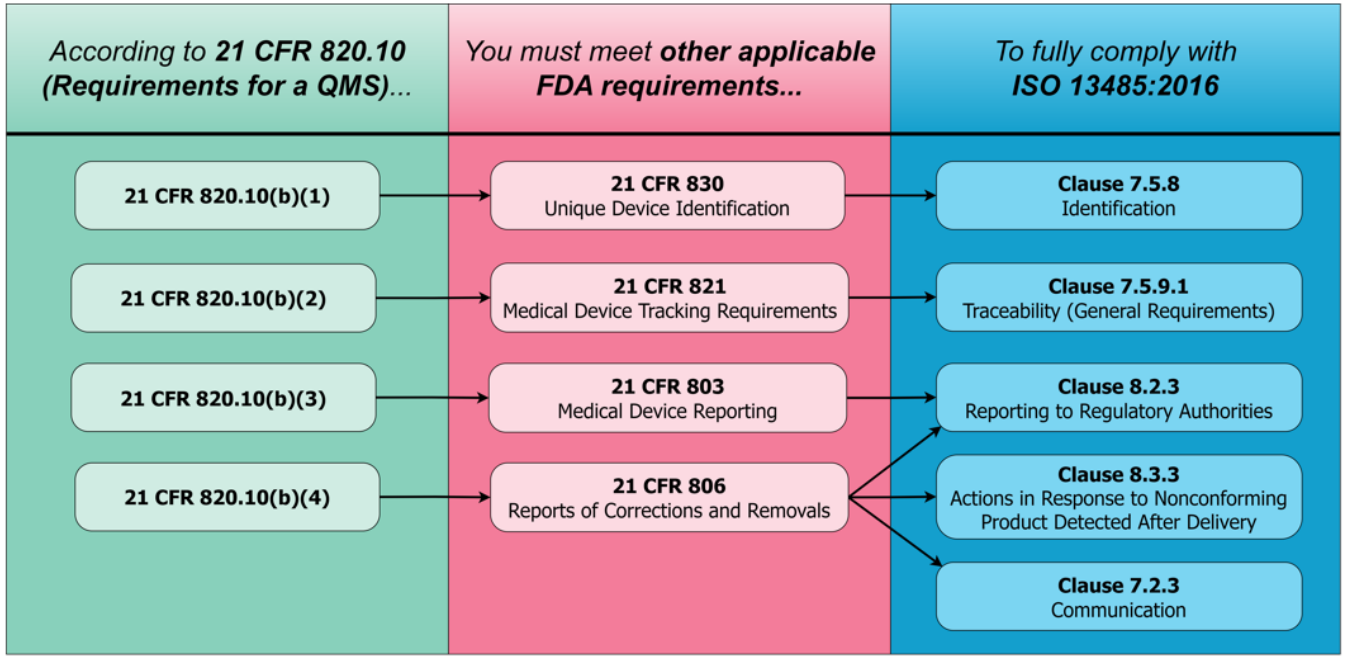
QMSR Key Terms and Definitions



Linkages/Applicable Regulatory Requirements

(§820.10)

Other Applicable FDA Requirements

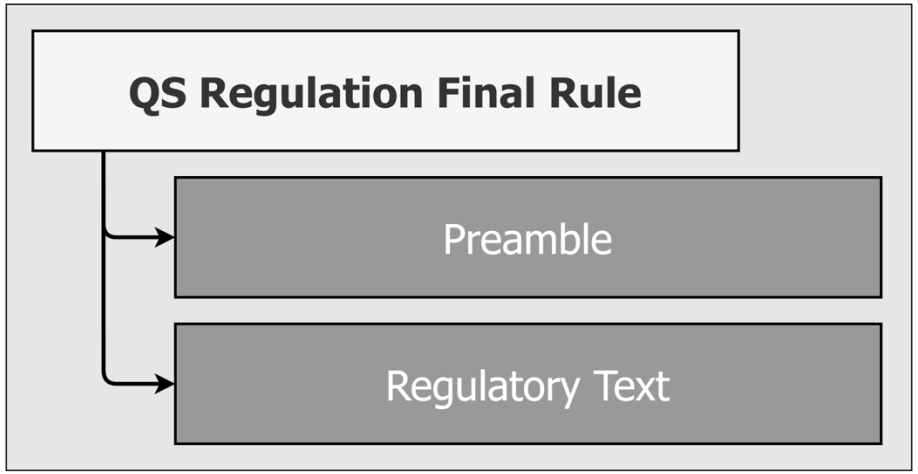


Traceability

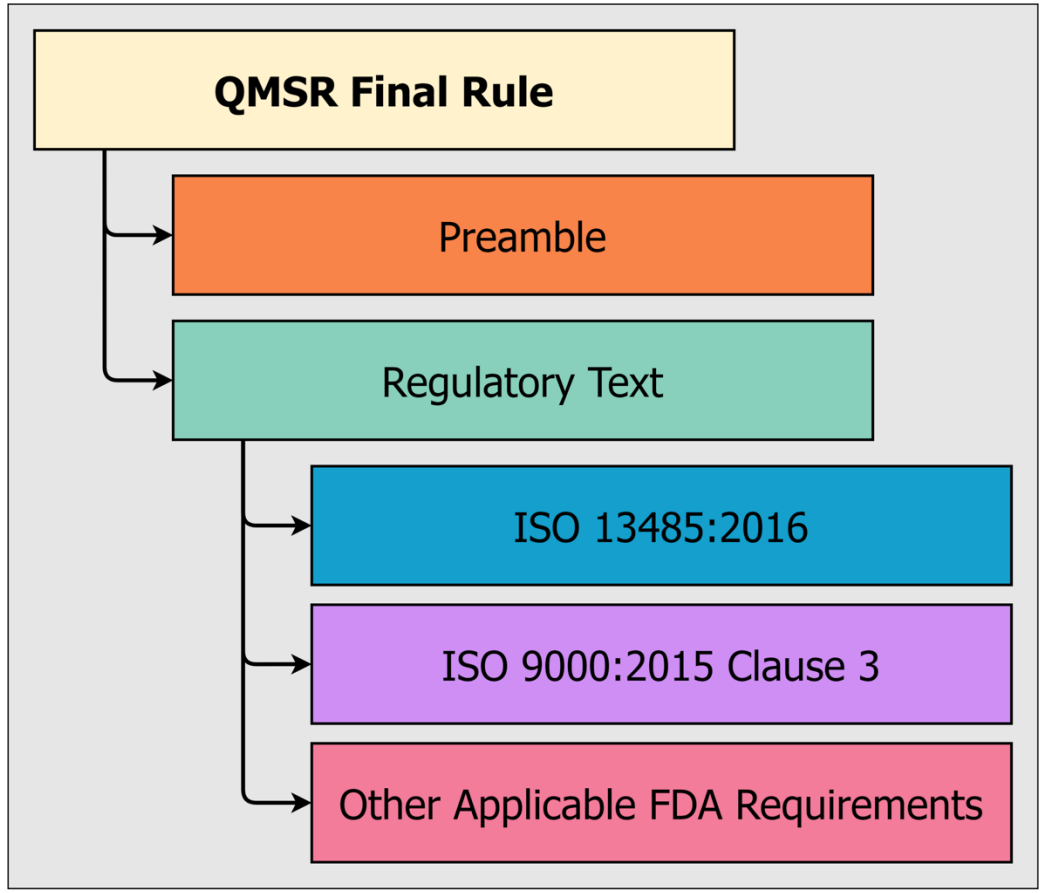
- Add a requirement to ensure that devices that support or sustain life, comply with the traceability requirements, in addition to just implantable devices as outlined in Clause 7.5.9.2

The New QMSR Regulatory Landscape

Before



After



Ways to adapt to regulatory changes

- Identify and understand the regulatory changes.
- Conduct Gap Analysis
- Identify Differences
- Revise processes and procedures to incorporate changes

Ways to adapt to regulatory changes

- Train employees on revised processes and procedures
- Implement new processes and procedures
- Monitor implementation of revised processes and procedures

Ways to adapt to regulatory changes Summary

Familiarize	• Familiarize yourself with FDA regulations and applicable standards
Conduct	• Conduct Requirements Assessment/ Gap Analysis
Implement	• Implement robust documentation
Foster	• Foster a Culture of Compliance

FDA Implementation Activities

- Updating technology systems
- Training of personnel
- Revise [and/or develop] relevant regulations, policies, procedures, inspection process and other documents impacted by this rulemaking
  - ✓Compliance Program
  - ✓Guidance Documents
  - ✓Standard Operating Procedures, Work Instructions, Templates, etc
- Communication

References

- QMSR Final Rule: Federal Register Notice

https://www.federalregister.gov/public-inspection/2024-01709/medical-devices-quality-system-regulation-amendments

- Quality Management System Regulation: Frequently Asked Questions (FAQs)

https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp/quality-management-system-regulation-final-rule-amending-quality-system-regulation-frequently-asked

Thank you!

Questions?