Case Study

CeloNova BioSciences, Inc.: Improving Operational Efficiency with ISACA's CMMI MDDAP

(Medical Device Discovery Appraisal Program)

The Business Need

As a small privately owned medical device company, CeloNova BioSciences, Inc. (CeloNova) understands how imperative it is to be on the forefront of quality initiatives in order to demonstrate its competitive edge and leadership in the industry. CeloNova was an early adopter in the Case for Quality Voluntary Improvement Program (CfQ VIP or VIP), which was launched in collaboration with FDA, the Medical Device Innovation Consortium (MDIC), and the medical device industry to improve device quality and patient safety. VIP utilizes ISACA's CMMI Medical Device Discovery Appraisal Program (MDDAP) as the framework by which medical device manufacturers can measure their capability to produce high quality devices against a proven set of best practices as part of their continuous improvement journey from compliance to quality. Program participants are eligible for regulatory modifications in recognition of their engagement, transparency, and commitment to quality. With VIP, the FDA partners with participants to allow organizations that fully engage in the program to achieve tangible benefits.

The Business Challenge

In this highly regulated industry, companies like CeloNova maintain quality management systems to comply with the code of federal regulations. However, while regulatory requirements define the work done within these systems, work done outside of these systems tends to be less structured, sometimes causing friction when these activities and work-streams interact.

Company Background

CeloNova BioSciences, Inc. is an innovative global medical device leader transforming the treatment of cardiovascular disease and addressing the treatment gap in patients at high risk of bleeding. CeloNova develops, manufactures and markets a family of products based upon its novel Polyzene™-F (PzF) nanocoating technology, a revolutionary surface coating designed to optimize implant interaction within the body. CeloNova is currently selling the FDA and CE Mark approved COBRA PzF™ NanoCoated Coronary Stent in both US and international markets.

CeloNova is developing new PzF applications for implantable medical devices that will help patients and change the practice of medicine around the world. CeloNova is an industry leader in advancing the Medical Device Discovery Appraisal Program (MDDAP) by demonstrating above and beyond transparency and accountability.

For more information, go to **celonova.com**

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CeloNova believed that by participating in VIP, the company could deliver on its business goals to (1) maintain lean, efficient operations while meeting all necessary legal and regulatory compliance requirements, and (2) sustain and demonstrate its competitive edge. Participating in VIP was a natural fit for CeloNova at its growth stage. Specifically, CeloNova sought to:

- Improve the culture of quality at CeloNova, creating value for patients and customers
- Validate CeloNova's reputation and trustworthiness through an independent appraisal of organizational capabilities
- Focus on continuously improving processes

To this end, CeloNova made the decision to embark on a multi-year journey that went on to involve a Capability Level Benchmark Appraisal that would challenge the organization and demonstrate its ongoing commitment to quality.

The Solution

How CMMI Helped CeloNova BioSciences: VIP, MDDAP, and the Capability Level Benchmark Appraisal

The initial MDDAP Appraisal is standardized to provide a baseline view for all new industry participants. The Practice Areas targeted for improvement in Year One were:

- Requirement Development and Management (RDM)
- Planning (PLAN)
- Monitor and Control (MC)
- Managing Performance and Measurement (MPM)
- Configuration Management (CM)
- Process Quality Assurance (PQA)
- Technical Solution (TS)
- Product Integration (PI)
- Estimating (EST)
- Governance (GOV)
- Implementation Infrastructure (II)

After completion of the first appraisal, CeloNova decided to challenge their organization by pursuing a Capability Level Benchmark Appraisal, the first ever conducted through the VIP program, with a broader set of Practice Areas and higher levels than the standardized appraisal. The new Practice Areas and practice group levels (Level 2 = L2, Level 3 = L3) targeted for improvement in Year Two were:

- Decision Analysis and Resolution (DAR)- L2
- Risk and Opportunity Management (RSK)- L3
- Organizational Training (OT)- L3
- Process Management (PCM)- L3
- Supplier Agreement Management (SAM)- L3

In Year Two these Practice Areas were raised from L2 to L3:

- Governance (GOV)
- Implementation Infrastructure (II)
- Managing Performance and Measurement (MPM)

In Year Two these Practices Areas remained at L2:

- Estimating (EST)
- Planning (PLAN)

> "CeloNova's investment in CMMI has enabled our start-up medical device company to deliver our cardiovascular innovations at or above the quality levels of larger, more established, medical device competitors. CMMI's process challenges our Quality Management System assumptions while ensuring that we build an 'end to end' culture of quality throughout our organization."
>
> Carl St. Bernard
> CEO
> CeloNova BioSciences, Inc.

Addressing Improvement Opportunities

To address opportunities identified in the first year around managing performance and measurement, CeloNova created a metric summary that contained all of the monitored process outputs and the operational definitions of each (what, when, where, how, and who). CeloNova examined what was measured and why and verified the metrics were aligned and useful to the business. The list now contains metrics related to planning and production outputs as well as quality systems.

In the second appraisal, CeloNova received improvement opportunities around decision analysis and resolution, governance and risk and opportunity management. In response, CeloNova analyzed this feedback and took a series of actions to address opportunities in these Practice Areas.

- Decision Analysis and Resolution (DAR): CeloNova created a process for capturing formal decisions (including matrix, work instructions, how and when)
- Governance (GOV): CeloNova created a process to ensure corporate goals cascaded to individual departments and showed direct links between those corporate goals, department goals and measurable objectives
- Risk and Opportunity Management (RSK): CeloNova applied risk management principles to critical equipment to prioritize and anticipate risks

MDDAP provided CeloNova with insight for baselining and optimizing key organizational capabilities and critical business processes while improving the interaction between functions. This insight gave CeloNova a new appreciation for the importance of a codified approach to organizational processes.

Key Performance Goals Achieved

Lessons Learned

Preparing for the Benchmark

The Capability Level Benchmark Appraisal identified opportunities for CeloNova to improve how they implemented processes and their overall business performance. In preparation for the Benchmark, the site and appraisal team gathered over 240 artifacts for the selected Practice Areas. These artifacts were intended to demonstrate actual applications and examples over a four-month period. By reviewing these artifacts, the appraisal team was able to translate results through the CMMI model to help CeloNova understand the interaction between different organizational processes.

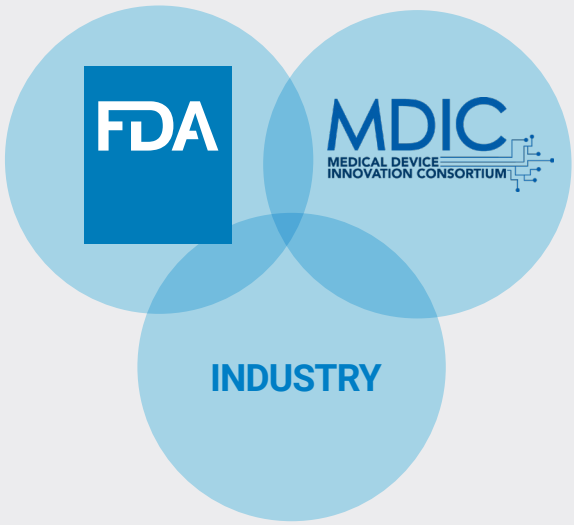
Participating in VIP and utilizing the MDDAP framework supported the already vigorous quality culture at CeloNova. Participation visibly demonstrated CeloNova's commitment to continuous improvement and improved patient outcomes. In addition, CMMI V2.0's modular approach gave CeloNova the flexibility to select Practice Areas that aligned most closely with their business goals.

CeloNova now sees the quantitative and qualitative results of the processes they perform every day, with each employee achieving a full sense of ownership and accomplishment. CeloNova is proud to be the first participant in VIP to complete a Capability Level Benchmark Appraisal, which adds external validation and credibility to their accomplishments.

"We want to applaud and thank the entire CeloNova team for trusting CMMI V2.0 with your performance improvement. With this appraisal, **CeloNova is the world's first Capability Level Benchmark appraisal,** proving another CMMI V2.0 promise of being able to be tailored and demonstrate performance benefit to any type or size of an organization."

Ron Lear
Chief Architect
CMMI

WHAT IS THE MEDICAL DEVICE DISCOVERY APPRAISAL PROGRAM (MDDAP)?



This program brings together the FDA, the Medical Device Innovation Consortium (MDIC), and the medical device industry to work together to enhance device quality and patient safety.

ISACA®

For more than 50 years, ISACA® (www.isaca.org) has advanced the best talent, expertise and learning in technology. ISACA equips individuals with knowledge, credentials, education and community to progress their careers and transform their organizations, and enables enterprises to train and build quality teams. ISACA is a global professional association and learning organization that leverages the expertise of its 145,000 members who work in information security, governance, assurance, risk and privacy to drive innovation through technology. It has a presence in 188 countries, including more than 220 chapters worldwide.

CMMI®

ISACA's CMMI enables organizations to elevate and benchmark performance across a range of critical business capabilities, including product development, service excellence, workforce management, data management, supplier management, and cybersecurity. For more than 25 years, thousands of high-performing organizations have achieved sustainable business success through CMMI adoption and demonstrated their ability as capable business partners and suppliers.