MDIC Case for Quality: CAPA Process Improvement

CASE FOR QUALITY
CAPA WORKSTREAM

FDA, MDIC & Industry Members

What is Changing?

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance focused</td>
<td>Solving problems to improve quality</td>
</tr>
<tr>
<td>“One size fits all”</td>
<td>Risk-based/fit-for-purpose</td>
</tr>
<tr>
<td>“A punishment”</td>
<td>Impact-focused</td>
</tr>
<tr>
<td>Documentation focused</td>
<td>Compliance requirement</td>
</tr>
<tr>
<td>“A privilege”</td>
<td>“One size fits all”</td>
</tr>
</tbody>
</table>

What is the Proposed Framework?

Proposed CAPA Framework: Two Main Flows

External Events & High Risk Trends

Fast Track CAPA (Embedded in QMS)

Internal Events & Low Risk Trends

External CAPA (Traditional CAPA Record)

What are the Benefits?

- More issues addressed
- Safer, better products faster!
- Less burden/cost
- Engaged and excited employees
- Compliant

Why should I sign up?

Be the first one to take advantage of the benefits

Help shape the future of CAPA

How do I sign up?

Contact your organization’s #makeCAPAcool team representative if you do not yet have a representative, contact the Program leader (kathryn.merrill@medtronic.com)

Provide written communication of your desire to pilot the process.

Contact information should include how you meet the minimum enrollment requirements:

- No OAI’s
- Good Standing with Regulatory bodies (obtained applicable certificates)

#makeCAPAcool Project
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- “Clearer path”
- “Fit-for-purpose”
- “Impact-focused”

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