# PM.3

180 PROJECT MANAGEMENT SERIES

# Optimizing Medical Device & Pharmaceutical Project Management Organizations

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in partnership with:

PMINLS
PROJECT MANAGEMENT IN LIFE SCIENCE

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## Exploring Project Management Series

Welcome to **180 recruiting + consulting's** project management series created in collaboration with **Project Management in Life Sciences (PMinLS)**. This series consists of three pieces and explores the project management function, becoming a project manager within the medical device or pharmaceutical industries and project management trends within life sciences organizations.

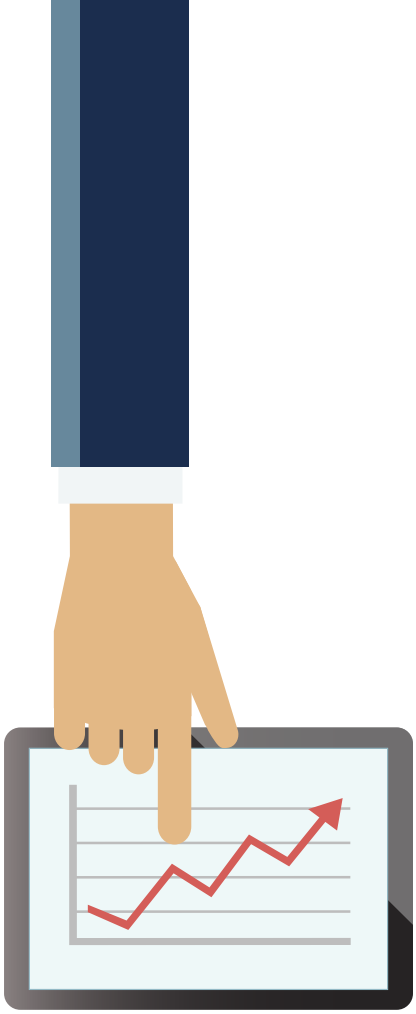
- PM.1 - Is Project Management Right for Me?
- PM.2 - Becoming a Project Manager within the Medical Device or Pharmaceutical Industries
- PM.3 - Optimizing Medical Device & Pharmaceutical Project Management Organizations


## A Special Thanks


A special thanks to Project Management in Life Sciences (PMinLS), Dee Suberla, Craig Josephson, Jennifer Erpenbeck, Annette Johnston, Kevin Grossenbacher and Karen Zylberman who all contributed meaningfully to this project.


PMinLS is a group of individuals interested in the pharmaceutical, medical device and biotech world of project management. PMinLS provides an environment to expand and strengthen life science related project management capabilities. If you are interested in learning more about this organization including membership and upcoming events, please visit www.pminls.com.

# Optimizing Medical Device & Pharmaceutical Project Management Organizations



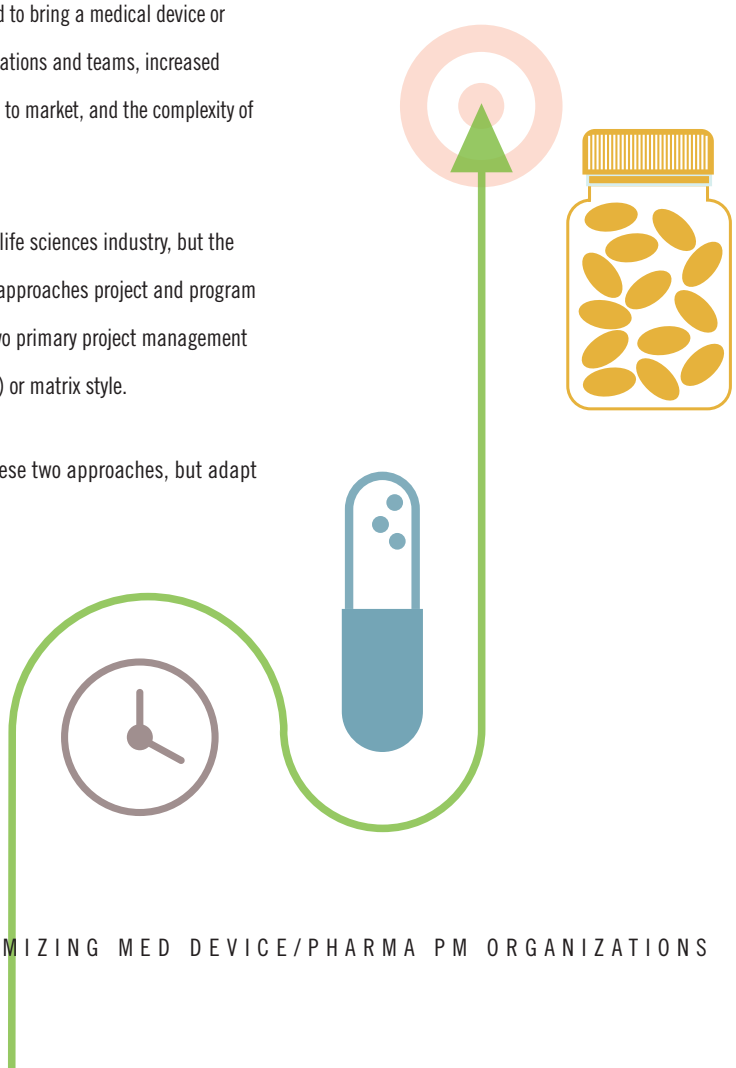
Today's medical device and pharmaceutical companies are faced with many challenges; faltering research and development (R&D) productivity, increased product complexity, a demanding regulatory environment, and product pricing pressures. All the while, the most pressing objective of any pharmaceutical or medical device company is to deliver safe and effective products to patients as quickly and cost effectively as possible.

The need to manage complexity, budgets, timeline pressures, organizational challenges and now frequent multi-organization collaborations has established an environment in which project and program management expertise has become a necessity within life sciences organizations.

However, how can project and program management be best structured within life sciences organizations? Given the broad range of functional expertise that is required to bring a medical device or pharmaceutical product to market, the global nature of many organizations and teams, increased incidences in which organizations are collaborating to bring products to market, and the complexity of products makes this question a challenging one to answer.

Project management is still a fairly immature discipline within the life sciences industry, but the discipline is developing quickly. While every life sciences company approaches project and program management differently to best suit their organization, there are two primary project management organization "camps" – a central project management office (PMO) or matrix style.

The reality is that most organizations gravitate toward one of these two approaches, but adapt the core style to meet their needs.



# Primary Project Management Organizational Approaches

## Centralized Project Management Office (PMO)

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Companies that follow this approach "house" projects and program managers within a PMO, ultimately reporting to the head of the PMO. The head of the PMO is typically a senior vice president executive position. There are pros and cons to this approach. On the pro side, it is much easier to establish project management procedures, performance metrics, and other points of consistency across the organization. Additionally, project management as a discipline is often elevated and given a larger voice within the organization, given that the PMO head has visibility and a voice within the company's executive team. The autonomy of reporting can also help in a highly political organization where a PM feels there may be reprisal for reporting bad news to the executive team. However, there are potential cons to a PMO approach. Given the multifunctional nature of bringing a pharmaceutical or medical device product to market, a formal PMO structure may be too rigid. There may be too much pressure for project and program managers to conform to directives from the head of the PMO, rather than address the goals and unique needs of a particular project.

## Matrix-Style Project Management

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A matrix (or lateral) project management approach results in project managers being dispersed throughout the organization, working with different functional areas involved in the project through efficient collaborative channels. In comparison to a centralized PMO approach, matrix management involves cross-functional interactions with authority and responsibility being shared among the participating groups. Pros of a matrix-style model include the ability for stakeholders to more fluidly collaborate and the approach for a specific project to be tailored. Additionally, given the increasingly complex nature of most pharmaceutical and medical device products, a matrix-style approach allows project managers to utilize and grow specific therapeutic area expertise. For instance, a project manager may develop tremendous expertise in oncology, in addition to their core skills as a project manager.

However, cons of a matrix-style approach can include confused reporting structures, a challenge establishing and disseminating project management standards across the organization, and, given that there is no PMO head, sometimes a lack of voice within the executive ranks.

## Blended Project Management Structure

B

Some organizations may have a support PMO that heads up tracking, enterprise-wide tracking and fundamental expectations for all project management organizations. Project managers report into the businesses and spend all of their time with cross functional teams. Occasionally, there is a dotted line reporting structure to the PMO. They generally have a small staff and may be able to support high priority projects with meeting facilitation, scheduling or other items when needed.

Although most life sciences organizations lean either toward a centralized PMO or matrix-style approach, every organization adjusts these general styles to meet their needs. Additionally, organizations tend to go through evolutions of which style is best for them. Although a matrix-style approach might have worked well eight years ago, a given medical device company may find that a centralized PMO is better suited to their needs today.

## Project Management Maturity

In addition to an organization's core approach to project management structure, it is important to be aware of organizational project management maturity. The life sciences industry, as a whole, does not have extremely high levels of project management maturity. However, some companies are more mature than others in this regard and the industry is rapidly moving toward greater levels of maturity. One fundamental message during the maturation process is that Project Management is organizational. Project Managers, no matter how brilliant, cannot overcome the obstacles of an organization that does not embrace the collaborative and cooperative culture required to maximize results.

The Project Management Maturity Model is a great roadmap for organizations seeking to increase their level of project management maturity and competency. Once the initial level of maturity and areas for improvement are identified, a plan can be defined for an organization to take the necessary steps toward advancing project management maturity and improving performance.

### Project Management Maturity Model

| Level | Organization | Project Manager/Team |
|---|---|---|
| **5** Optimizing | • Management by project is integrated into business model<br>• Systematic skill building/PM career path<br>• Senior managers partner with project teams to eliminate obstacles to success | • High level of project management competence<br>• Strive for optimal team composition<br>• Focus on innovation, learning and continuous improvement |
| **4** Integrated | • Resource assignments based on clear priorities<br>• Training available across the organization<br>• Active sponsorship<br>• Increased data allows fact-based decisions | • Increased cross-functional collaboration & processes<br>• Diverse teams<br>• Focus on high performance<br>• PM processes are standardized |
| **3** Organized | • Standardized approach to project management<br>• Attention on problem solving, trend analysis and improvement<br>• Sponsors defined, but skills and commitment may vary | • Core and extended team established for all projects<br>• Increased ownership for overall success<br>• Common approach and training for core teams (fundamentals level) |
| **2** Repeatable | • No integrated project focus<br>• Fear of delivering "bad news"<br>• Senior management interest on perceived top priority projects<br>• No real control of project portfolio | • Individual project teams agree to common approach<br>• Focus on scheduling and tracking milestones<br>• Dependence on individual project manager for introducing discipline |
| **1** Ad-Hoc | • Undefined project management practices<br>• Projects not clearly linked to business strategy<br>• No real sponsorship exists | • Individuals use different approaches to projects<br>• Resource and team commitment not consistent<br>• Functional orientation<br>• Processes are unpredictable |

*Source: Poof! You're a Project Manager, provided by Action for Results, Inc.*

## Increased Utilization of Contract Project Managers

The prevalence of contract project managers is increasing within the life sciences industry for a variety of reasons. Although each company's approach to utilizing contract project managers is slightly different, the following are some general themes being observed across the industry:

### "Relief Valve"

Many life sciences companies are restricted in terms of adding headcount even though they face rigorous and escalating project management demands. These companies often utilize contract project managers whose cost is generally categorized as an operational expense rather than an increase in personnel.

### Deadline-Driven Intense Projects

Regulatory changes or other factors sometimes create an immediate need for very demanding work with a specific deadline. After the deadline, the project is complete and the need no longer exists. For example, serialization deadlines in the pharmaceutical industry or the Unique Device Identification (UDI) initiative in the medical device industry require resources for a specified period of time. It may not be financially prudent to staff an intense, very specialized, deadline-driven project with full-time employees.

### Specialized Knowledge

Both the pharmaceutical and medical device industries have become increasingly specialized. Contract project managers often have a depth of knowledge in a very specific area and can be a great resource to an organization or team in need of their expertise.

### Fresh Insights

More and more organizations are beginning to value the broad perspectives and fresh thinking that contract project managers can bring to their organization. Contract project managers generally have recent experience at numerous organizations and bring these fresh perspectives to the table.

# From the Life Sciences Project Management Trenches

While all the information we have shared with you is a culmination of many years of project management, medical device and pharmaceutical industry experience, we felt it was important to invite project and program management leaders actively working within the field to directly share their experiences and insights.

We spoke with the following four project management leaders: Craig Josephson, former Head, Portfolio & Program Management Office, ICU Medical, Annette Johnston, Senior Project Manager, Abbott Laboratories, Diagnostics Division, Karen Zylberman, Senior Director, Global Program Management, Takeda, and a project management executive from a leading pharmaceutical organization.

### Please describe how project management is structured within your organization.

**Karen:** There are a few different project management pockets within Takeda organized to meet the needs of the business. For example, the regulatory project management group and clinical operations project management group are very functionally aligned. The team of Global Program Managers, however, is a cross functional team now organized by therapeutic area that supports all of the specific product programs in Takeda both before new drug application (NDA) and after approval.

Additionally, there is a group of project managers who support products pre-proof of concept (POC). Once POC is established, the program rolls into the appropriate therapeutic area unit. We also have project managers dedicated to post-marketing projects. Although always a work in progress, Takeda has found success organizing project management by functional area where appropriate.

Because Takeda does not have a central PMO, project manager leaders within the organization band together to contribute to a Center of Operational Performance (COOP). We meet regularly to drive consistency and standards across the organization.

The decentralized project management organization is currently working well for Takeda. However, I think when you have a centralized PMO, the head of the PMO is typically an executive-level person who has a frequent voice with senior executive leadership. When you decentralize you lose that higher-level voice. We realized quickly that we had no official champion within the organization. The COOP has given us more organizational visibility, credibility and a larger voice. Additionally, senior leadership has noticed and recognized that we need a voice and has worked to facilitate that. However, our experience losing program management voice is a consideration for companies considering a decentralized approach.

**Craig:** There is quite a range of how life sciences organizations view and approach the project management discipline. While some medical device and pharmaceutical companies have very mature approaches to project management, many life sciences organizations do not. In part, project management maturity is related to the maturity of the overall organization and its experience moving products through the development pipeline and ultimately to market. This said, in life sciences organizations, maturity of organizational project management practices is often directly related to executive leadership's perception of professional project management's value and their support for the practice within the organization.

ICU Medical offers a great example of robust utilization of project management within a medical device organization. In the first half of 2017, ICU acquired what was the Hospira medical device portfolio from Pfizer. I established a project management organization that is strategically customized to meet the needs and demands of ICU's business. Specifically, due to the diverse functions needed to develop medical device products, ICU's centralized PMO is divided into four functional areas.

The first functional team within ICU's PMO is dedicated to project management administration and they dubbed this group their Project Management Center of Excellence. It's a small function and is not led by a director, but the team members within this group are focused on driving organizational consistency. Specifically, ensuring that each project manager is using the same techniques and tools across their projects. Project management practice consistency not only leads to efficiency within the PMO, but also leads to efficiency for functional managers as they review project information represented by consistent metrics and reporting approaches.

The other three teams within ICU's PMO are functional teams and these teams consist of a group of project managers led by a director. One team is a very traditional medical device project management, waterfall style team that follows the FDA design controls rules. The development of all tangible, touchable products are led by this team.

The second team is a software-focused team that utilizes agile project management and other approaches well-suited to software development. The third and final project management execution team is focused entirely on partnerships. Partnerships project managed by this team are not necessarily vendor relationships, but often peer partnering relationships – perhaps a solution that will integrate in some way with an ICU product, or perhaps some type of marketing agreement.

**Pharma Leader:** Within Abbott there are currently several different approaches depending on the kind of project, although that's changing. We have a PMO, and the PMO is the support for launching more than 100 new products for our new line of instruments. In the past, I had worked as a project manager in a manufacturing plant, and they used to manage their own cost improvement, margin improvement, continuous improvement projects, and report those through the plant's management. Separately, there was a technical team that managed product modification and product improvement projects. These project management teams would report through their respective division, which eventually the plants would report to as well. But now, the PMO which was just formed last year, is starting to work toward margin improvement globally.

The formation of the PMO has allowed us to become far more focused and efficient. Before the establishment of the PMO we had capital projects that were managed by a capital project program director, continuous improvement projects were managed by the continuous improvement program director, and the technical support projects were managed by the technical support director. As I said, these efforts are merging into the newly established PMO.

The organizational strategy for both Abbott Laboratories and the industry at large has been a bit cyclical. Many life sciences organizations tried centralized PMOs before, then dismantled them and placed project management teams within the groups they were working with. However, the availability of collaborative technology has really changed the game and is allowing us to enjoy the efficiencies of a centralized PMO. We now have better tools for tracking that reduce the hundreds of unconnected spreadsheets. Now, we have the tools to put everything into a SharePoint where we can look at everybody's timelines, and there are tools for scraping and analyzing the timelines. These tools were not necessarily available before.

### Are contract project managers more common within the industry from your observation? What are the pros and cons of this trend?

**Craig:** In addition to a PMO being strategically structured to meet the needs of the company, staffing strategies must also be considered. Many companies faced with headcount and other resource restrictions find that integrating contract project managers is an effective solution. Additionally, some companies take the specific project into consideration.

My view is that a project that is well defined from beginning to end and is not in your core business is a good candidate for contract project managers. For example, the Unique Device Identification (UDI) initiative touched nearly every product in our portfolio. The initiative spanned about three years and impacted many areas of the business like new automation equipment for operations, labeling changes, adjustments to the way regulatory filings are done and many other areas. This was a very intense initiative over a very defined period and given the non-core nature of the work, it was work that after completion, will not be done again. It is tough to ask management to increase employee headcount for work that, again, is not core to the business and you know will have a definitive conclusion.

**Pharma Leader:** Contract project managers are more effective in their role when we have communicated to them why they have been brought in, what their roles and responsibilities will be, and when they are encouraged and supported to think or manage outside of the box. One of the benefits of contract project managers is that they bring outside experience and different perspectives from other companies and a freshness which serves them well in being taskmasters for smaller, time-sensitive projects.

### Has project management organizational strategy changed in recent years within your company or, from your observations, in the industry at large?

**Pharma Leader:** More and more companies are moving to a hybrid matrix type of model where project managers have specific therapeutic area (TA) expertise. Basically, PMs these days are professionals who have expertise in project management and they also have experience in and focus in one or more therapeutic areas.

When project management is organized by therapeutic area, it tends to be more in tune with recent filings and approvals within that TA, and can effectively leverage this knowledge to build better development plans. The hybrid matrix approach allows the organization to be focused without the potential of silo creation which can occur in a pure matrix model.

Overall, the organizational trends in the life sciences industry are offering project managers exposure to further educational opportunities which develop new skills that propel companies forward. I remember very distinctly, many in the industry used to think, "Oh, he/she is just a project manager, they don't really need to learn anything. As long as they're good task masters, they're organized, they don't need additional training."

Project management is coming into its own as a discipline that requires knowledge sharing, best practices, and experience, all of which is being recognized and supported by executive leadership within the industry.

The complexity involved in managing most projects today and the increased number of cross-company collaboration projects in the industry have further elevated project management as a profession. These collaborations are tremendously beneficial, but --require skilled project management to execute the collaboration effectively and work in a partnership setting.

### What role do you believe project managers have to play in the effort to increase R&D productivity within life sciences organizations?

**Karen:** I believe project managers have a very large role to play and this is where I think the program management team can shine at Takeda. The senior leadership team has been looking at where Takeda is in comparison to some key cycle time benchmarks across the pharmaceutical industry. Currently, we are in the middle of the pack, but there is the organizational drive, backed by senior leadership to be in the top one percent. We have made a company-wide commitment to nimbleness and agility to get there.

Many tasks and initiatives within the drug development process – filing specific reports for instance – tend to take a given period of time simply because a historical process has been followed for a long time. We are working very hard to change that mindset, challenge ourselves, challenge each other and look for efficiencies wherever we can find them to reduce drug development timelines.

Finding ways to better manage an effort is project management's core skill and we have a very exciting opportunity to shine, while working with purpose each day to get life-saving drugs to patients in need.

**Pharma Leader:** As I mentioned before, skilled project managers are vital in the management of multi-organization collaborations. Such collaborations will continue to increase in this industry and I believe project managers will continue to play a pivotal role in improving R&D efficiency in such complex settings. A project manager that has the unique skill set to positively impact their team's output by motivating team members, understanding skill and process gaps, proactively managing risks and problem solving in a team setting across multiple functional areas and especially in cross-company collaborations will contribute greatly in increasing the likelihood that drugs will be brought to market with minimal delay.

# Closing Thoughts

The work of life sciences organizations will continue to increase in complexity. Additionally, the prevalence of multiple organizations collaborating to bring products to market will also increase. These pressures, in addition to many others in the industry, make the work of project and program managers even more important. Each company will need to make organizational structural and staffing decisions that are right for their specific strategic objects. At **180 recruiting + consulting**, we strive to help both organizations and individual professionals with these efforts.

To that end, in addition to this piece that discusses project management structural considerations within life sciences organizations, we created two additional pieces to help professionals interested in life sciences project management explore the field:

- PM.1 – Is Project Management Right for Me?
- PM.2 - Becoming a Project Manager within the Medical Device or Pharmaceutical Industries

**We hope these resources are helpful to both you and your team.**

## About 180 recruiting + consulting

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PROJECT MANAGEMENT IN LIFE SCIENCE

## About Project Management in Life Sciences (PMinLS)

PMinLS is a group of individuals working in, or interested in the pharmaceutical, medical device and biotech world of project management providing an environment to expand and strengthen life sciences related project management capabilities.

The face-to-face quarterly meetings are free and are hosted by life science companies in Northern Illinois. PMinLS is a membership organization. The annual fee gives members access to additional benefits such as free webinars and other members-only benefits.

Dee G. Suberla, PMP, MBA is the Founder and President of Project Management in Life Science. She is also the author of Poof! You're a Project Manager and Other Delusions of Grandeur.

For more information about PMinLS including membership information and upcoming events, please visit: www.pminls.com

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