Into the Deep End: Mastering a New Industry While Driving High-Stakes Projects [1, 2]

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Abstract

When I transitioned from the non-regulated world of semiconductors into medical device project management, I expected a learning curve, but not the sprint that awaited me. Only weeks into my new role, new city and new coworkers, I was handed the type of project that had never been attempted internally. Completing it would help the company close a competitive gap and enter a new market. The challenge: limited resources, a tight budget, and a 12-week timeline before regulatory submission. While I was still learning the regulatory landscape, a second similar project emerged, and I was asked to lead that one as well.

With no established roadmap, I needed to build one quickly. I sought out mentors, asked countless questions, and immersed myself in design controls, regulatory expectations, and clinical evidence requirements. To avoid duplicated work and stretch our limited bandwidth, I proposed merging both projects. Consolidating the teams brought alignment, reduced redundancy, and created a unified path forward.

Partnering with an external consultant, we developed an evidence model that balanced regulatory rigor with internal process efficiency. Step by step, we defined a minimum viable product that supported business goals, maintained high quality, and enabled access to a new patient population.

In this paper, I will share how rapid learning, cross-functional collaboration, and strategic trade-off decisions enabled me to deliver two high-impact projects during a major industry transition. This experience illustrates how adaptive project management can drive innovation even under tight constraints in a highly regulated environment.

[1] Editor's note: Second Editions are previously published papers that have continued relevance in today's project management world, or which were originally published in conference proceedings or in a language other than English. Original publication acknowledged; authors retain copyright. This paper was originally presented at the 18th Project Management Symposium at the University of Texas at Dallas in May 2026. It is republished here with permission of the author and conference organizers.

[2] How to cite this paper: Oliveros Villalba, A. (2026). Into the Deep End: Mastering a New Industry While Driving High-Stakes Projects; Originally presented at the 18th Project Management Symposium at the University of Texas at Dallas in May, republished in the *PM World Journal*, Vol. XV, Issue XI, November.

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1. Introduction

Career transitions can be tough but industry transitions may be even more challenging. My first transition occurred within my first three years as a process engineer. This my first role after completing my PhD in Electrical Engineering and I quickly realized that I was better at scheduling work, managing tasks for the technicians and coordinating priorities with the other engineers and my manager to improve the factory processes. Little did I know that these tasks that I preferred to do were more aligned with project management. This realization steered me in the direction of finding a role where I could thrive and develop skills as a project manager. From there, I proceeded to do my first career pivot, from a process development engineer role to a project management role in a software organization that was completely new to me.

I focused on learning project management from other colleagues and took introductory classes to help me succeed in this new role. From then on, I went to do several and different roles inside a semiconductor technology company but I still felt that something was missing and I decided to pursue my passion in helping others through my work with technology, which took me to the medical device industry. As an engineer by training and a project manager by trade I focused on those transferable skills that I had learned and the soft skills that made me the leader I have become. Becoming a project manager allowed me to cultivate problem solving skills, prioritization of the right tasks, being able to match the business visions with the project goals, building teams and making them successful and more importantly being at the service of my team.

After many interviews and reaching out to my network I found a role that perfectly aligned with my career vision to grow even deeper as a project manager. At some point in my career, I received advice from one of my managers: Do not change more than one variable at a time when making a transition, however there are times that we need to take risks because the benefit may outset the risk in the long run. In this case I was able to change a couple variable but the most challenging: I moved cities and ventured into the Neuromodulation industry. Anchored in my project manager learning and manager abilities I leaned into my toolbox ready for the challenge.

A career transition from the semiconductor to the medical device industry presents opportunities to excel and challenges. Coming from an industry driven by speed, scale, and engineering precision, I entered a sector defined by regulation, safety, documentation rigor, and patient impact. In addition, the competitive pressure to stay ahead and continue to be the lead medical device manufacturer amounts to additional pressure to perform flawlessly quickly as a new employee with industry experience. Although I anticipated new terminology and processes, I did not anticipate how quickly I would be asked to demonstrate mastery.

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High stakes

Within weeks of joining the organization, I was assigned to lead a project to expand our customer reach that had not been attempted internally within the last 10 years, in which the design control processes had changed. The project's successful completion was essential for entering a new market segment tied to patient outcomes that would be supporting with a novel approach. Making all this more challenging were the tight resources and a fast-approaching 12-week regulatory deadline. While I was still learning what "design controls" and "clinical evidence" meant in practice and understanding who the key players in the organization were, leadership approached me with a second project similar in scope, urgency, and ambiguity.

The stakes were high. Against this backdrop, I had to create clarity where none existed, build alignment across multifunctional teams, and accelerate my understanding of regulated development all while delivering outcomes that met both business goals and regulatory requirements. This paper describes how I approached these challenges, the decisions that shaped the work, and the lessons that emerged.

2. Problem Definition

The situation was complex because it required working fast and there were four challenges: lack of precedent, aggressive timelines, limited resources, and a personal knowledge gap.

Lack of Internal Precedent

The project assigned to me was unique and required a new methodology to generate supporting clinical evidence based on real world evidence, which had an impact on design control deliverables. There was a project with scope similarities in regard to the labeling updates required but timeliness and staffing were much different.

Without internal process guides, templates, or lessons learned, the team had to be creative to interpret the FDA guidance[1]

expectations. This created both an opportunity and ambiguity for the team. Every step demanded fresh interpretation of regulatory expectations which in some cases meant to create some documents from scratch and prioritize the different phases in the design control process to define a product that was acceptable by the regulatory agency and competitive in the market.

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Aggressive Timelines

Given the business need to launch the product during very important critical conference, our regulatory submission deadline was 12 weeks away. This project was expected to support a business strategy that hinged on rapid market entry. Each component clinical protocol development, internal reviews, risk assessment, evidence modeling, among others had to be completed at a pace that stretched existing practices.

At the same time a second project with nearly identical requirements surfaced midway through the first, with the advantage that the team was fully staffed. Running them separately would have doubled the workload and ensured teams were duplicating efforts.

Limited Resources

Bandwidth was a recurring obstacle. And this was a cross-functional project that needed experts in different areas: regulatory affairs, quality, clinical, marketing, and R&D, which were already operating at capacity. For instance, we could only get 20% of the time of the regulatory affairs partner, the quality team had to supplement the workload with a contractor and I had one clinical subject matter expert across both projects.

Knowledge Gap

With only a few months into my industry transition, I was still developing fluency in:

- Design-control requirements
- Regulatory classifications and submission mechanics
- Clinical evidence expectations
- Cross-functional roles in regulated product development

In a matter of days, I needed to accelerate my learning and deliver results.

3. Approach and Strategy

After recognizing the problem at hand and the stakes, I proceeded to design a strategy centered on rapid learning, process and timeline optimization, and strategic consolidation.

Rapid Learning Strategy

I leveraged a template that I had created with a mentor at a previous company and defined a 30-60-90-day plan to help me establish clear goals, key contacts and recurring

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meetings, a comprehensive table of 1:1 meetings with a suggested timing, topic and purpose of the discussion (see example in Figure 2). This allowed me to work with my manager on they expectations and to work with her as a key partner in this process but with the independence this project required.

Key Contact Inventory

Contact Name	Position	1:1 Frequency	Expectations /Comments	Notes (Personality / Work Style / Etc.)
John Doe	Quality	Weekly	Understand Design Control process Identify deliverables for Design Control Traceability Risk assessment process	Responsive/Busy
Jane Doe	Clinical science	Weekly	Evidence generation process consult/define Experience from simlar projects	Team oriented

Figure 1. Example of priority stakeholders and 1:1 meeting tracker.

Seeking Mentors and Subject-Matter Experts

I worked with on of my project manager colleagues to shadow her in her job and attended cross-functional meetings she hosted to observe how she framed problems and looked for solutions with the team and to analyze the type of interactions across the different disciplines involved in the project. We also discussed key terminology, processes and documents the project manager was responsible for during the project lifecycle.

Because regulated projects also have a heavy labeling component I reached out to individuals in the technical writing and operations organizations to understand not just the development of the content but the impact to operationalize the product later. It was also critical that I understood where issues and risks may arise so I could lead the cross-functional team to take the right decisions during scope planning.

I supplemented the expert meetings with reading internal procedures, past regulatory submissions, and FDA guidance documents applicable to our product category. I learned that for medical products to be successful it is necessary to understand:

- Evidence is needed to support claims, which also need to be aligned with the regulations.
- How to define the risk/benefit profile for the product and support it with relevant evidence.
- Anticipate potential deficiency questions and how to be better prepared during the agency review.

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Process and timeline optimization

With the help of the team members from data science, development quality, technical publications, systems and clinical engineering and operations, I proceeded to define a work breakdown structure aligned to workstreams that would satisfy the regulatory, clinical and quality needs of the project. Figure 2 illustrates the WBS. This also helped the team understand their roles and interdependencies.

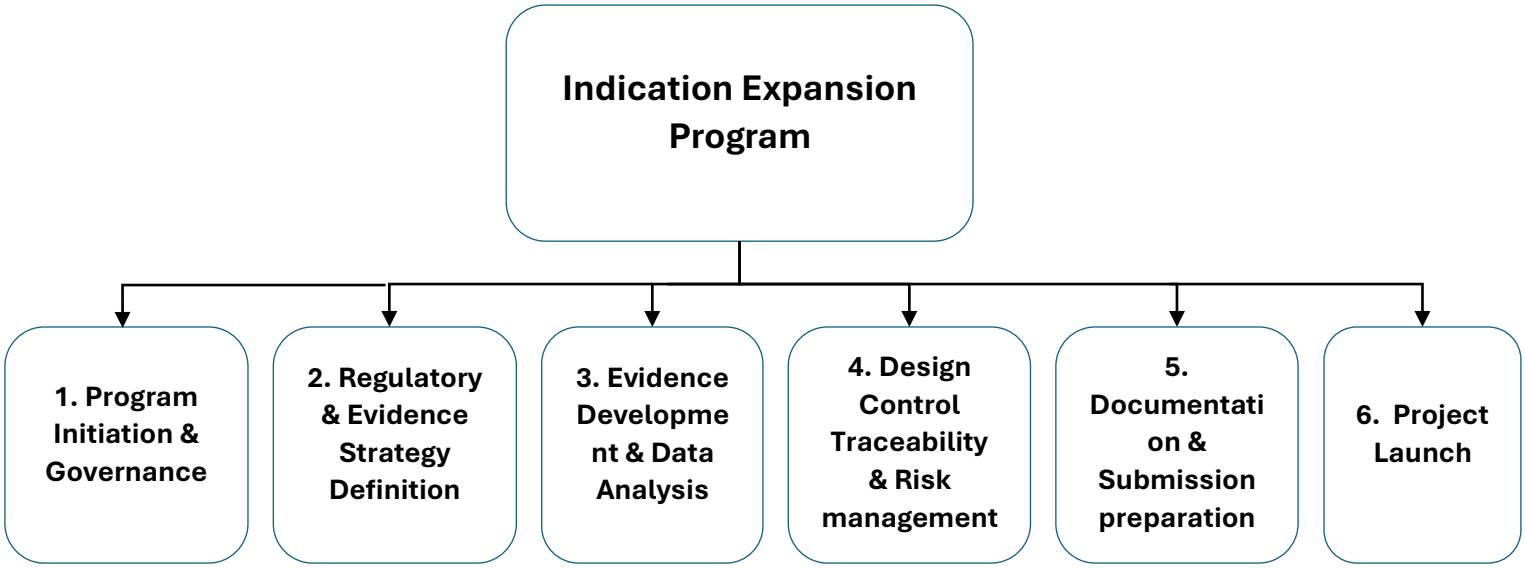


Figure 2. Project WBS

Defining a Minimum Viable Product (MVP) for Regulatory Submission

Given the time constraints, and our limited resources, the need to deliver a strong evidence package was a priority. We applied the concept of a "minimum viable product" to evidence development that could later support the agency package submission and the product. We reviewed the regulation and the minimum requirements for the type of submission we were pursuing. The MVP came down to:

- Essential data to support clinical evidence and claims.
- Risk profile and mitigations.
- Labeling updates pertinent to the submission.

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Other deliverables were previously discussed with the development quality team to be deferred to the next phase with the proper rationale. This approach ensured that quality and safety were preserved, the resources were used efficiently and the submission remained achievable within the 12-weeks goal.

Partnering with an External Consultant

As mentioned previously, the support from the regulatory partner was limited, in addition with the internal experience to consolidate and prepare the type of clinical evidence required. For these reasons, we engaged an external consultant with deep regulatory and clinical insight that would help us identify the gaps and prepare a competitive package that would allow the indication expansion to have a higher chance of approval.

The consultant led: the evidence-model development, the review of regulatory precedents, interpretation of clinical-data expectations, the definition of the relevant labeling content updates and the submission package preparation. While I focused on leading our internal project deliverables, cross functional and stakeholder alignment and the modification of internal processes to allow a smooth product launch.

The consultant not just augmented our resource capacity but by bringing them onboard we accelerated our understanding of what would be acceptable to regulators, helping us avoid misaligned approaches early, improved efficiency and confidence in the final evidence package.

Proposal to Merge the Two Projects

When the second project surfaced, my immediate concern was delivering to the leadership expectations considering the constraints. The best outcomes occur when you frame a perceived obstacle as an opportunity. There was a clear advantage, the new project had already been approved with a fully staffed cross-functional team and a similar scope. It quickly became apparent that running the two efforts independently would not be beneficial since it would generate unnecessary costs.

I proceeded to do an analysis of where the opportunities for consolidation were and at what point of project number 1, we would merge with project number 2. The rationale for the merger included:

- Shared functional partners.
- Shared platforms that would support both products.
- Overlapping evidence requirements.

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- Opportunity to create a repeatable internal template.
- Similar timelines to launch.
- Potential reduction in operational efforts prior and post-launch.

Securing Buy-In

Prior to securing leadership buy-in I worked with teams that would benefit heavily by the consolidation: operations, marketing and commercial, technical publications and regulatory affairs.

I presented the cost of parallel development versus the efficiency of consolidation. Leadership and cross-functional teams aligned once they recognized that a unified approach would:

- Enable operational savings. For example: we could consolidate patient and clinician relevant content updates (warnings, precautions, adverse events) into one manual update.
- Remove unnecessary packaging updates for different boxings of products in a short amount of time, i.e. three months.
- Consolidate resources and eliminate duplicate work.
- Minimize the impact on post-market processes at different launch dates in a short amount of time to only once.

The merger transformed the program from two isolated efforts into a coordinated strategic initiative.

4. Results and Discussion

This project demonstrated how strategic consolidation and adaptive leadership can drive successful outcomes in a regulated environment. By merging two evidence development efforts into a single coordinated program, the team delivered measurable operational, business, and professional benefits while also revealing broader lessons for managing complex, high-constraint initiatives.

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Project Outcomes and Operational Effectiveness

Consolidating the programs significantly reduced the overall resource burden by minimizing duplicated activities and aligning functional contributions across teams. Importantly, this effort resulted in the creation of a repeatable evidence-generation template, establishing a scalable model for future projects. These results underscore the value of creating structure early and iterating as information becomes available, an approach rooted in adaptive leadership.

Process Improvements Through Cross-Functional Collaboration

The project introduced new workflow templates, clarified expectations for evidence development, and standardized internal review processes. These improvements were driven by early and sustained cross-functional collaboration among clinical, quality, and regulatory stakeholders. By integrating specialized expertise upfront, the team reduced rework, accelerated decision-making, and improved submission quality. This reinforces the principle that regulated projects succeed not through siloed excellence, but through coordinated, multidisciplinary engagement.

Efficiency Gains Through Strategic Consolidation and MVP Thinking

Merging the two projects proved to be a key efficiency lever. Strategic consolidation reduced waste, eased pressure on constrained functional teams, and improved documentation consistency—an essential requirement for regulatory submissions. Additionally, the team applied a minimum viable product (MVP) mindset to evidence development, focusing on what was sufficient to meet regulatory standards rather than pursuing exhaustive documentation. This approach balanced rigor with pragmatism, challenging the assumption that more information always equates to higher quality in regulated settings.

Role of External Expertise

The involvement of external consultants was transformative, providing contextual regulatory knowledge that internal teams were still developing. Their guidance accelerated progress, and increased confidence in decision-making. This highlights the value of selectively leveraging external expertise to complement internal capabilities, particularly during periods of organizational learning or market expansion.

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Professional Development and Leadership Growth

On a personal level, the experience accelerated competency in regulated project management and strengthened relationships across clinical, quality, and regulatory teams. Leading a complex and ambiguous initiative built confidence in navigating uncertainty, influencing without authority, and making strategic trade-offs.

The key highlights from this experience can be summarized as follows:

- **Ask early, ask often.** Don't be afraid to ask questions and ask for help, rapid learning depends on humility and curiosity. Most of the times people enjoy talking about their job.
- **Structure reduces anxiety.** When in doubt a WBS and a draft roadmap gives teams direction. Bringing a draft with ideas to the team can help shape the structure.
- **Merge where possible.** Consolidation removes duplication, prevents divergence and allows efficiency.
- **Balance speed and quality.** An MVP approach ensures disciplined prioritization and prioritizing the right tasks with limited resources.
- **Invest in relationships.** Trust and relatedness accelerate alignment in high-pressure environments.
- **Use ambiguity as opportunity.** When no process exists, use this opportunity to have the freedom to design a better one.

5. Conclusion

Delivering these two projects and finding the ability for consolidation within a new role, new environment, and new regulatory context was a challenging but transformative experience. By embracing rapid learning, fostering cross-functional collaboration, and applying adaptive project-management principles, I successfully led the team and navigated stakeholders' expectations while delivering high-impact agency submissions that advanced both business strategy and patient access.

This experience demonstrates that innovation is not just about new products or technologies, process innovation in regulated industries is needed and possible even under tight constraints. When project managers combine structured planning with flexible

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execution, engage the right expertise, and make intentional tradeoffs, they can lead teams through complexity and deliver outcomes that shape the future of the organization and pave the way for new ways of working.

6. References

[1]Framework for FDA's Real-World Evidence Program, available at https://www.fda.gov/media/120060/download.

About the Author



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Alexandra Oliveros is a Program Manager with nearly a decade of experience in the technology sector, known for adaptive leadership, cross-industry versatility, and ability to deliver high-impact programs. She began her career at Intel Corporation and now leads new product development initiatives within Abbott's Neuromodulation R&D PMO. Alexandra is PMP certified and holds a PhD in Electrical Engineering and an MSc in Biomedical Engineering from the University of South Florida.
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