# MAKE CAPA COOL | Workstream Report Out

02/25/19
Project Chair: Kathryn Merrill (Medtronic)
#makeCAPAcool Project

CASE FOR QUALITY CAPA WORKSTREAM

Leverage cross-industry best practices and collaboration to fundamentally recast CAPA as a continuous improvement (CI) framework

Industry-wide struggle resulting from the current CAPA Framework

Executive Steering Committee Sponsors: Luann Pendy, Joe Sapiente

Project Chair: Kathryn Merrill (Medtronic)

FDA, MDIC & Industry Members:

- FDA
- MDIC
- Medtronic
- Exponent
- Hologic
- Illumina
- Johnson & Johnson
- Baxter
- Stryker
- Siemens
- Boston Scientific
- Dassault Systemes
- BD
- McKinsey & Company
- Grant Thornton
Our target is the reduction of patient risk, the improvement of CAPA effectiveness and the reduction in burden to drive product quality improvements.

**Today**

<table>
<thead>
<tr>
<th>CAPA</th>
<th>Risk</th>
<th>CAPA</th>
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</table>

Fewer problems solved. Reduced improvement over time.

**Future**

Find and fix

- Find it internally and empowered to go fix it
- No action plan needed, know what to do

More problems solved. Greater improvement over time.

**Not all problems are created equal!**

- Do what is appropriate for the problem.
- Process does not tell you how to do continuous improvement, but if you do it well, you will not have many CAPAs. Rewards early improvement.
- Non-patient impacting issues would not demand a CAPAs.
- Documented root cause analysis might not be required for every problem.
We are following a proven, structured approach

<table>
<thead>
<tr>
<th>Sep - Nov</th>
<th>Nov 7-8</th>
<th>Nov - Dec</th>
<th>Dec - Jan</th>
<th>Feb - Mar</th>
<th>Mar - Jun</th>
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<tbody>
<tr>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
<td><strong>6</strong></td>
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<tr>
<td>Workshop Prework</td>
<td>Design Thinking workshop</td>
<td>ORA interviews and FDA/Industry expert feedback</td>
<td>Iterations 2-4 developed and tested in pre-pilots</td>
<td>Pilots</td>
<td>Recommendations and rollout plan</td>
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1. **Benchmark**
   - to understand best practices: 10 interviews with Non-Medical Device industries

2. **User survey**:
   - 6 companies, 30+ responses, 300+ pain points, 400+ ideas

3. **Exploring regulations**:
   - from 21 CFR and ISO to China GMP

4. **Prototyping solutions**

5. **1st Iteration Developed**

6. **2 day F2F + 15 participants, incl. process SMEs, regulators, design thinking experts**

7. **Insights from ORA inspectors (7 + interviews)**

8. **Pressure testing with participating companies, McKinsey and industry experts**

9. **Framework Verification activities**:
   - Multiple Team Reviews & Redlines
   - McKinsey panel of Experts
   - Sponsor Reviews
   - FDA Team Member reviews & feedback

10. **Refining the solution through 3 more design iterations**

11. **Focused retroactive pilots with multiple companies to understand high-level impact & effectiveness of the Framework (past CAPA reviews)**

12. **Verifying Changes proposed against other regulations (ISO, MDSAP are out of reach to change.)**

13. **Piloting 4th Iteration with real-time quality data**

14. **Piloting CAPA process best practices (e.g., CAPA summary) and review with ORA representatives**

15. **March 27-28: Team F2F meeting in Chicago to review pilot results, refine and finalize the framework / recommendations**

16. **Write up recommendations, incl. white paper, best practices for the industry, recommended updates to QSIT**

17. **Syndicate with the key stakeholders and align on the rollout plan**

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**TODAY**
Best practices were identified using industry Benchmark organizations with strong continuous improvement programs

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Management &amp; Support Infrastructure</th>
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<tbody>
<tr>
<td></td>
<td>Supporting Culture &amp; Behaviors</td>
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</table>

10 cross-sector interviews
Aerospace, Finance, Software, Automotive, Semi-conductor, Shingo

Key learnings translated into the proposed CAPA framework

- When everything is important, nothing is.
- Main focus must be to protect the patients/customers
- Drive alignment on what is important to facilitate resource & priority assignments (Leadership Culture of Quality)
- Risk based approach to problem solving. Not all problems are treated the same.
- Internal problems addressed at the lowest possible level, and escalated as needed. (Problem Solving Culture)
Design thinking workshop started with a Hopes & Fears exercise – engaging hearts, not only minds

The CAPA workshop began with a kickoff exercise to understand the participants’ hopes and fears

(# of responses)

<table>
<thead>
<tr>
<th>Hopes</th>
<th>Select quotes</th>
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<tbody>
<tr>
<td>Flexible, simple and efficient</td>
<td>Increasing the energy around taking problems early and 5 fast in medical device</td>
</tr>
<tr>
<td>Alignment of compliance and quality</td>
<td>We find a simple, efficient and effective solution to engage users with continuous improvement</td>
</tr>
<tr>
<td>Energize industry</td>
<td>Define a CAPA ecosystem that will improve product quality and align industry and FDA on the “same-side”</td>
</tr>
<tr>
<td>Positive patient impact</td>
<td>New process that will improve patient outcomes</td>
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</table>

<table>
<thead>
<tr>
<th>Fears</th>
<th>Select quotes</th>
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<tbody>
<tr>
<td>Minimal change from today’s process</td>
<td>Current challenges hold us back from big change</td>
</tr>
<tr>
<td>A more complex process</td>
<td>Too complex and FDA centric; solution is not simple enough to transition</td>
</tr>
<tr>
<td>Resistance by industry</td>
<td>Internal resistance to change; solutions we find aren’t used by the business</td>
</tr>
<tr>
<td>Resistance by regulators</td>
<td>A CAPA system not accepted by global regulators</td>
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</tbody>
</table>
Design thinking workshop: 3 Key pain points in CAPA

1. Not clear when to open a CAPA (What qualifies)
2. Not clear relationship with other systems (NCR, CI) resulting in overlaps and duplication
3. Lack of planned resources for CAPA process
After ideation and 4 iterations, we arrived at the proposed CAPA Framework 4.0

Highlights
1. External Signals escalate directly to CAPA
2. Internal Signals leverage affected quality systems, with a pre-defined CI loop
3. We can still escalate to CAPA, after we have had time to work through an issue. If CI does not work, we escalate.

1 To match ISO definition, defined “problem” as exceeding freq./ severity levels 4 for major findings only (relate to product)
2 The intent of an effectiveness check is to verify the corrective action has mitigated what was intended. In cases where the V/V meets this intent, an additional effectiveness check is not required.
**Table Summary:**

- **Pre-Defined Continuous Improvement Loop:** Organizations can embed Corrections/Corrective Actions within existing QMS processes & define a risk based approach for CAPA Escalation.

- **Pure PA:** Process Enhancements will remain outside the regulated space.

### Table: Required CAPA Elements a Business can Embed within their respective QMS Systems.

<table>
<thead>
<tr>
<th>INPUT SOURCE</th>
<th>Continuous Improvement Loop</th>
<th>CAPA Escalation</th>
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</table>
| Non-Conformance  
[Unexpected Defects] | Embed: Corrections/Corrective Actions within existing QMS processes. | Define when a compliance event will escalate to CAPA  
[Leverage Risk / Patient Impact/Repeat] |
| OOT/Out of Cal | Define process to allow an Embedded CI loop prior to assessment for CAPA escalation. | Define when a trend will escalate to CAPA  
[Leverage Product/User impact/High risk.] |
| Compliance Events  
[Internal/External Audits] | | |
| Trends | | |
| Process Enhancements  
[Pure PA] | Cover with Quality Improvement projects outside regulated space. | |
5 Pilot Summary & Status

Retrospective Pilots leveraged to support CAPA Framework design iterations:

Key Pain Point: Not clear when to open a CAPA

✓ Progress Check of CAPA Escalation path
  • 2 Organizations
  • 17 CAPA’s reviewed
  • 6% Escalated to CAPA
  • Captured learnings

Real-time data Pilot in Progress to support FINAL CAPA Framework design iteration:

2-Part Pilot:
1. Executive Summary form good practice – Review with FDA
2. Real time application of CAPA Framework – Collection of data

Key Pain Point: Not clear relationship to other systems (NC, CI etc.)

✓ Progress Check of Continuous Improvement Loops
  • 3 Organizations
  • 35 CAPA’s
  • 83% leverage embedded CI loops
  • Captured learnings

Good Practice Form

Real Time Data Collection

Standard CI Loop Flows

Regulation Review Sub-team formed to review ISO, MDSAP, 21 CFR 820 impact

Team F2F in March to finalize the Framework & draft write-up
Afternoon Group Discussion Questions

1. What **barriers were faced** as a part of the **Maturity Model** Project?
   - In comparison, what **barriers** would your organization need to face to **roll-out the CAPA Framework**?

2. What would be **needed** in your Organization/Agency **to make this CAPA Framework work**?

3. What would you **worry about not getting done** right if we **followed the new CAPA Framework**?
# Updated Project Charter: Redesign the CAPA Process as a Continuous Improvement Framework

## [makeCAPAcool Case for Quality Workstream]

### Description
Leverage cross-industry best practices and collaboration to fundamentally recast CAPA as a continuous improvement (CI) framework.

### MDIC CIQ Steering Committee Lead
- Luann Pendy
- Joe Sapiente (Support)

### Interim Milestones and Completion Dates

<table>
<thead>
<tr>
<th>Start</th>
<th>Finish</th>
<th>Duration</th>
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<tbody>
<tr>
<td>Q3 2018</td>
<td>Q2 2019</td>
<td>9 Months</td>
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### Problem Statement
CAPA is currently a compliance-centric process rather than a continuous improvement cycle. CAPA is very costly and effort-intensive, with the perception of limited value. Other industries leverage their CAPA processes as a continuous improvement vehicle that implements cost-effective changes in a much shorter timeframe driving higher product quality. The opportunity is to leverage cultural & procedural best practices across various industries to design a compliant medical device CAPA process that drives continuous improvement, higher product quality, improved patient safety.

### Outcomes
- Outline of a CAPA process framework, based on cultural & procedural best practices, which is effective and easy to understand/use.
- Outline a less burdensome process to execute CAPA actions
- Communication plan for the benefits of the CAPA process as a continuous improvement mechanism.

### Benefits
- Improved product quality and patient safety
- Significant reduction in the cost of poor quality
- Resets culture to the original premise of corrective and preventive action to achieve continuous improvement rather than transactional compliance
- Significant reduction in the overall time to investigate and implement CAPAs
- Inversion of the current proportion of corrective vs. preventive actions.
- Decreases the amount of time required to fix problems.
- Leans out the quality management system (QMS)

### Key Dependencies
- Identification and commitment of industry SMEs willing to collaborate
- Availability of applicable Benchmark companies to meet the project timeline.
- Alignment with other competent authorities (Non-US regulatory agencies)

### High Level Implementation Plan
- Identify dedicated support team members for Working Group and hatch Cross-Industry participation (with FDA attending)
- Develop report-out plan between makeCAPAcool team & the Steering Committee.
- Define CAPA, outline detailed current state of CAPA process, benchmark within non-Medical Device industries, and understand the strengths/opportunities & pain points of the current process to identify critical improvement areas.
- Leverage analysis outputs to define and develop a framework and operating model for continuous improvement with understanding of how this will impact regulations (including ISO, MDSAP).
- Test the CI Framework with the Working Group and deliver a future state CAPA process by Q2 2019
- Draft a white paper (produced 18-24 months after), to capture team recommendation

The team is now piloting a proposed CAPA framework!