

QUALITY MATTERS

Implementation Of A Quality Management System For The
Regulatory Processes Of A National Regulatory Authority

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Discussion Overview



- **What is quality for a National Regulatory Authority like CDRH?**
- **The CDRH Quality Management System (QMS)**
- **Reflections**

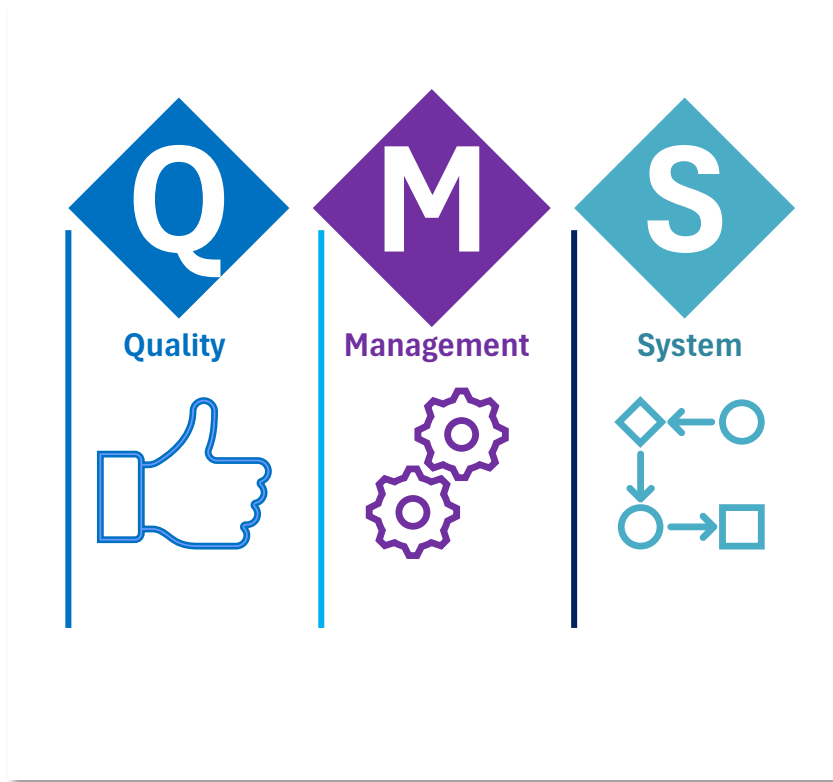
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What is quality for a National Regulatory Authority like CDRH?

Quality Management and QMS*



Quality Management* is about how we oversee our products, services, and programs to ensure they consistently meet customer expectations and maintain high-quality standards.



A Quality Management System (QMS) is a formal system and structure of processes, roles, responsibilities and procedures required to **achieve effective quality management**.



A QMS **helps coordinate and direct** an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.



While some use the term "QMS" to describe the ISO 9001 standard or the group of documents detailing the QMS, **the term QMS actually refers to the entirety of the system**.

[*What is a Quality Management System \(QMS\)? | ASQ](#)

What is quality for a National Regulatory Authority like CDRH?

Embracing ISO 9001 Core Values and Concepts*



- **ISO:9001** is a standard used by organizations to demonstrate their ability to **consistently** provide products and services that **meet** customer and regulatory requirements and to demonstrate continuous improvement.
- As an international consensus on **good management** practices, ISO 9001 is the world's most popular and commonly used standard. It can be adopted by any organization
- ISO 9001 is based on **seven quality management principles**
- The requirements delineated in ISO:9001 **focus on meeting** customer and other interested parties' **requirements**.
- ISO:9001 is a **certification** that certain formal processes are being used within a company for their management of Quality Control

*[Quality management principles \(iso.org\)](https://www.iso.org/qualitymanagementprinciples)

What is quality for a National Regulatory Authority like CDRH?

Embracing ISO 9001 Core Values and Concepts



Benefits of an ISO 9001:2015 QMS

1

Leadership Commitment



Support and resources to ensure CDRH's success

2

Satisfied Customers



Products and services that meet customers' requirements

3

Excellent Customer Service



Customers are treated with dignity and respect

4

Better Products & Services



High-quality products and services and reduced risk of errors

5

Productivity & Efficiency



Improved work products and effectiveness of process through fact-based decision making

6

Satisfied Employees



Transparency, efficiency, and simplicity improve work experience and promote work life balance

What is quality for a National Regulatory Authority like CDRH?

Embracing ISO 9001 Core Values and Concepts



Quality at CDRH supports ensuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices and radiation emitting products

Key Tenets of CDRH Quality



- **Transparency, standardization, predictability, and simplicity** are themes CDRH uses to serve their customers and stakeholders
- **Customer focus** allows CDRH to understand customer needs and seek opportunities for improving CDRH products and services that foster **continuous improvement** efforts.

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The CDRH Quality Management System (QMS)



PROTECT AND PROMOTE THE PUBLIC HEALTH: CDRH's ISO 9001:2015 certified Quality Management System (QMS) supports the Center's Mission and Vision

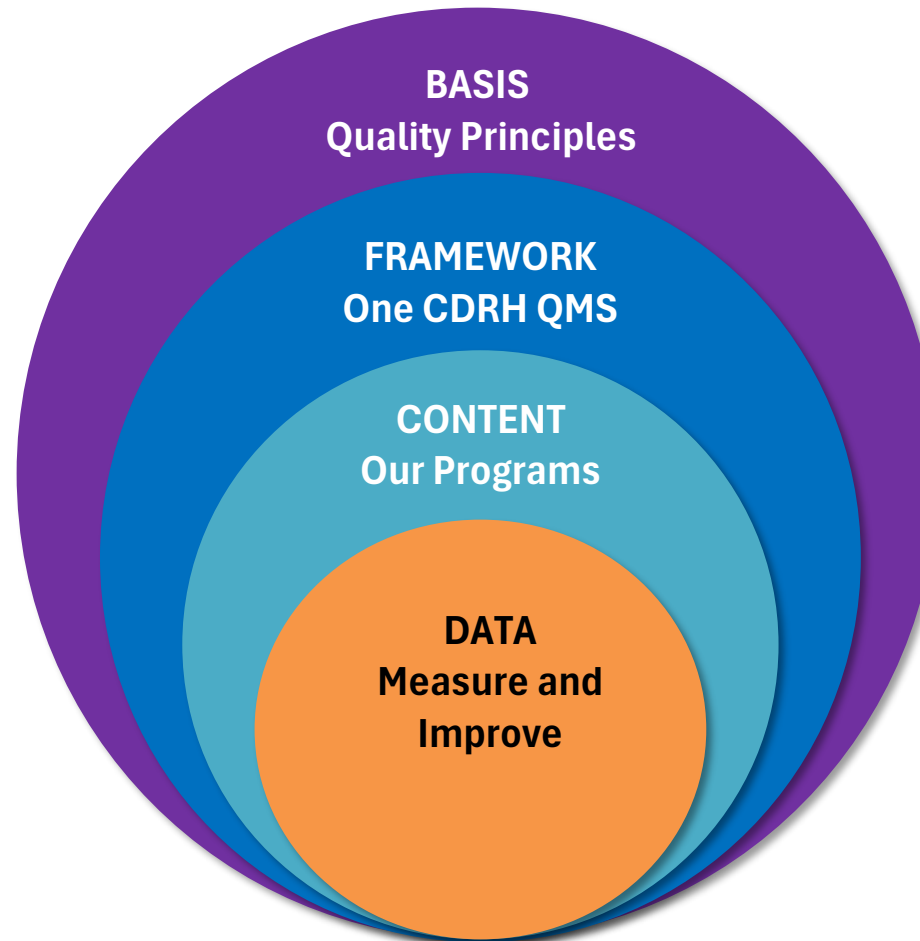
1 CDRH is committed to delivering high-quality products and services

2 CDRH's commitment to quality starts with its Quality Policy –

The Center for Devices and Radiological Health's (CDRH) mission is to protect and promote the public health by providing high-quality products and services that meet applicable requirements and the needs of customers. CDRH is committed to the continual improvement of its quality management system.

The CDRH Quality Management System (QMS)

High-level Overview



BASIS: Our Quality Principles

- CDRH Mission and Vision
- CDRH Requirements
- ISO:9001 Standards
- CDRH Quality Policy
- Process Improvement (PI)

FRAMEWORK: One CDRH QMS

One Center-level QMS and action, activities that are traceable and based on data and incorporate customer input.

CONTENT: Our Programs

Expectations

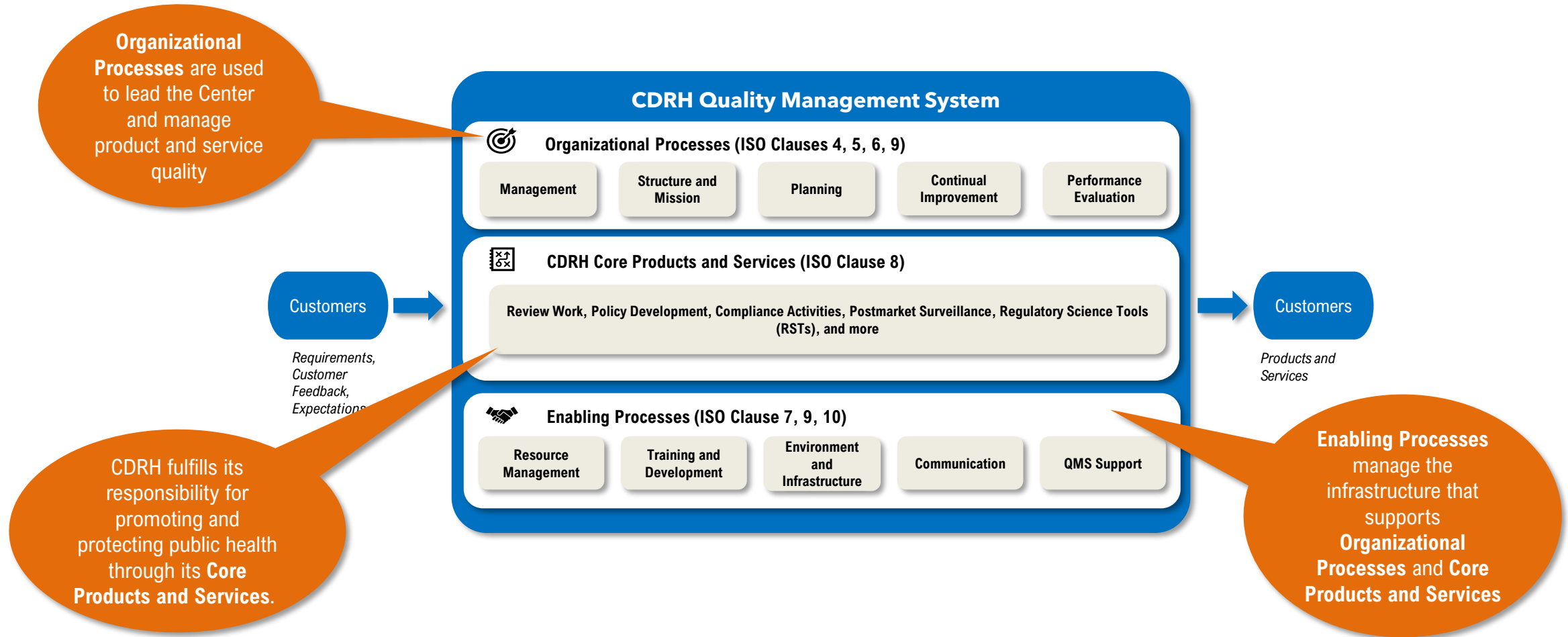
- Appropriately documented
- Can demonstrate meeting requirements
- Can identify risks and opportunities

DATA: Measure and Improve

- Quantifiable metrics to track performance
- Justifiable Improvement that data, ideas, customer input

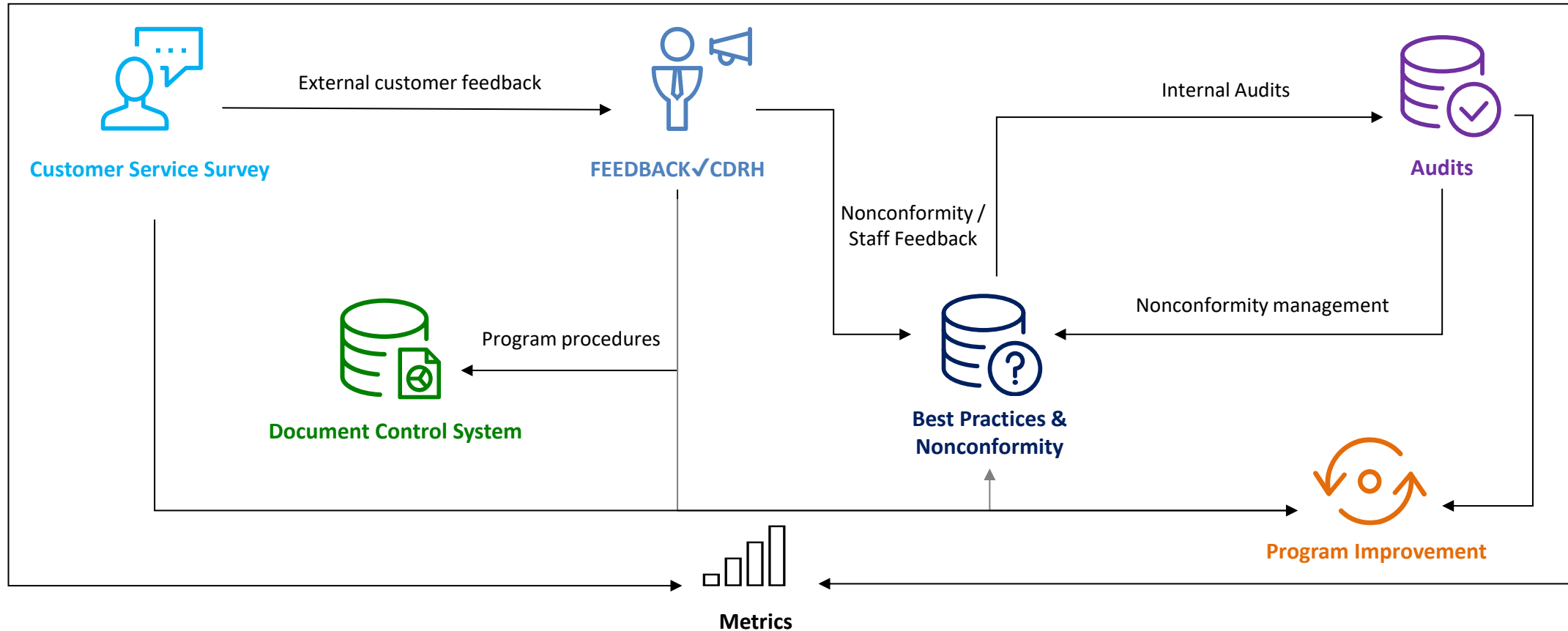
The CDRH Quality Management System (QMS)

How CDRH Manages Quality



The CDRH Quality Management System (QMS)

Managing Quality with the CDRH QMS Infrastructure



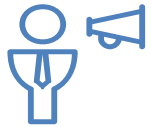
- The CDRH QMS infrastructure supports the Center QMS and **ISO:9001 compliance**.
- QMS processes bring a level of **rigor and standardization** to programs across the Center

The CDRH Quality Management System (QMS)

Managing Quality with the CDRH QMS Infrastructure - Voice of the Customer



Feedback mechanisms help assess effectiveness, customer satisfaction, and drive improvements



FEEDBACK✓CDRH is a One Stop Shop for staff to submit ideas, suggestions and issues.



The **CDRH Customer Service Survey** is available to external and internal customers. All CDRH staff must have a link to the **CDRH Customer Service Survey** in their signature block

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?ID=2010&S=E>

Managing Quality with the CDRH QMS Infrastructure

Managing Quality with the CDRH QMS Infrastructure - Documented Information



Programs use the **CDRH Document Control System (DCS)** to document their structure, processes, roles, responsibilities and procedures



The **CDRH DCS** stores and makes available QMS documentation to CDRH

The **CDRH DCS** supports consistency and standardization and houses all CDRH's mission critical procedures in one central repository

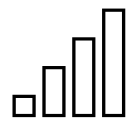
In addition, programs use established **record management** guidelines to manage important information that must be kept organized and controlled

Managing Quality with the CDRH QMS Infrastructure

Managing Quality with the CDRH QMS Infrastructure - Continual Improvement



Programs use feedback from customers, **Metrics**, and the **Audit** system to assess if processes are working as intended. Results are discussed at meetings, including **Quality Management Reviews**



Input from staff and customers as well as results from monitoring **Metrics** and internal **Audits** help identify **Best Practices** to share and **Nonconformities** to address



Review of data drive **Program Improvements**

Managing Quality with the CDRH QMS Infrastructure

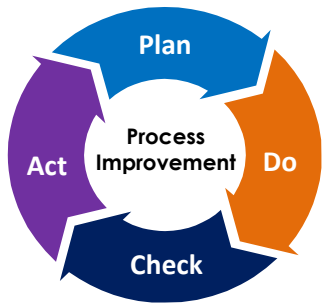
Supporting a Workday in a Truly Seamless and Integrated way



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Reflections

The CDRH QMS follows a “Plan, Do, Check, Act” methodology



Thank You!

Excellence, then, is not an act but a habit. | Questions?

Will Durant