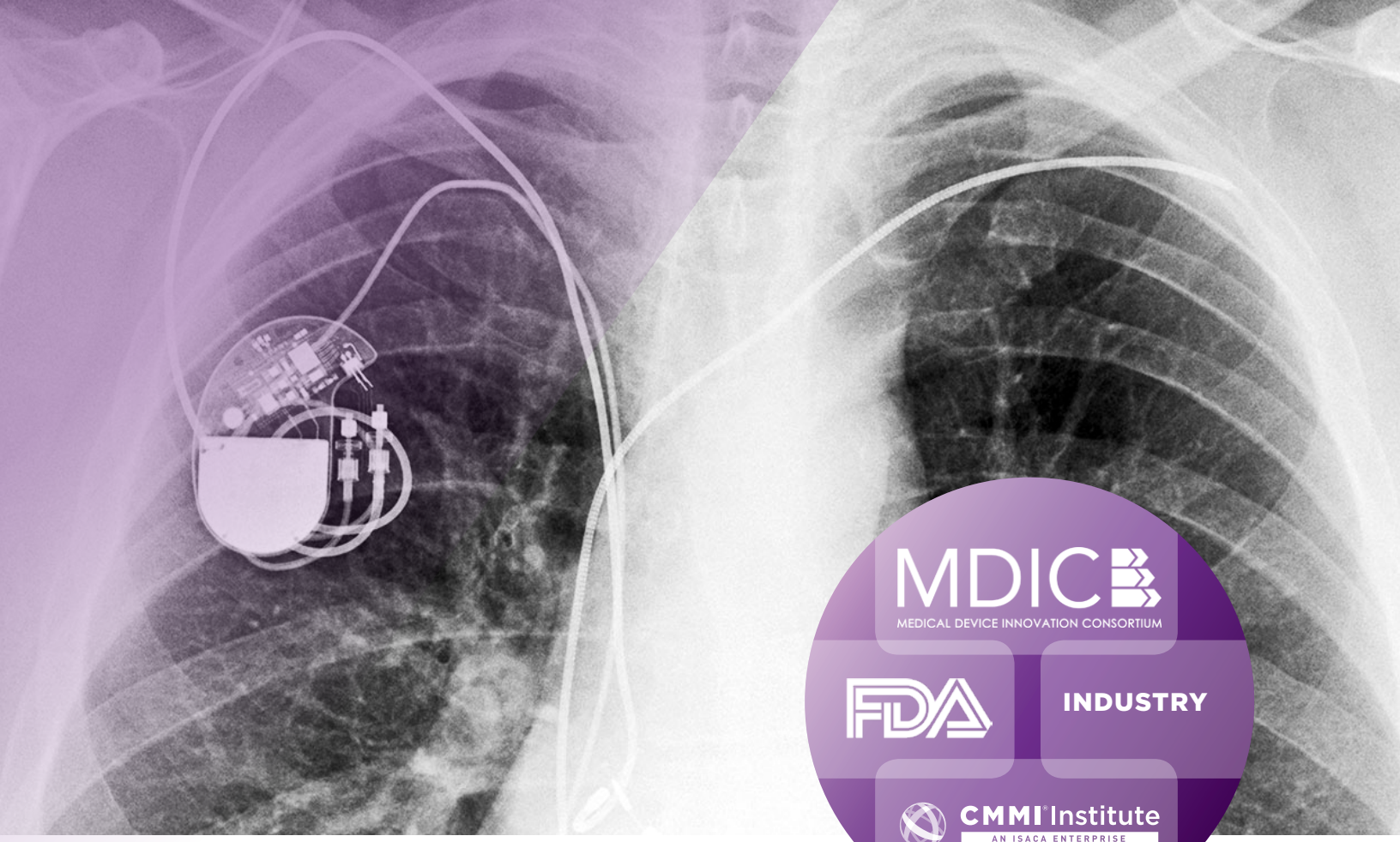
CMMI® Institute
AN ISACA ENTERPRISE

Medical Device Discovery Appraisal Program (MDDAP)

CDRH VOLUNTARY MEDICAL DEVICE MANUFACTURING AND PRODUCT QUALITY PILOT PROGRAM

Learn how your organization can improve its capabilities to deliver high quality products.



The Problem

During an in-depth review of device data and industry feedback, the FDA found no decrease in Official Actions Indicated (OAIs) despite compliance to regulations. Compliance, while important, was not enough.

With limited resources to regulate a growing industry, the Center for Devices and Radiological Health (CDRH) looked to define an alternative risk-based approach that would be more efficient and effective.

Comparably, the medical device industry has been constrained by regulatory burdens, limiting manufactures' ability to implement additional product innovations while getting those devices to market in a timely manner.

The FDA launched the Case for Quality, a joint effort between CDRH, the Medical Device Innovation Consortium (MDIC), and industry, to understand and fill this gap between compliance and quality.

The Solution

INTRODUCING THE MEDICAL DEVICE DISCOVERY APPRAISAL PROGRAM (MDDAP)

CDRH launched the Voluntary Medical Device Manufacturing and Product Quality Pilot, leveraging the CMMI framework and appraisal methodology to help medical device manufacturers better understand, measure, and improve their capabilities to deliver high quality products.

Recognizing their need to also change, the FDA is adjusting the regulatory activities and submission requirements for participating manufacturers in an effort to support their individual improvement journeys and reach industry goals such as:

REDUCED DEFECTS/REWORK

REDUCED COSTS

ACCELERATED TIME TO MARKET

INCREASED CUSTOMER SATISFACTION

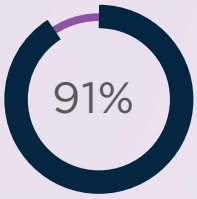
Ultimately, this pilot endeavors to improve patient safety by cultivating a culture of quality across the entire medical devices ecosystem. Based on the pilot's initial success, the FDA has already announced their intention to transition the pilot towards a full program in 2019.

About CMMI® Institute

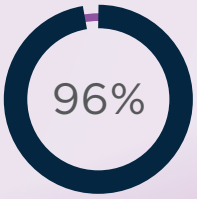
CMMI Institute offers solutions that provide insights for baselining and optimizing key organizational capabilities such as product development, service excellence, enterprise data management, and cybersecurity. The Capability Maturity Model Integration (CMMI) is a globally-recognized set of best practices that enable organizations in any industry to improve performance, key capabilities, and critical business processes. For over 25 years, CMMI appraisals have helped organizations identify strengths and weaknesses, providing a clear and individualized road map for continuous improvement. CMMI has been adopted by over 10,000 organizations in 106 countries around the world.

What Participants Think of the Program

According to a CMMI Institute survey of early adopters who completed an appraisal in the first 6-months of the Medical Device Discovery Appraisal Program:



BELIEVED THE APPRAISAL IDENTIFIED IMPROVEMENT AREAS TO INCREASE OVERALL PRODUCT QUALITY.

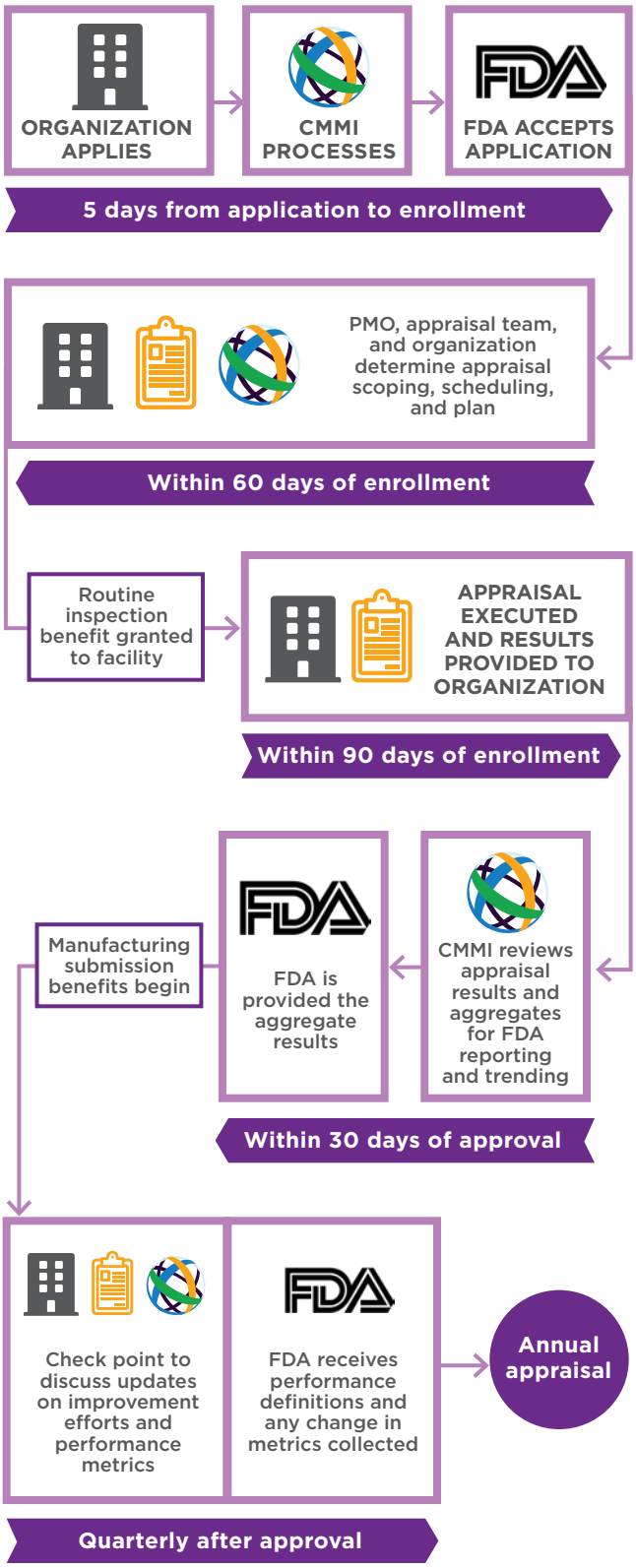


HAD A POSITIVE EXPERIENCE WITH THE APPRAISAL APPROACH AND EXECUTION.

WOULD RECOMMEND THIS PROGRAM TO OTHER ORGANIZATIONS.

How the Pilot Program Works

These changes reduce the burden and disruption of inspections, accelerate the review and approval process for changes, and shift resources to innovation and improvement.



Business Benefits & ROI

REMOVAL FROM INSPECTION WORKPLAN

Reduced disruption and costs by $20k-$140k.

STREAMLINED AND ACCELERATED SITE CHANGE SUBMISSIONS

Increased innovation with more submissions, improved employee morale, faster time to market for device improvements, and re-deployment of FTE resources, saving $10k-$500k.

SITE CHANGE SUBMISSIONS

Easier and faster transfer of products for reduced distribution costs.

PMA INSPECTION WAIVED

Reduced disruption and faster time to market, meeting patient needs.

IMPROVING FDA RELATIONSHIPS

Better working relationship with the FDA as a result of building trust through open conversations and transparency.

Get Started Today!

To learn how your organization can improve its capabilities to deliver high quality products, visit:

cmmiinstitute.com/MedicalDevice

For more information, email:

MedicalDevice@cmmiinstitute.com

To listen to participant experiences, watch the MDICx Quarterly Webinar updates:

cmmiinstitute.com/MDICx-Webinars

To read more about the pilot details and participant experiences, view this articles series:

cmmiinstitute.com/medtech-insight-articles