Product Development for Pharma – First time Right!

Inception:

Our client is a leading company in the Pharmaceuticals, Biotech, Agrochemicals and Specialty Chemicals industries. They provide Active ingredients, Intermediates, R&D services and Solutions to the leading companies in the world.

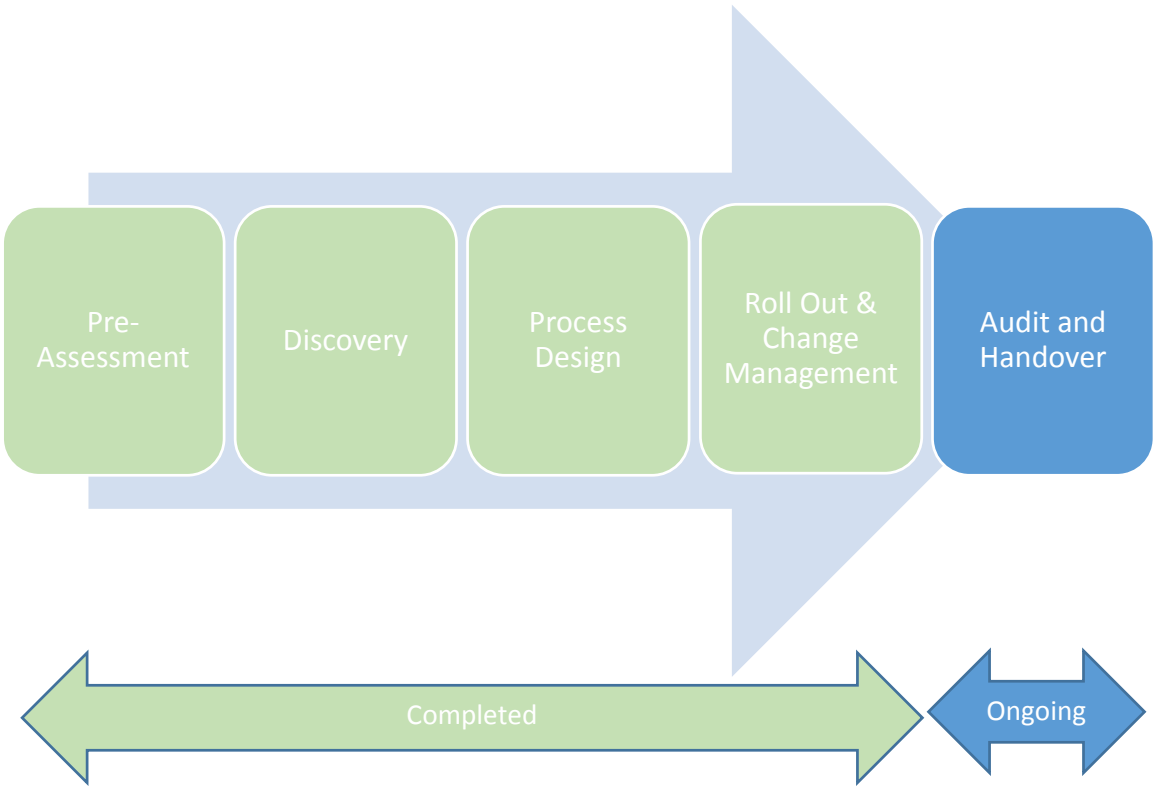
In 2015, the client engaged PMSoft to fine-tune the product development processes and project management practices in order to achieve the philosophy of "first time right". This led to the birth of the initiative.

Some of the key features of the initiative were as follows.

1. Buy-in right from the top (Management Council of the company and the Chairman)
2. Covering the entire organization (not just select BU's or departments)
3. A strategic re-design of the product development process (not just a Band-Aid solution for a point problem)
4. Involvement of the stakeholders from across the board and all the sites of the Company – from the Corporate headquarters to the manufacturing locations

Phases:

The chart below explains the various phases in the journey.



In subsequent sections, we shall describe the activities taken up during each of these phases and the major accomplishments of the initiative.

Pre-Assessment:

During the early days of the initiative, PMSoft initiated a pre-assessment to understand the current state of competency and perspective in the client organization. This assessment was based upon PMSoft's proprietary PMDisha® model. Some of the important findings of the assessment were as follows.

1. The organization was at the PRIMARY, i.e. the most rudimentary stage of PM competency.
2. However, the perspective of the organization was that they were at ACTIVE or PROACTIVE stage (in different business units).
3. The perspective of the Senior management was much lower than the team members, i.e. the management seemed to be more conscious about the lack of the competency than the team members.

Individual as well as organization level reports were prepared on the basis of this assessment. After the assessment a detailed roadmap was drawn up that described specific actions that were required to enable progression from the current to the desired level. This formed the scope of the initiative.

Discovery:

During the discovery phase, PMSoft consultants visited all the corporate and manufacturing locations to get a hands-on understanding about:

1. The types of projects and other activities taken up at different locations in different BU's
2. The current methods used for managing the end-to-end life-cycle of such activities (the "As-Is" process)
3. The roles and responsibilities of different stakeholders
4. The current good practices
5. The current challenges and issues

After the discovery phase, detailed reports summarizing all these issues were presented. These served as the input to the next stage – the design of the "To-Be" or desired process.

Some of the salient observations from the Discovery were as follows.

1. There was no documented process or measurement systems in place for even the mainstream business activities (e.g. filing a DMF, completing a Contract manufacturing order, etc.).
2. Due to strong functional structure, there was no focus on the product development activities. There was no single person or department accountable for the commercialization or success of the products.
3. There were significant delays in the launch of products largely due to rework caused by lack of adherence to good practices of development.
4. Though there was no lack of technical or domain expertise, the results were not in line with business plans.

Process Design:

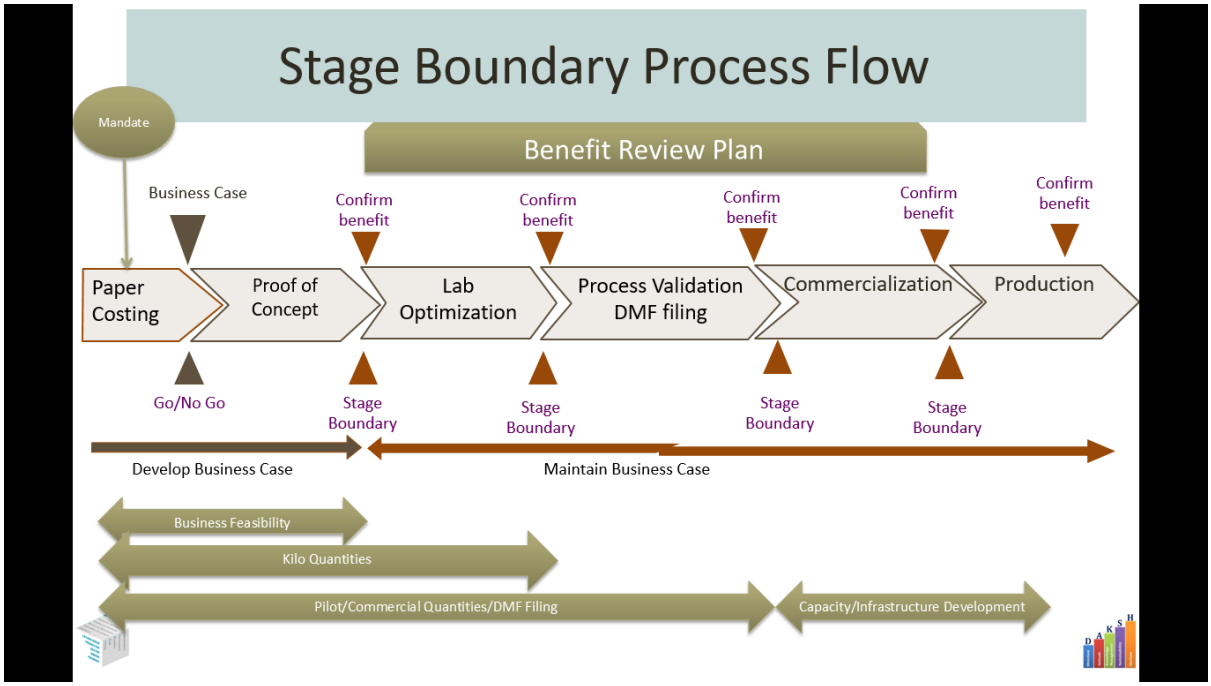
Extensive workshops were conducted with the senior departmental leaders to determine the desired process. These included representatives from:

1. Research and Development (Synthesis as well as Analytical)
2. Technology Absorption Team
3. Operations

4. Quality Assurance, Control and Regulatory Affairs
5. Finance and Procurement
6. Business Development; etc.

There are two parts of the evolved process. The Development Process describes the development life-cycle and the Management Process describes how overall control will be exercised over the life-cycle.

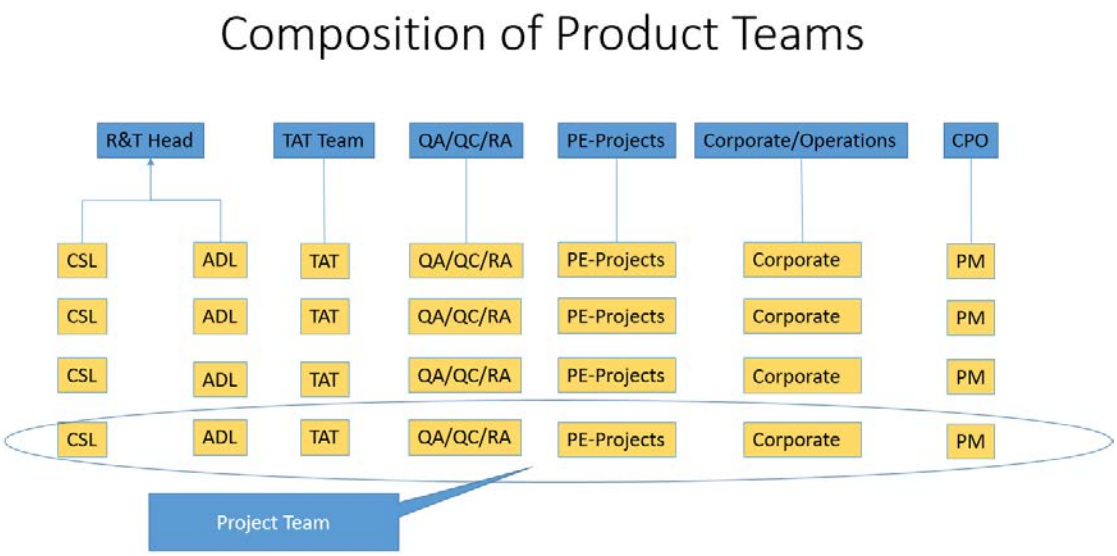
An example of the depiction of the overall process and control for New Product Development in the Pharma business is given below.



Some of the key differentiators of the "To-Be" process are as follows.

1. **PRINCE2 ® based process.** As the client is an international company and works with global clients. It is important that it chooses a process framework that is globally recognized. The process is based upon the PRINCE2 ® framework. This provides a solid theoretical foundation that was then tailored for the client.
2. **There is no "one size fits all" process.** Based on our study, we identified 6 different project types and each has different development processes and stages associated. For example:
    a. *New Product Development:* Process development for a new API or Active ingredient that will result in the filing of a DMF or Registration
    b. *CDMO:* Delivering either a process or a sample or commercial quantities of an API or active ingredient based upon a customer received order and Tech Pack
    c. *Plant Modification:* Creation of a new plant or modifications to an existing plant for accommodating a new process
    d. *Improvement:* Modifications to an existing process to improve cost, yield or other parameters
    e. *Commercialization:* Scaling up an existing process to commercial scale and transferring ownership to Operations
    f. *Infrastructure:* General infrastructure improvement projects either related or unrelated to existing product or group of products

3. **Focus on Products – not Projects.** The core business of the organization revolves around products. In the quest for project excellence, the focus on products should not be lost. Projects play an important role – but represent only a small part of the product life-cycle. Hence a key decision was taken to develop Product Managers – not Project Managers.
4. **Setting up a Central Product Office.** A formal structure called the Central Product Office was set up in order to set up end-to-end accountability for products. For each business unit a Product Owner was appointed who would lead the team of Product Managers. The picture below indicates the structure of the CPO.



The team for a specific project would come together for a specific duration comprising of experts from different functions. The Product managers would manage all the projects that form the product life-cycle – all the project types described above.

5. **Emphasis on continued business justification.** Organization undertakes projects in order to realize business benefits. The business benefits have to be clearly articulated in the beginning in the form of a business case. The business case has to be formally approved by the senior management. Further, at every stage, the validity of the business case has to be confirmed as indicted above. If the business case is invalidated for any reason (e.g. change in business environment, inability to meet cost targets, technical difficulties, etc.) then the continuation of work on the product has to be questioned.
6. **Creation of explicit stage boundaries for exercise of management control.** In accordance to the PRINCE2 ® principle of managing by stages, the To-Be process establishes development stages for every project type. The stage boundary provides an opportunity to formally collate the outcomes of the previous stage, get all the stakeholders together to discuss the outcomes and confirm the business case as mentioned above.
7. **Application of Agile principles – unique in the industry.** In the Pharma and Crop industry, some of the stages may be fairly long – often running into several weeks and months. Application of principles from Agile methodologies like Scrum allow breaking up each stage into shorter milestones called Sprints. Each sprint will be of 1-3 weeks duration, with a specific set of targeted outcomes. At the end of the Sprint is a Demo, where the outcomes from a Sprint are discussed. This helps in setting up frequent checkpoints within a stage. These practices helped build Transparency, Feedback and Control on the product stages. Use of Agile techniques may be common in the Software industry but its application in the

Pharma and Crop industry is a unique practice that was successfully adopted at this organization.

8. **Development of an IT system for process discipline and tracking.** Just as an ERP (Enterprise wide Resource Planning) system manages the data and work flows of business processes, the client needed a system to manage the Product and Project management processes. As part of the initiative, an EPM (Enterprise Project Management) system was implemented. Some of the salient features of the IT system are as follows.
    a. The system is cloud based and accessible securely from anywhere with an internet connection.
    b. The workflows for all the six project types mentioned above are configured, reflecting the desired or To-Be process.
    c. It is based upon Microsoft EPM solution and accompanied by a Microsoft Sharepoint repository where all the historical references about specific products are archived – creating a searchable knowledge base
    d. It has custom built dashboards that means senior management is able to view important product information easily and from anywhere.

Process Roll-Out and Change Management

Any change has the potential to be disruptive and is likely to be resisted by the stakeholders. A major objective for the initiative was NOT to disrupt the day-to-day business of the organization and achieve a smooth rollout. Several specific actions were taken to make this a reality.

1. Change management was owned by a member of the Management Council and a steering committee was established which regularly reviewed progress at the highest level in the organization.
2. Involvement of the key stakeholders and functional leaders from both the Business Units was ensured from day one.
3. Roadshows were conducted at each location right in the beginning and frequently during the process to ensure everybody was aware what is going on.
4. A Management Development Program spanning over 4 months with 6 modules and offline assignments was conducted for about 30 team members chosen from both the BU's. Some of them went on to become Product Managers and Product Owners and others helped manage the change in their respective departments and functions.
5. A 2-day training on the Power of Teams to emphasize the horizontal and vertical structures was conducted covering about 200 team members at different sites.
6. A 4-day intensive functional managers was conducted to bring the key functional leaders on-board with the initiative.
7. Further workshops including IT system requirements capture workshops, IT system training, etc. provided opportunities to involve a large section of the team.

Audit and Handover

After the rollout of the process, the Product Managers and Central Product Office started rolling with the product and project initiatives. The IT system was also handed over to the client team and they began using it to document the projects and product information.

During this period, the PMSoft consulting team moved to the background, providing only advisory services and conducting offline and online audits to ensure that the principles of the system are being followed.

This 3 month period ensured that any challenges in assimilating the process in the real world are addressed smoothly.

Achievements

This has been a truly transformational initiative for the client and has already brought in some significant wins for the organization. Some of the early achievements and improvements we have already observed are the following.

1. **Cancellation of unviable projects.** At least 3 projects in the Pharma BU were cancelled due to the invalidation of the business case. By making them transparent, the initiative helped save precious resources and time that would have been otherwise been wasted.
2. **Reduction in overall product life-cycle.** By bringing in best practices in scheduling and management of constraints, the overall product life-cycle has been reduced by nearly 30%.
3. **Clearer prioritization resulting in limited WIP.** After the resources were mapped, some key constraints became apparent. This allowed us to prioritize projects so that critical projects were not starved of resources and conscious decisions could be taken.
4. **Faster Management Reviews.** The monthly project reviews have become much more focused as all the critical information is already present and known in the form of dashboards. This saves senior management time, allowing them to focus only on the exceptions and wherever decisions are needed.