

MEDICAL CASE STUDY

Optimizing & Harmonizing CM Across a Complex Business Model

BACKGROUND

Oftentimes the most challenging part of implementing change is understanding the magnitude of change and configuration management and the value it brings to the organization. Managing change is not a simple task; it requires careful planning, effective communication, and a strong leadership team to guide the organization through the seas of transformation.

As complex organizations grow and diversify, they often face challenges related to multiple business units, diverse processes, varying technologies, and geographically dispersed teams. To ensure businesses continue their evolution, organizations must focus on continually optimizing and [harmonizing their processes](#). This includes core business processes such as Configuration Management (CM).

CM processes within my organization had become complex, outdated, costly and a potential source of compliance gaps. Therefore, our organization initiated a program to enhance our processes to achieve a core set of enterprise-wide business goals. A critical element to meeting these objectives was to harmonize across 14 locations.



BUSINESS GOALS

Before embarking on any change initiative, it is vital for leaders to understand the need for change, align on a set of business pain points and focused areas of improvement. These help to create a compelling case for change, thus motivating key stakeholders to join for the ride. In justifying our journey, of overhauling our use & implementation of CM, the business aligned on the following objectives:

01

COST SAVINGS

Maintaining existing systems had become expensive and challenging to sustain in the quickly evolving medical industry. Building a single, shared, end-to-end system would help eliminate duplicate and wasteful practices.

02

INCREASED EFFICIENCY

Various CM processes have proved to be logistically challenging. Implementing a single, shared, and harmonized process would allow us to reduce bottlenecks and inefficiencies throughout various parts of our business.

03

DIGITAL THREAD & DIGITAL TWIN

Leveraging CM2 industry standard best practices, our organization set out to establish a digital thread to serve as the digital backbone integrating our data model from early-stage R&D through manufacturing and Integrated Logistics Support (ILS). Creation of a true digital thread is key to ensuring product quality and traceability. Furthermore, the baselined digital thread would allow our businesses to create a real-world counterpart (digital twin) providing valuable analytical insight throughout the product lifecycle. This requires a clear source of truth for all data and connected tools to ensure data integrity.

04

REDUCTION IN CYCLE TIME

Harmonization into a single end-to-end PLM process will consolidate outdated, stagnant, and complicated processes. In implementing CM2 best practices we targeted reduction of cycle time as the main driver given the streamlined nature of our project.

05

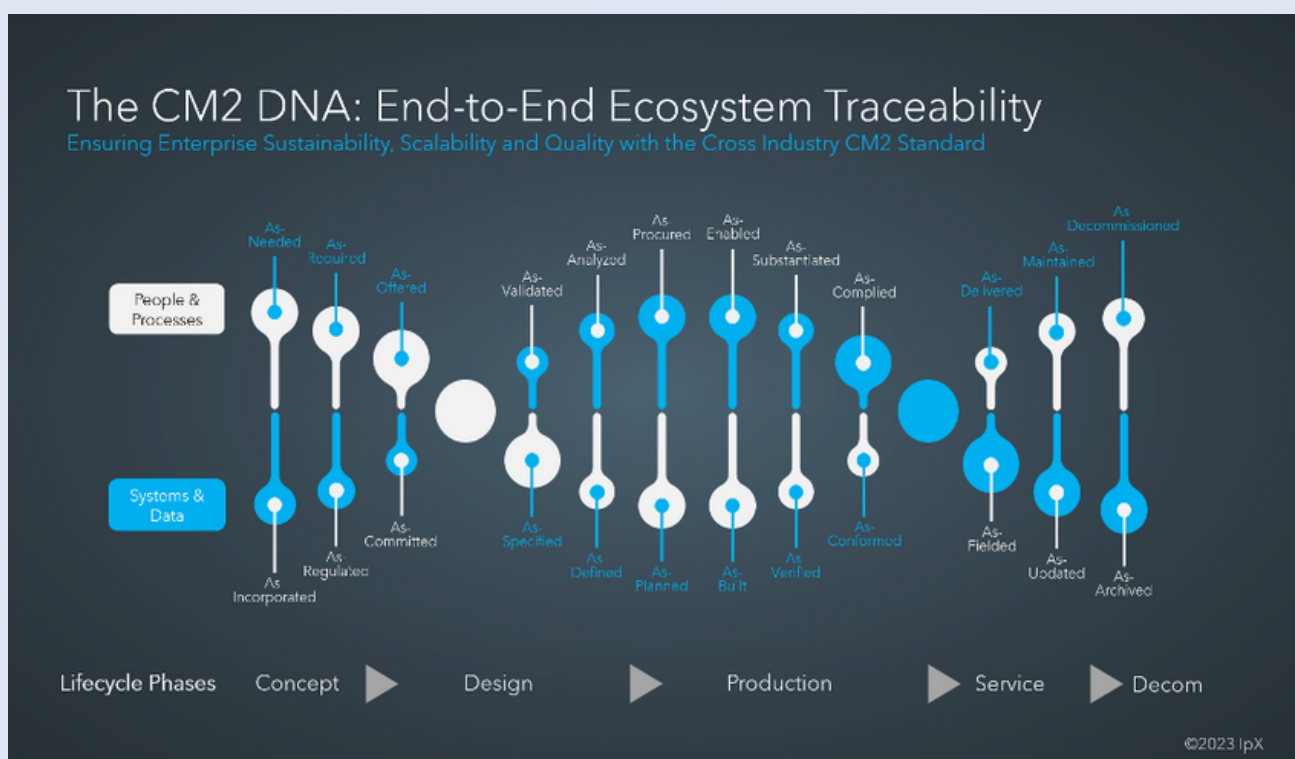
ACCELERATE TIME TO MARKET

A robust CM process provides mechanisms for various business functions to collaborate effectively, while maintaining a much-desired digital DNA. This combined with the previously mentioned goals would allow our business to reinvest savings into our R&D pipeline and accelerate time to market. Ensuring data integrity and robust communication is key to efficient and effective processes.



THE ROLE OF CM2

Achieving these goals in a complex global business requires a thoughtful and strategic approach. Therefore, we leveraged many of IpX's CM2 best practices to implement clear organizational strategies to help drive towards the goals mentioned above. The following CM2 elements have been critical to our success and have helped drive transformational change.



ASSESSMENTS

01

Establishing and understanding the current CM baseline proved to be a critical first step. As discussed in multiple CM2 courses, completing robust business model assessments provide a baseline needed to understand the true state of the business. These [assessments](#) served as the backbone for our CM transformational journey. Assessment reveals what the organization is practicing, where audits identify gaps against the documented business process.



02

PLAN DEVELOPMENT AND IMPLEMENTATION

Attempting to implement change across a complex business in one fell swoop can be overwhelming and counterproductive. A phased approach allows for a more manageable and focused implementation that the organization can adopt without disruption. This methodology was leveraged and allowed us to test the effectiveness of the proposed changes starting with a targeted audience. The insights gained from these initial implementations provided insight on the broader rollout strategy. Thus, allowing for adjustments and fine-tuning as needed.

03

CM2 TRAINING

Placing [CM2 certified individuals](#) in key positions made our goal more attainable. It became evident that the CM2-C and CM2-P courses helped equip our team with the knowledge, skills, and mindset necessary to strategize, plan and implement transformational changes effectively. This knowledge enabled quick answers to the organization at times when the reason for change was questioned.

04

PRODUCT LIFECYCLE MANAGEMENT SYSTEMS

A foundational piece of our journey was the selection of a PLM tool that could leverage many of the CM2 best practices, including the industry best practice CM2 closed-loop change process. To help achieve our goals, we leveraged Scaled Agile Framework (SAFe) development methodologies which drove agile product delivery while maintaining organizational agility.

05

STEERING/GOVERNANCE

Establishing a [robust steering/governance model](#) was a key piece of CM2 training and was also critical in our success. Leadership buy-in has been critical when implementing this magnitude of a change. They play a pivotal role in guiding, supporting, and championing the change effort. By establishing a top-down team structure we gained their active engagement in successfully navigating complexities, resistance and challenges. This allowed the team to obtain the necessary vision, influence, resources, and support to drive successful change.

06

ORGANIZATIONAL CHANGE MANAGEMENT

Change cannot be driven by a single individual; it requires a dedicated team of change agents who champion the transformation. As discussed in various CM2 training courses, the change management team should consist of individuals with diverse skills, expertise, and representation from various departments within the organization. These individuals are key as they consistently “take the temperature” of the organization, communicate the vision, address concerns, and provide support to employees/end users throughout the journey. This team of change agents also helped train throughout. Organizational change management is a necessity for success and needs to be resourced and funded as such, not seen simply as a nice to have.



07

ESTABLISHING CLEAR & ROBUST METRICS

To monitor the effectiveness of the project, it has been essential to establish clear metrics and key performance indicators (KPIs) aligned with the desired outcomes. Regularly measuring and monitoring progress against these KPIs has helped identify areas of improvement and any deviations from the intended project goals. These insights provide leaders with the visibility needed to understand the effectiveness of our optimization project and allow the larger team to make data-driven decisions going forward.

**+50K****Users Onboarded****+50%****Cycle Time Reduction****+26k****Change Requests Generated****CONCLUSION**

In conclusion, optimizing and harmonizing CM across a complex business is a transformative journey that requires strategic planning, clear communication, and a commitment to continuous improvement. By streamlining processes, promoting collaboration, and aligning goals, organizations can unlock their full potential, achieve higher performance levels, and remain agile in the face of ever-changing business landscapes. Establishing robust KPIs help provide leadership visibility into the level of success and key areas of improvement. Embracing CM2 core principles has allowed our business to successfully navigate through the complexities of operations while achieving previous identified goals, including a ~50% reduction in cycle time while impacting over 50k thousand users through the harmonization of 14 global locations. Optimizing CM is not a one and done initiative, it is a continual effort to ensure CM is a flexible fit for purpose solution that ensures the evolving needs of the business are met.

Diego Valencia, CM2-P, IpX Contributing Congress Member, brings over 15 years of experience in various R&D and Quality Systems roles within Pharmaceutical, Consumer and Medical Technology sectors. While being an active member of the IpX congress, Diego serves as manager of Quality Systems at Johnson & Johnson. As part of his role he has been tasked with leading efforts to implement a new Change & Configuration Management process across their Medical Technology companies. In addition to leading the implementation across various companies, Diego has been responsible for defining business requirements, serving as a CM2 expert and establishing resource models to maintain implemented changes. [Connect on LinkedIn](#)

