



Technology Transfer Project in a Global Biopharmaceutical Company

A “young” biopharmaceutical company, with only one product already on the market, was experiencing difficulty in introducing new drugs to the market. With 12 products in various stages of product development in the pipeline, senior management needed to define a structured Technology Transfer process. The client engaged Tefen to work closely with cross-functional departments including: Operations, Research & Development, and Quality.

Challenge

Being a relatively new organization, the company was expanding by hiring resources from similar biopharmaceutical companies. This led to blending of different cultures and different understanding of how a Tech Transfer should work. In addition, it forced a solo mentality throughout the organization, where decisions were made within departments, as opposed to reaching a common organizational goal.

The client needed to: Define a standard process for Tech Transfer, create a governance structure for quick decision making, reduce cycle time to get the product to market quicker, and eliminate rework and multiple hand-offs.

How Tefen Helped

To understand the client’s needs, Tefen performed a diagnostic which included a review of past Tech Transfers to lay out the Process Map and analysis of documentation. After reviewing the documentation from the different

departments and individuals, Tefen was able to understand the activities that occurred over the past 2 years, present the actual scenario of the company based on data, and elaborate on the challenges that were ahead.

Tefen held a “Tech Transfer Vision” workshop with the client’s senior management to set a future vision for all tech transfers, which included robustness and phase appropriate transfer. Based on an agreed vision, Tefen worked closely with a cross-functional team, with representatives from 11 different departments.

A clearly defined path for each phase of Tech Transfer was defined. This included a definition of activities for each department, along with roles and responsibilities to ensure a coordinated completion of the Tech Transfer.

To ensure the process stayed on track, several Stage Gates at key milestones in the process were implemented. The stage gates included checklists and risk analysis to ensure the overall process met the preset goals. In this form, process governance was defined, along with decision making criteria, escalation, and setting of direction.

Tefen implemented its integrated Change Management model to ensure buy-in from the “doers”. The methodology links the soft people-adoption process and organizational change management aspects with the hard process improvement and project management aspects.

In addition to the Process and Project Management tools and methodology that Tefen implemented, the five soft-side considerations that Tefen helped define were:

Organizational Governance: Addressed the need for employees to understand the organization’s need, vision, means for change, measurable goals, accountability, and discipline.

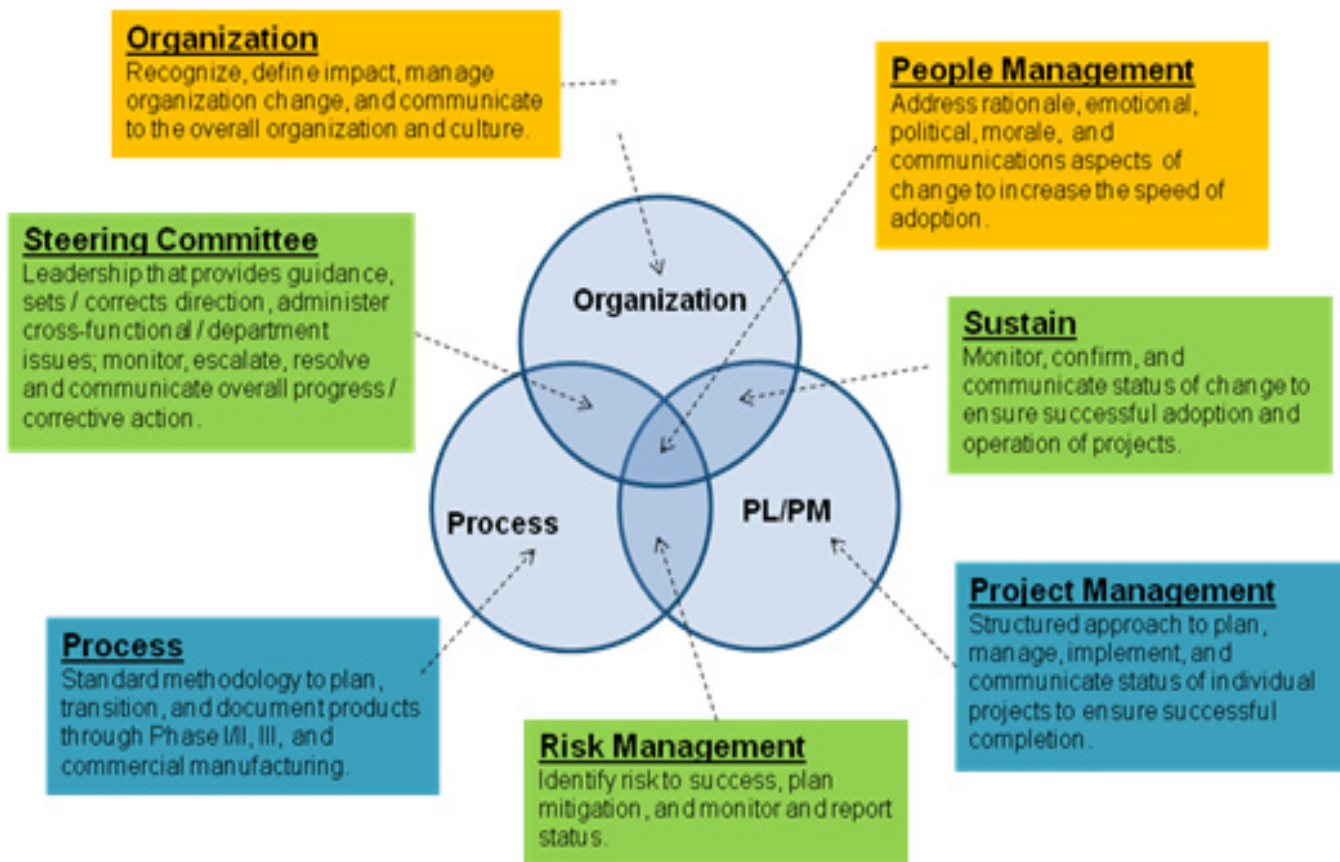
Culture Management: Tefen implemented actionable steps based on the adoption of the defined vision to overcome resistance to change.

Leadership: Commitment, as opposed to involvement, from the leadership team to manage the effectiveness of the Tech Transfer process. Responsibilities and roles were defined to ensure organization’s perception on target through program management, decision making, and effective communications.

Risk Management: As the Tech Transfer involved a cross-function team from multiple disciplines and cultural backgrounds, a people Risk management portfolio was developed. It helped Program Management reign in

on conflicts that inevitably arose during the course of the process, identifying critical change risks, developing mitigation, redirecting conflict resolution, and planning decision escalation early in the conflict period.

Sustainability: With a well defined process and governance in hand, it was critical to ensure the direction of the transition from current-state to future-state was maintained. Tefen helped build resource proficiency and controls to ensure the new Tech Transfer process was well grounded.



Performance Excellence Delivered

As a result of Tefen's engagement, the client saw a decrease in Tech Transfer cycle time by 25% on average. The client now had a well structured Tech Transfer process that was adaptable and scalable to the type of product and phase of transfer. This included the metrics and controls for measurement of success and an organizational governance process to support the vision.

About Tefen

Tefen is an international management consulting firm, committed to improving overall operational effectiveness for Fortune 500 companies around the world. The firm's main areas of focus include operations excellence, manufacturing, quality, customer service, research and development and supply chain management. With its "hands-on" approach philosophy, the company has achieved tremendous success in delivering quantifiable and value-driven results for its clients in a variety of industries, including healthcare, life sciences, general manufacturing, high-tech and financial services. All of Tefen's support programs are ISO 9001 certified. Tefen currently employs over 300 professionals worldwide.

For additional information, please contact:

Cristina Priamo, Marketing Associate

Tefen USA

(646) 652-8259

cpriamo@tefen.com

www.tefen.com

