## **Regulatory Affairs Resource Forecasting** Optimization



Vertical	Manufacturing Pharmaceutical	Healthcare Port			Government	Business
Genre	Case Study	Project Review			gy Overview	
Client	A global pharmaceutical organization					
Situation	The Worldwide Regulatory Affairs group for a global pharmaceutical company was mandated to find a resource forecasting solution that would yield reliable, repeatable, results throughout the organization. A variety of different practices previously used, were inaccurate and inconsistent. Also, in the past they needed to hire consultants at great expense to perform analysis during organizational expansion/contraction periods. The Regulatory Operations, Regulatory Strategy, and Quality Assurance groups within Regulatory Affairs required sophisticated resource estimating algorithms and tools to more accurately predict global resource requirements for work activities performed across all business zones. The resource models and associated data would provide the organization a way to better understand and substantiate existing and future resource requirements. This was a necessity in an environment where attracting premium resources is critical as are the successful continuation of the corporation's premium resource partnerships.					
Objective	Develop a reliable, consistent capability for predicting global resource requirements that can be used throughout the worldwide Regulatory Affairs organization.					
Results	ProModel and the Regulatory Affairs organizations developed models to predict present and future resource allocations. They were then able to consider different scenarios as affected by project management and portfolio changes, as well as other internal and external drivers. The models were then validated by Business Operations and supported by Leadership Teams in all three operation areas. Three out of five Business Operation Managers in Europe and the US were assigned to use the models. They were able to easily update the models as needed and continue to use them to determine future resource requirements.					
	Forecasted FTE Resource Demand	stration	Phase II End G		hase III	

Each bar in the chart above represents a snapshot in time of the entire project portfolio and each color represents the resource demand for the phase.

Forecast Time Horizon

Pre-Clinical



## Solution

Core work teams for each of the Regulatory Affaris functional business units, e.g., Regulatory Operations, Regulatory Strategy, and Quality Assurance were established. These teams, along with expert consultants from ProModel, raised awareness so that many colleagues representing about 20% of the global organization contributed to the project's work efforts. This ensured the development of robust resource algorithms and acceptance by the worldwide organization.

15 resource models were designed and developed along with the Excel data input organizers to support them. After conducting a series of information gathering sessions with project team representatives for baseline input data, portfolios, templates, and resource algorithms, models were constructed in ProModel's Portfolio Simulator application.

The client achieved its objective and ProModel continues to support and address development issues as needed. Therefore Business Operations Managers spend less time updating the models and more time using them to make accurate resource predictions. For example, some models have been consolidated into fewer models to decrease the Operation Manager's efforts required for model maintenance and updating.



## Multiple Scenario Comparison (data in graph in fictitious)

The chart compares two resource requirement profiles based on a major Regulatory Affairs reorganization. The re-organization required both a reduction in headcount and a reduction in the work portfolio. Simulated FTE requirements before the reorganization (gray dotted line) required more FTEs than the organization's capacity (gray line). This illustrates the organization was not going to meet all its obligations and the project planners were not properly allocating workload.

The orange scenario was the result of planners properly projecting project work while also reducing total workload to support a staff reduction. Simulated work (orange bars) more adequately represented what the organization's headcount could handle (orange line) based on a forecasted headcount reduction. Management felt the projects were reasonable and reliable further leading to Portfolio Simulator becoming a trusted forecasting application.