



Medical Manufacturer Drives Operational Readiness for Acquisition and Growth with CM2

The Challenge

We were engaged to address systemic process and data challenges at a leading heart surgery equipment manufacturer (hereinafter "Medical Manufacturer"). These challenges were critical to resolve to enable a smooth integration with the Acquiring Corporation and to support aggressive corporate goals focused on global expansion and innovation.

The Medical Manufacturer's existing change model was "bottoms up" and heavily people-dependent, operating successfully largely because of "good people" rather than robust processes. This created significant risk and limited scalability. The acquisition amplified the need for a standardized, enterprise-wide configuration management system. Key challenges identified during the initial assessment included:

Inefficient Change Management (CM) / ECO Process:

- The poor Engineering Change Order (ECO) process, poor product data, and reliance on legacy PLM tools resulted in a slow response to patient and business needs. Changes were described as 25% hard to plan and execute. Analysis showed that 95% of ECOs spent 17-26 days in the approval stage alone. The previous mean approval time was 21 days. Approvals were often manual, driven by email ("soft review"), and inconsistent, leading to multiple re-approvals and scope creep.

Poor Data Integrity & Traceability:

- Legacy software tools caused product data to be disconnected (not traceable). Teams relied on "tribal knowledge" to find impacted documents. Critically, the Bill of Materials (BoM) often did not match between the drawing and the ERP system, requiring manual translation and leading to errors.

New Product Introduction (NPI) Maturation:

- The Product Development Process (PDP) was adopted, but it was rigid (a waterfall model) and document-driven rather than activity-driven. This often led to functional deliverables being "crammed... 2 weeks before the gate," impeding proactive engagement and process standardization.



THE CM2 FRAMEWORK: THE ENGINE OF TRANSFORMATION

The Solution: CM2 Framework & IpX Engagement

We positioned the CM2 (Configuration Management) framework as the "True North for Enterprise Calibration" and the industry standard for the Digital Thread, providing a comprehensive, agile, and scalable model. The engagement focused on three core workstreams: Change Management, New Product Introduction, and Obsolescence.

The initial CM2 Training Self-Assessment scored the Medical Manufacturer at 110, placing the organization in the 'C' maturity band, indicating that confidence in CM2 principles was growing as corrective action was declining. The goal was a structural shift toward institutionalized change.

The engagement followed a planned progression to define the To-Be Process and align the Medical Manufacturer with the Acquiring Corporation's PLM tool. This included creating a Functional Requirements Specification (FRS) with acceptance criteria.

Implementation: Near-Term CM2 Roadmap

Our plan established a phased approach to transform the Medical Manufacturer's operations, focusing on foundational principles to drive Robust Impact Assessment and Efficient Execution.

Phase 1: Robust Impact Assessment (The "Front Half")

This phase focused on the Investigation Request (IR) and Change Request (CR) process to ensure a Robust Impact Assessment was performed prior to committing resources.

- Establish the Change Leader (CL): A clear, single point of responsibility for driving the change, improving assessment quality.
- Enterprise Change Assessment (ECA): Introduce a cross-functional review and functional checklists to accurately scope and assess the impact of the change up front.
- Change Review Board (CRB): Implement a CRB to act as the formal decision-making body, establishing a consistent set of decision-makers to make the Business Decision (Go/No-Go) for a change.
- Full-Track/Fast-Track: Establish clear criteria for routing changes to ensure rigor is appropriate for the nature of the change, with 80% of changes directed to the Fast-Track path for quick, less complex changes.

Phase 2: Efficient Execution (The "Back Half")

This phase, with a 2023 scope, focused on the Change Notice (CN) process to manage Efficient Delivery.

- Change Implementation Leader (CIL): A new role established to own the coordination of implementation activities, ensuring delivery to the plan.
- Change Implementation Board (CIB): A coordination body to provide Enterprise Coordination, managing delivery and prioritization across functions.
- Detailed Execution Plan: Implement planning templates and metrics to manage cost, schedule, and execution, ensuring changes are prioritized against enterprise goals and organizational capacity.



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Data and NPI Transformation

The core of the strategy was to transition from tribal knowledge to a structured business process model centered on clean, connected data.

Digital Thread & Single Source of Truth:

- The future state required Interconnected Systems to serve as a Single Source of Truth across the enterprise. Data must be stored electronically, linked between structures to enable automatic traceability, and transferred among systems (PLM, ERP, MES) to align the As-Designed (Engineering) □ As-Planned (Manufacturing) □ As-Enabled (Operations) baselines.

NPI Maturity:

- The goal for NPI was to transition from a document-driven to an activity-driven mentality. This requires defining functional deliverables for each department and formalizing the functional sub-processes to ensure teams are proactively engaged early in the PDP process.

The Value

Effective change management was identified as a key enabler and a competitive advantage. By adopting the CM2 framework and implementing a phased, CM2-aligned roadmap, IpX provided the Medical Manufacturer with the necessary operational foundation to:

Scale Business Operations:

- Transition from reliance on a few "Experts" to a system with clear Roles & Responsibilities, making the business scalable.

Accelerate Global Commercialization:

- By improving data integrity, connectivity, and efficiency, the organization would achieve the stated goals of global expansion and innovation.

Improve Productivity:

- Establish a single source of data and process enablement for key stakeholders to reduce cycle times and expedite the process of finding correct data quickly.

The successful implementation of this roadmap shifted the organization's focus to Robust Impact Assessment and planned, Efficient Execution, ensuring the newly acquired entity operates with the CM rigor required by the acquiring corporation's enterprise environment.