Agenda

1. Project Overview & Progress
2. Framework 6.0 Overview
3. Pilot Results Summary
4. Next Steps & Afternoon Working Session
#makeCAPAcool Project

CASE FOR QUALITY CAPA WORKSTREAM

Industry-wide struggle resulting from the current CAPA Framework

- Problem Solving
- Thousands of Employees
- CAPA

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

CMMI Appraisal’s have independently identified that CAPA has become an exercise in compliance.

Regulations permit problem solving to be ‘commensurate with risk’ (i.e., continuum).

Today’s Pain points demonstrate a more bucketized application might be needed to drive consistency.
We are following a proven, structured approach.

**Ecosystem journey**

**Workshop Prework**
- Benchmark to understand best practices: 10 interviews with Non-Medical Device industries
- User survey: 6 companies, 30+ responses, 300+ pain points, 400+ ideas

**Design Thinking workshop**
- 2 day F2F + 15 participants, incl. process SMEs, regulators, design thinking experts
- Understanding Users
- Prototyping solutions
- 1st Iteration Developed

**ORA interviews and FDA/Industry expert feedback**
- Insights from ORA investigators (7 + interviews)

**Iterations 2-4 developed and tested in pre-pilots**
- Refining the solution through 3 more design iterations
- Focused retroactive pilots with multiple companies to understand impact & effectiveness of the Framework

**Pilots**
- Piloting 4th Iteration with real-time quality
- Regulatory Sub-team Align terminology to aide in understanding against current regulations (820, MDSAP, ISO)

**Recommendations and rollout plan**
- March 27-28: Team F2F meeting in Chicago reviewed pilot results, refined and finalized the framework 6th Iteration
- Write up recommendations, incl. white paper, best practices for the industry, recommended updates to QSIT
- Syndicate with the key stakeholders and align on the rollout plan (Beginning in August)

**Current Activities:**
- Weekly Meetings/reviews with the Editor.
- Team meetings/alignment activities ongoing (End of July)

**Whitepaper to include**
- Framework Recommendation
- Regulatory implications
- Continuous Improvement best practices.

**Key Pain Points:**
1. Not clear when to open a CAPA
2. Unclear relationship with other systems (NC/CI) resulting in overlap & confusion.
3. Lack of planned CAPA resources
Updates since last presentation: Live pilot results

3 ‘Paper’ Pilots helped develop Framework 6.0

<table>
<thead>
<tr>
<th>Pilot</th>
<th>Purpose</th>
<th>Results</th>
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<tbody>
<tr>
<td>Retrospective CAPA review 1</td>
<td>• Key Pain Point: Not clear when to open a CAPA</td>
<td>• Decision path to open High Risk CAPA was clear.</td>
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<tr>
<td></td>
<td>• Progress Check of CAPA Escalation path</td>
<td>• 6% of 17 escalated</td>
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<tr>
<td>Retrospective CAPA Review 2</td>
<td>• Key Pain Point: Not clear relationship to other systems (NC, CI etc.)</td>
<td>• All Quality events addressed by todays’ process are covered by Framework</td>
</tr>
<tr>
<td></td>
<td>• Progress Check to Verify Lower Risk Flows (no orphan events etc.)</td>
<td>• 17% of 35 escalated</td>
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<tr>
<td>Real-time Pilot</td>
<td>• Pilot Framework using Real-time data to capture expected variation.</td>
<td>• Confirmed Key pain points were addressed using real time data.</td>
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<td></td>
<td>Integrate lessons learned into final Framework iteration.</td>
<td>• Lessons learned collected for inclusion in whitepaper.</td>
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<tr>
<td></td>
<td></td>
<td>• Addition of a stand alone flow, specific to trends. (Framework Rev. 6.0)</td>
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| Issues that went through the pilot | 201 |
| Issues through traditional flow | 167 |
| Issues that would go Lower Risk Flows | 34 |

~70% Traditional CAPA

~30% Lower Risk flow(s)
Updates since last presentation: F2F Meeting March 27-28

- 17 participants representing 9 companies and FDA
- 4 companies presented pilot results and learnings
- Aligned on key definitions
- 3 working groups developed drafts recommendations for:
  - Framework 6.0
  - Regulatory implications / Recommendations for QSIT updates
  - Best practices recommendations for the industry
Proposed CAPA Framework 6.0

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.

- **External Quality Data Sources**
  - Track & trend: Yes
  - Acceptable
  - Risk Assessment: Unacceptable

- **Internal Quality Data Source (Trend)**
  - Has NC product escaped?
    - Yes: Lower Risk (Existing QMS Processes)
    - No: Assess Risk when exceed threshold
      - Has NC product escaped?
        - Yes: CAPA
          - Leverage existing QMS processes to manage actions.
          - (Include Enhancements)
        - No: PA or Enhancements
          - To prevent occurrence

- **Internal Quality Data Source (Non-Trend)**
  - Has NC product escaped?
    - Yes: Assess Risk when exceed threshold
      - Has NC product escaped?
        - Yes: Higher Risk
          - CAPA
            - [With Executive Summary good practice, V/V leveraged for effectiveness when applicable, PA for identified root cause only]²
        - No: Med - Low Risk
          - Lower Risk (Existing QMS Processes)

**Pilot Results**
- ~30% Traditional CAPA
- ~70% Lower Risk flow(s)

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.

CAPA Escalation can be used as a Business Decision anywhere within the Framework at Company’s discretion.
### High Level Comparison of Key differences between the Traditional CAPA & Low Risk Flow

<table>
<thead>
<tr>
<th>CAPA Element</th>
<th>High Risk CAPA Process [No Change]</th>
<th>Low Risk CAPA Process [Risk Based Response]</th>
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<tbody>
<tr>
<td>Root Cause* Analysis Documentation</td>
<td>The thought process and methodology used to identify ‘root cause’ would be captured as a part of the Higher Risk CAPA process.</td>
<td>Regulation requires ‘Cause’ to be identified vs. ‘Root Cause’. Therefore, not requiring demonstrated proof through documentation of specific root cause analysis tools does not violate the regulation. Therefore, the proposal is allow for the assignment of ‘Cause’ without capturing the thought process and method used. Document the cause in the permanent record. Comment: This is not to encourage less rigor, but to shift the focus from compliance to continuous improvement. For instance, an organization could leverage an alternate problem solving template like DMAIC/PDCA. The CAPA record would be without the additional documentation rigor needed to ensure the language be defendable in an inspection. Only the identified cause would be captured in the existing QMS system. This opens up problem solving to all levels of the organization and moves the focus back on problem solving vs. compliance.</td>
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| Effectiveness Check | A specially designed, targeted effectiveness check for the identified root cause will be completed. | Less rigorous effectiveness check could be leveraged without violating regulation. For instance, a site can correct and then trend to ensure effectiveness of a corrective action. Examples: Ongoing monitoring of key quality parameters to ensure no negative impact. This would also detect a recurrence. Passive monitoring (current system and controls in place today) that would identify a recurrence. If it reoccurs, you can respond to it. Quick Fix Corrections– Verify parts are now good (No effectiveness checks required for corrections.) Comment: This proposal would encourage the development of strong monitoring and control systems at an organization. |

*Root Cause implies the absolute deep underlying root cause. In contrast, the regulatory requirement is that the cause is established. (Culture Change needed in both Agency & Industry)*
New Framework is working to bring clarity & encourage collaboration

<table>
<thead>
<tr>
<th>2 Sides</th>
<th>Same Side</th>
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<tbody>
<tr>
<td>‘You cannot be trusted’</td>
<td>Both striving together for same goal</td>
</tr>
<tr>
<td>‘Transparency is limited’</td>
<td>2 winners</td>
</tr>
<tr>
<td>‘We are not on the same side.’</td>
<td>Framework viewed with a mind-set of trust by both.</td>
</tr>
<tr>
<td>Clear winner of loser of the exchange.</td>
<td>Win together, Fall together</td>
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#makeCAPA cool 2020 Pilot Goals
- Sites demonstrate faster problem solving cycles
- Sites demonstrate stronger continuous improvement behaviors/culture.
Next steps

1. Complete Draft Whitepaper (End of July)
   ✓ Professional Editor assigned to help the team

2. Review against initial pain points from industry and FDA (July)

3. Circulate with Executive Steering Committee, ORA members, Key Stakeholders (August)

4. Develop Case for Quality Charter for 2020 Pilot Phase (July/Aug)

We need your input to shape our 2020 Pilot!

• What must be included in the MDIC Pilot Program for the Framework to be successful (considering FDA/MDSAP)?

• What steps would be needed to formalize the Framework as an industry standard?

• What would drive adoption and implementation across industry.

• How could/should we measure the impact and success of the Framework