

Introducing a Quality Management System into the Mayo Clinic Cancer Center Clinical Research Office

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BACKGROUND

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The Mayo Clinic Cancer Center (MCCC) Clinical Research Office (CRO) serves the clinical investigators and research participants across the MCCC's academic medical centers in Arizona, Florida, and Minnesota, as well as throughout the Mayo Clinic Health System in Minnesota and Wisconsin. This organizational complexity and wide geographic distribution of staff contributed to a lack of standardization of training programs and core business processes. While numerous processes and procedures were developed, the utilization of these by CRO staff was inconsistent and ineffective.

A robust Quality Management System (QMS) was needed to achieve a manageable and sustainable infrastructure for the CRO training, process, and procedure materials. The QMS must be specific and optimized to the needs of the CRO to ensure that it is effective and provides value to the staff. The QMS would cover the following quality system elements (QSE): organization and leadership; customer focus; personnel and training; standard operating procedures; documents and records; monitoring and assessments; and event management.

Development and implementation of these QSEs would ensure effective training of CRO staff. The definition of core business processes, their inputs and outputs, and key performance and quality metrics, will enable better management of operational performance. Once implemented, the cycle of monitoring and continuous improvement will be engaged.

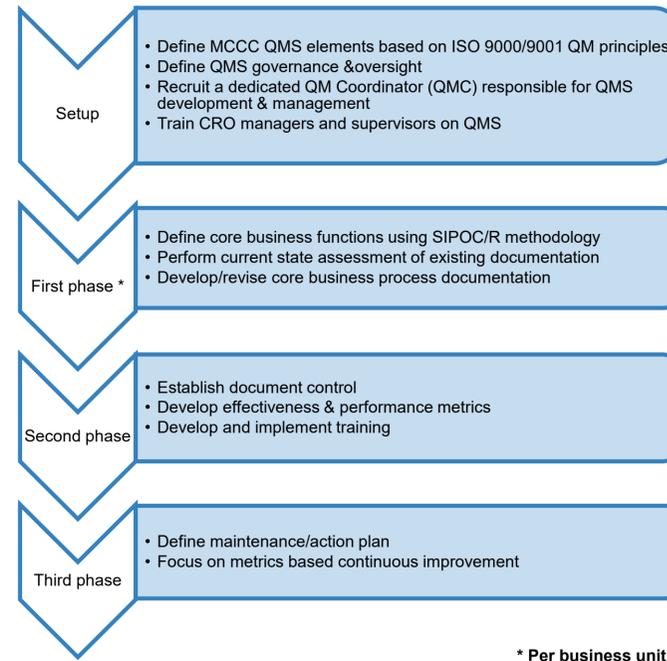
Recommendation was for the MCCC CRO to establish and maintain a stable and living QMS.

GOALS

GOALS TO ACHIEVE

- Create a culture of quality for the CRO.
- Create an optimized QMS to support:
- Performance and management of core business processes,
- Their supporting documentation,
- Support continuous improvement.

SOLUTIONS AND METHODS



OUTCOMES

IMPLEMENTING QMS

- Established awareness, vision, and importance of QMS within MCCC Leadership
- Hired a dedicated QMC
- Confirmed subject matter experts
- Began creation of core business processes
- Reestablished a desire and culture to engage in QMS
- Developed training

QUALITY MANAGEMENT ELEMENTS

- **Leadership Commitment & Culture:**
 - Creating visibility of successes, building coalitions, setting expectations, and navigating barriers are just some of the roles this key partner will need to play.
- **Management System Operations**
 - Leads development and ensures sustainability of the QMS.
- **Process Management**
 - Utilizing SIPOC to ensure all activities work together toward a common goal and achieve results valued by internal and external customers.
- **Documentation System**
 - The foundation supporting all other elements by defining standards, responsibilities and providing consistent resources.
- **Competence, Awareness & Training**
 - Development and implementation of a training and education program built off of the Documentation System, including necessary competencies for personnel performing their work.
- **Measurement & Analysis:**
 - Utilizing metrics to develop evidence-based decisions and assess goal-based tracking.
- **Event Management:**
 - Define process by identifying trends, root causes, and corrective and/or preventative actions, allowing organizations to capture and analyze information from events or activities that do not meet Sponsor or regulatory expectations.
- **Customer Service & Satisfaction:**
 - Identify customer needs and expectations and determine if successful.
- **Continuous Improvement**
 - Ensure continuous and evolving customer expectations are addressed.

FIGURE 1



Figure 1 represents the Quality System Elements (QSEs) used to determine and establish the Mayo Clinic Cancer Center Quality Management System (QMS)

LESSONS LEARNED

- Consider the historical context – Failed attempts to implement and sustain QMS in the past may require intentional efforts to build desire and buy-in for the effort among staff
- Set expectations around early success – If negative history exists, much of the early work will involve change management to cultivate engagement; gaining support and creating allies are key successes, in their own right, worth celebrating
- Gain credibility with early wins – Go where the action and need are; focus on pain points and areas of greatest risk to win support of key stakeholders

"Sustained success is now the goal of the standard. Success is the end to be achieved. Quality Management is the means for achieving this end."
- Unknown

FUTURE DIRECTION

- Continue to mature QMS and use a change management approach to evolve processes and procedures.
- Continue to engage staff in reinforcing the quality management principles and enhance adoption and learning.
- Create a dashboard of key performance indicators that aligns with the core business processes.

REFERENCES

- ISO, <https://www.iso.org/obp/ui/#iso:std:iso:9000:en>.