

## **Implementing a Quality Management System (QMS) Into a Comprehensive Cancer Center**

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### **1. Background**

Mayo Clinic Comprehensive Cancer Center (MCCCC) serves investigators and research participants across the academic medical centers in Arizona, Florida, Minnesota, and Health System (Minnesota, Wisconsin, and Iowa). This organizational complexity and wide geographic distribution of staff contributed to a lack of standardization of training programs and core business processes. While numerous resources were developed, processes and procedures were seldom used by staff, causing the resources to be ineffective and the workflow inconsistent. A robust Quality Management System (QMS) was needed to achieve a manageable and sustainable infrastructure for training, process, and procedural materials.

### **2. Goals**

The 2020 goal was to establish governance and oversight for the QMS. This led to the development of the Quality Management Coordinator (QMC) role, which is responsible for the development, management, and continuous improvement of the MCCCC QMS. To achieve this, MCCCC QMS principles and quality system essentials (QSE), based off ISO 9001:2015, were implemented.

By the end of 2023, QMS oversight was moving into the maintenance portion of QSE; thus the original 2020 goal was revised to how to maintain oversight while retaining stakeholder interest and feedback.

### **3. Solutions and Methods**

Implementation of the 2020 QMS required an in-depth assessment of MCCCC existing documentation (i.e., archive, update, gap) to identify scope of needs for each business unit (i.e., study coordinators, regulatory unit, etc). During this review, it became increasingly evident that for QMS to become established, implemented, and maintained, it was vital that business unit leadership supported QMS.

- Created Subject Matter Expert (SME) working groups
- Enterprise accountability
- Knowledge checks as new, revised, or even the archival of SOPs

By 2023, QMCs needed to identify ways to manage operational performance to measure inputs and outputs by MCCCC core business processes, i.e., key performance and quality metrics. The current state of available metrics was cataloged as a way for QMCs to maintain and sustain the QMS. This included collaborative discussions with SMEs and leadership to capture:

- All current metrics were addressed in standard operation procedures (SOPs) for easy determination of trends and gaps
- New metrics and/or tools were established and implemented within the SOPs
- Feedback monitoring and continuous improvement tools were presented to teams to track unit requests, gaps, and any other additional feedback
  - “Suggestion box” REDCap tool was implemented in January 2024
- Track suggestions
- Dashboard transparency
  - “QMS” office hours implemented in January 2024

- Obtain feedback
  - “SME workgroups” implemented in quarter 3 of 2023 and ongoing implementation rollout across units
    - Establish accountability with unit resource and feedback

#### **4. Outcomes**

Creating a culture of quality and competencies in quality management for our managers, supervisors, and staff is essential. Having an effective system and oversight structure is essential for maintaining a QMS.

#### **5. Lessons Learned and Future Directions:**

##### **Lessons Learned**

- Involve the end users
- Communication is everything
- Create a feedback loop
- Mature the system

##### **Future Directions**

Our future direction is to continue to mature the QMS and use a change management approach to revision of processes and procedures. We will continue to engage the staff to reinforce the quality management principles; enhance adoption and learning; and in addition, maintain the cycle of continuous improvement.