WORLD CONFERENCE ON QUALITY & IMPROVEMENT

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ART and SCIENCE OF QUALITY

QMS for Data Driven Decision Making and Growth

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10:00 AM – 11:15 AM

Learning Objectives

- Understand what a Quality Management System (QMS) is from:
  - A macro and micro perspective
  - Current records and adding new data streams
- Determine which elements to address in designing and deploying a QMS
- Understand how to create a QMS on the foundation of current databases and streams of data
- Identify how a QMS helps the organization reach its goals

Agenda

- Introduction and Overview of QMS
- The 9 Essential Activities for Building a Robust QMS
- Tips for Getting the QMS Information Embedded

The Impact of QMS – An Overview

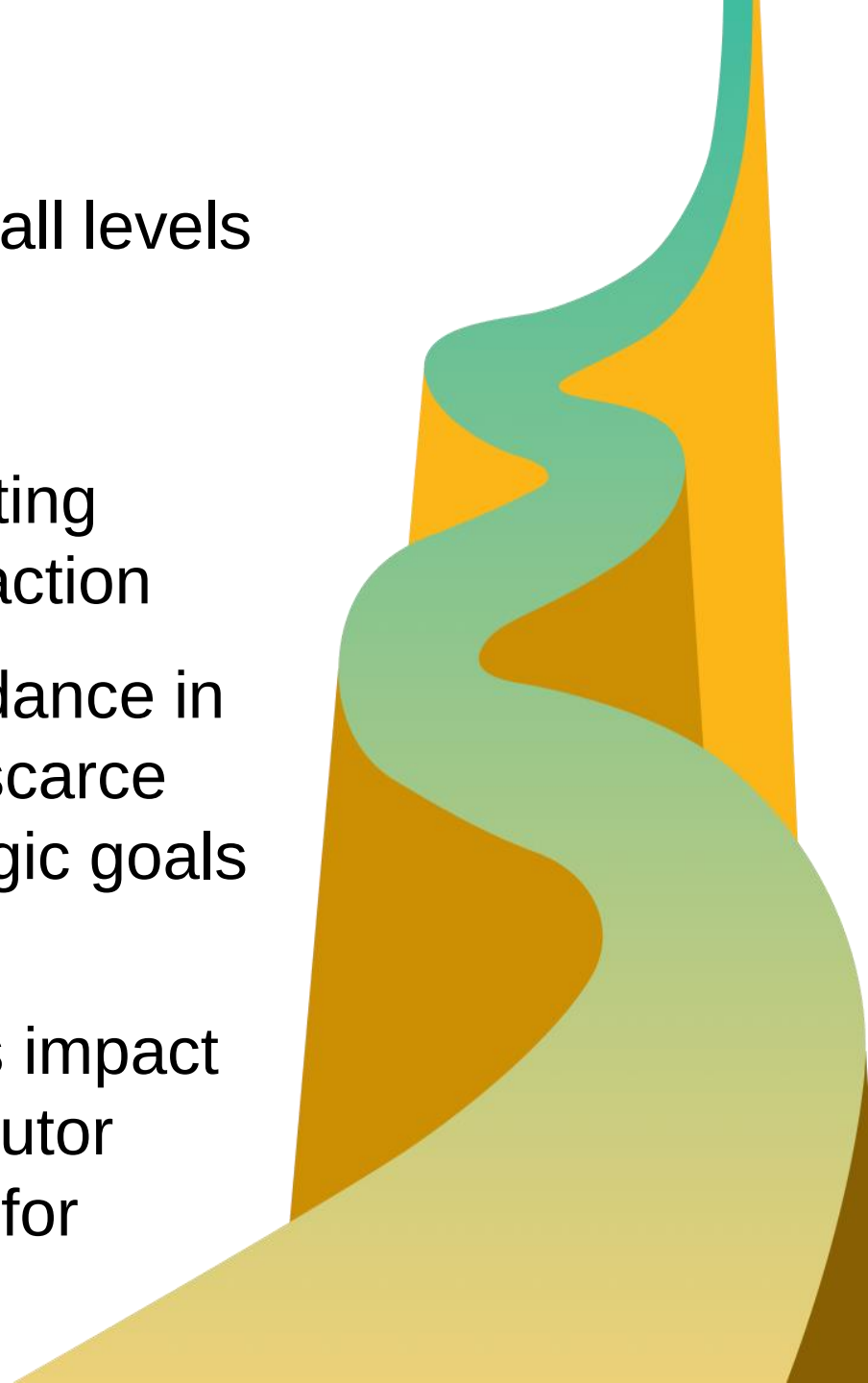
Voice of the Customer is vital to a business' success, requiring large-scale, visible documentation of **how an enterprise deploys strategy, data, and communications by conveying information about quality** throughout the organization.

A quality management system, or QMS, contributes to customer satisfaction and retention with its data.

A QMS can **drive improvements** in supply chain efficiency, quality service and regulatory compliance, and assists in **controlling costs and uncovering opportunities** for innovation, growth, and enterprise gain.

Introduction

- A Quality Management System is useful to all levels of the organization
  - High Level: QMS enables effective risk management, reducing ‘surprises’ impacting finances, reputation and customer satisfaction
  - Middle Management Level: provides guidance in the decision-making needed to allocate scarce resources for maximum impact on strategic goals
  - Front-line Positions: enables a clear understanding of how individual activities impact the whole, supports learning from contributor processes, identification of opportunities for improvement



Introduction (cont.)

- Organizations often have large amounts of data, some of it: a) superfluous; some b) a bit useful; some c) critical to success
- QMS can provide information that drives better, more informed business and technical decisions…
- …in a timelier manner, as well as moving from a long-lagging to close-lagging, or from close-lagging to leading metrics
- The world of “Big Data” and cost-effective tools for handling data of all types allows substituting relatively inexpensive data for valuable, even expensive assets. That’s a good trade-off, however…
- …to deliver on this potential, the organization needs a structured approach

Common Structural Elements

- The typical QMS structure may include some, or all, of the following elements:
  - Document Control
  - Customer Complaints Management
  - Non-Conformance Management (NCR)
  - Failure Mode and Effects Analysis (FMEA) all 3 parts*
  - Deviations
  - Root Cause Analysis (RCA)
  - CAPA – Corrective Action Requests (CAR)
  - CAPA – Preventive Action Requests (PAR)
  - Warranty Claims
  - Validation & Verification
  - Supplier Quality Management
  - Audits Management
  - Training & Certification Management
  - Change Management
  - Risk Management
  - Feedback/Feedforward Management
  - Inspection Management
  - Calibration & Maintenance
  - Dashboards

*Design FMEA, Process FMEA and Monitoring & System Response FMEA

Understand, Design, Deploy, & Update QMS

Phase **01** **Understand** the **Situation**

Current Decision-Making Needs
Current Data Assets
Current Data Characterization

The better the understanding of the organization's:

1. near term and likely future needs
2. current data assets and their configuration

The less painful and fewer resources consumed in the initial deployment and data transitions

Phase **02** **Design** & **Deploy**

Define & Deploy QMS Framework – Now & Future

Based on the immediate needs of the organization, create a map of the capabilities desired and the current elements as well as additional elements needed to reach those capabilities. Determine future needs and capacity to plan for scalability. Create a plan for staged deployment and planned cycles of learning

Phase **03** **Modify** & **Update**

Add Capability as Organization's Needs Mature

As the organization matures in its use of data for decision-making and the mindset shifts from long-lagging data to close-lagging, from close-lagging to leading, revise and update the data sources and the data analysis tools used. Help decision-makers leverage this new mindset and gain advantage from newly available approaches

Quality Management System

QMS Overall

- Integrated Process & Quality Planning
- Document Control
- Records Archival & Retrieval

Organizational Management Respo nsibility

- Quality Strategy & High-Level Policies
- Integrated Business & Quality Planning
- Management Monitoring & Reviews

Resources Management

- Training & Skills Re/Certification
- Equipment Management
- Facilities Management

Customer Requirements & Expectations

Customer Satisfaction & Feedback

Metrics, Analysis & Closed Loop Feedback

- Monitoring of Inputs, Process & Output s
- Customer Complaints & Non-Conformances
- Internal Audits of all Operations Including Support
- Supplier Audits
- Quality & Continuous Improvement Teams

The Offering – Integrated Product & Service

- Traceability – as Designed, Built, Shipped
- Advanced Offering Quality Planning
- Engineering Change Orders/Notifications – Process & Product/Service
- Validation of Processes
- Control Plans for All Processes Driven by FMEA, Using SPC & RCA/CAPA
- Mid-Level Policies, Procedures & Work Instructions

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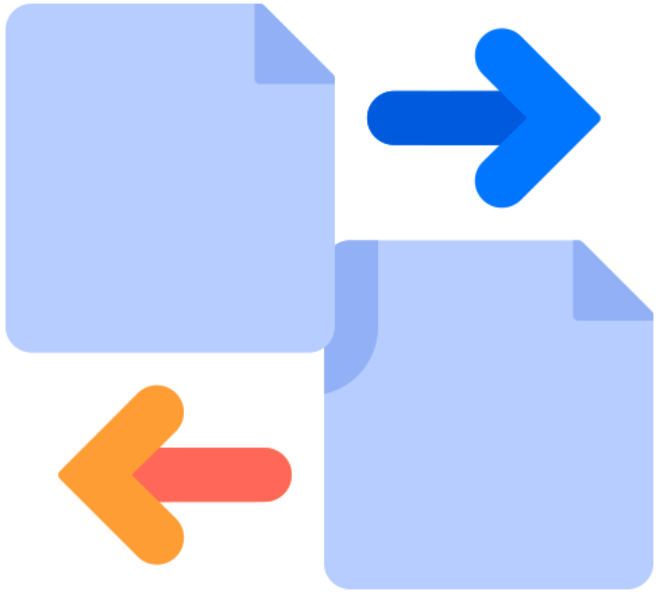
1. Review Current Potential QMS Assets

- Most difficult initial QMS efforts deal with existing data residing in many locations and in many configurations
- Inventory the organization's current data assets. Of those, which:
  - Should be in the initial QMS versus later
  - Support the strategy
  - Leverage C. I. activities…address internal/external customer concerns
  - Support monitoring and audit activities

2. Gaps in Information Needed and Plans to Close Them

- Existing data assets may not adequately address current needs
- First understand what current needs are. Inventory existing data and the ability to address needs and gaps
- If time allows, update the data asset and then migrate to the QMS

3. Bring Elements to Common Level to Allow Integration



- Data from multiple sources and configurations can be challenging
- For existing data:
  - Fully characterize to use as is, or
  - Modify to transition it
- For multiple sites/similar data sets:
  - Standardize/convert for access or migration

4. Survey the Organization on Uses & Needs

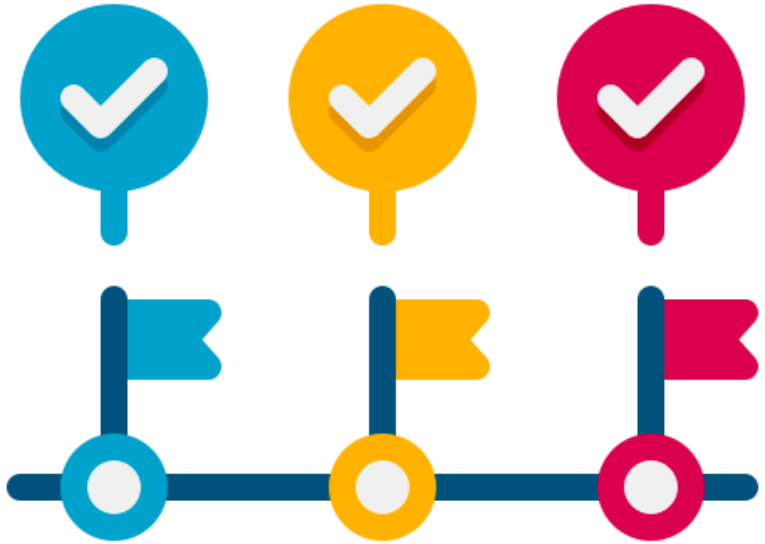
- Survey the key users: ie. Providers, Patients, Finance
- Determine needs and future activities expected
- Determine the data needed, both current and future
- Compare the types of data available and determine ability to meet needs

5. Which Elements Offer the Greatest Return?

- What **consumes the greatest time** of internal customers?
- What information is **most valuable** to (re-)design efforts?
- What performance areas are of **greatest concern** to customers?
- What **blocks of information/data resources** will be needed to create the foundation of the QMS?

6. Take a Phased Approach

- Use a phased approach with expected results well-defined
- Start with current data assets:
  - Inventory, including structure
  - Evaluate quality of data
  - Augment where there are gaps



- Understand the dependencies between elements, proceed on an “on-condition” basis rather than an ”on-schedule” basis

7. Plan for Future Activities

- How will QMS serve the future needs of the organization?
- Can initial QMS design provide for the future activities?
- Where will data reside?
  - Current base or
  - Migrated to a newly created one

8. Create Administrative Structure

- How will the QMS be monitored and audited?
- How will maintenance, updates, and performance be assured to all users?
- How will connectivity, reliability, and security issues be addressed?

9. How to Leverage New Elements as Added

- How will additional elements:
  - Augment existing QMS
  - Increase the information available
  - Increase ease of accessing it
- Will a new element reduce the functionality of the QMS for other users? Pilot any new addition
- Understand the capacity of databases and how their performance can degrade as they grow

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Focusing the QMS Activities

- QMS is an effective tool for understanding how processes and systems perform, meet internal and external customer needs
- Maximize its value/design for:
  - Multiple customers
  - Current and future state
- A major aid to monitoring activities, driving data-driven decision-making, and better results across
  - the organization,
  - the supply chain,
  - the end-user of the product/service offering

Getting the QMS Information Out There

QMS design:

- Queried by all organization levels
- Drive dash boards
- Ad hoc and scheduled reports: senior & middle managers
- Regulatory entities and auditors
- Provide insights to focus C. I. resources; capture the most gains/improvement

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