Medtronic

QMS Transformation Program Monthly Update November 2022

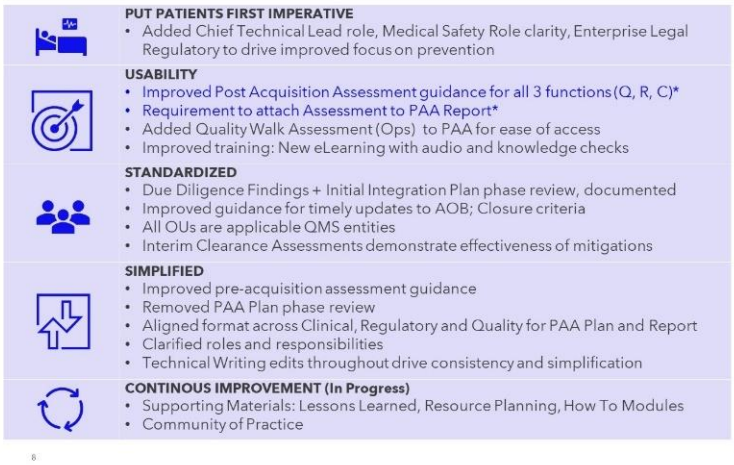
Q2 ACCOMPLISHMENTS AND REFLECTIONS

Q2 closed with some major accomplishments to celebrate:

- Three workstreams went live with their updated QMS documents (**Nonconforming Material, Manage Compliance, and Acquisitions and Integrations**).
- Keep reading for the detailed accomplishments of the Acquisitions and Integrations team!
- **Change Control and Handle and Report Complaints (Ph2)** had their QMS documents approved and released.
- Implementation status increased from **92% to 98%** helping us to continue to realize the benefits across the organization.
- Our newest workstream, **Control Environments**, kicked off.

CURRENT WORKSTREAM UPDATES

Acquisition Assessment and Integration Planning



The Acquisition and Integration workstream exceeded expectations when they delivered updated documents with a Go Live date of October 20th, 2022. The driver of this change was to address Patient Safety Quality Improvement Plan (PSQIP) actions that were part of an Enterprise-wide Corrective and Preventive Action (CAPA). The team was tasked with improving assessment rigor to reduce the number of quality issues from acquired products. They were challenged to produce high-quality results and accelerate to reduce the time it would take to release the updates. The team deployed several tactics from the recent A3 work on QMS document change duration that accelerated the schedule from an original February 2023 go live to October 2022 go live, reducing the duration

by over three months and allowing the CAPA aging to align with expectations. In addition to accelerating the timeline, the changes that were implemented will help future integrations by providing just-in-time training, simplifying steps and instructions, and improving guidance based on the voice of customer stakeholder input. This was a great example of collaboration between the PSQIP and QMS Transformation teams.

Enterprise Change Control (ECC)

What's New?

The initial MAP ECC process deployment has been delayed. The QMS Core Team and Steering Committee agreed on a wave implementation strategy, which will begin in Q4 (exact date TBD) with the MAP ECC process and system deployment, which will be followed by CAP and Legacy Agile (dates TBD). Escalations from local document assessments are being reviewed by the team as they come in, and individual follow-up discussions are being had as needed.

What's Next?

November 23rd Office Hours were canceled due to the holiday and will resume on December 7th. Train the Trainer and eLearning (Cornerstone) content have been updated and are available. Local implementation activities (Mass QCHs) will begin soon.

Handle and Report Complaints

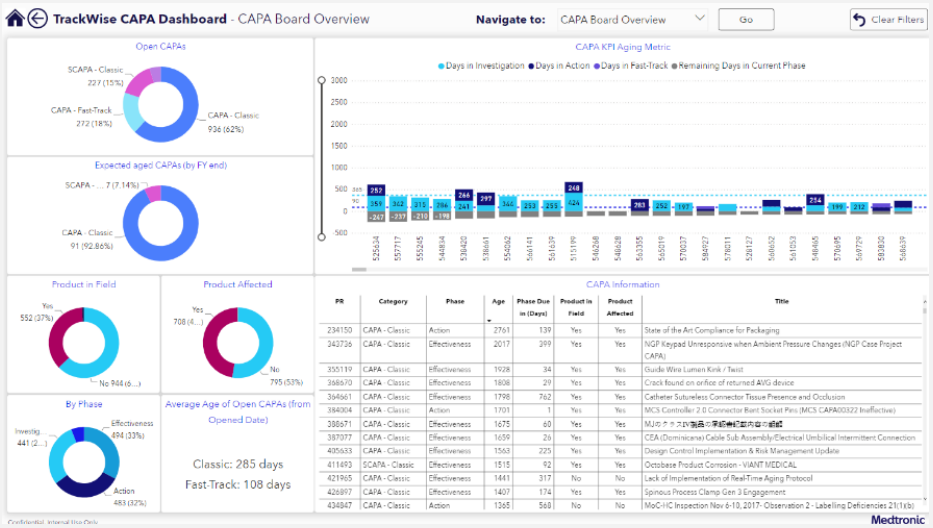
What's New?

Shared Enterprise documents have been updated and released and are currently being implemented locally. All QMS Entities that have been identified as in scope of the sub-process now have these QMS documents within their quality systems. There is an implementation timing delay in place for CRM and Neuromodulation. They now have an effective date of November 30th.

Manage CAPA

What's new?

The TrackWise CAPA Dashboard is live in addition to CSOD, which is the CAPA Certification Program for CAPA owners and a flash sale for Weaver Root Cause Investigation for CAPA training while a pilot for the CAPA specialist certification will begin next month.



Nonconforming Material

What's New?

Timing deviations for Grenoble and Galway Mervue have expired and these sites are now applicable to the enterprise documents. All other sites are working through the remaining implementation activities while teams are updating their IT systems to take advantage of the opportunities of the new procedures. Agile PQM was already updated. The first Community of Practice (CoP) was held earlier this month and all Single Points of Contact (SPoCs) were invited.

Equipment & Manufacturing Systems Lifecycle

What's New?

The workstream team is currently still moving through the Develop phase. Draft documents still need to be updated and finalized. The need for those updates has delayed the planned Stakeholder Review.

What's Next?

Once the documents have been updated and finalized, the Stakeholder review will be targeted for early next year. The team is still trying hard to meet their implementation date at the end of March 2023 or early April.

	Control Environments	Manage QMS Documents and Records	Evaluate and Select Suppliers & Segmentation/ASL
What's New?	Control Environments is the newest workstream of Q3. Documents have been drafted and are currently going through Technical Writing and Compliance reviews.	Documents in this workstream have gone through Technical Writing and Compliance Review and have moved to Process Owner and QMS Specialist reviews.	Content QCH is in post-release while Entity QCH is in the approve phase.
What's Next?	Once through Technical Writing and Compliance reviews, Control Environments will be moved to process owner and QMS specialist reviews, and later, its first Stakeholder Review.	The next major_milestone will be Stakeholder Review starting on November 29th with an expected end date of December 5th.	A reminder that the target implementation date is December 16th.

HIGHLIGHT: Improving the Escalation Process

Why change?

- Escalations have been managed via email, PowerPoint slides and meeting minutes.
- No data or metrics are easily accessible in the current state, which makes monitoring and measuring the process difficult.

What is the current situation?

- Escalations are managed in various ways (email, PowerPoint slides, meeting minutes)
- Measurement of counts and trends are not available.
- Finding the "right" person to submit the escalation can be challenging.

How will things be the same or different?

What's changing:

- A Smartsheet Form will be used to submit an escalation request.
- Using Smartsheet reporting capabilities, the owners of the escalations will be identified.
- Reports and Dashboards will be used to provide visibility to counts and trends.

What's staying the same?

- The Escalation pathway, roles and responsibilities will remain the same (i.e., Process Leader, Core Team, Steering Committee)

What are the benefits?

- Reduced time looking for historical information.
- One place for customers to go to submit their escalations.
- Ability to track and trend escalations.
- Visibility will help to move through the process quickly by planning appropriately.

What's Next?

- Please share this information and start using the updated process.
- Expand the scope to support maintenance escalations.

The escalation pathway and players stay the same, but the intake and monitoring process is improving. Please use this link to request an escalation for the following escalation types:

- **Tailor Request:** requesting to deviate from the Shared Enterprise document release package. This includes maintaining a local document in addition to implementing the documents within the release package
- **Out of Scope Request:** requesting to become out of scope for all QMS Transformation Workstreams
- **Stakeholder Review Date Change:** Requesting to change the stakeholder review dates (by +/- 3 days) for a scheduled change package that currently shows on the Release Schedule
- **Request for Implementation Delay:** Request a delay in implementation

See below for pathway details.

QMS TRANSFORMATION: LOOKING AHEAD

As many workstreams are in progress or soon to finish, new workstreams are starting preparations for their kickoff. **Store, Handle and Ship / Manage Supply Chain** is next to kick off in December while the remaining workstreams scheduled for FY23 are in various stages of pre-planning.

Planning for FY24 is already in the works and process leaders are beginning to think about the business needs of FY24. The process will start by accessing each Process Area individually for scope and priority and then building the QMS Transformation Schedule for the next fiscal year based on that information. Stay tuned to see the finalized schedule.

IN CASE YOU MISSED IT

Revisit our October Storytelling feature

It's been three years since the #makeCAPAcool program entered our work lives. Our very own, Kathryn Merrill, was there at the very beginning and shares her experience with Change Management Lead Jennifer Koss. Take a look back and relive how it all started here.

Have you read our latest "Did You Know?" Catch up Now! And stay up-to-date with our new Sharepoint site!