

Transforming R&D

Culture of Innovation Boosts Pipeline Performance

Challenge

Significant pipeline productivity challenges coupled with a complex quality system that bogged an eye care company down with administrative burden were also stifling innovation.

Solution

Quintiles first reduced R&D SOPs by 90%, realigning the remainder to match regulations more closely. Next, Quintiles worked with the customer to reorganize the business architecture to optimize performance.

Results

The customer achieved the desired transformation and streamlining of global R&D SOPs, paving the way for innovation.

Transforming Pharma R&D to Enhance Innovation

Against a backdrop of frequent, high-profile failures in late stage pharmaceutical development, the case for transformational change is clear. Today, only one-quarter of candidates in Phase II development advance to Phase III, and a further one-half fail to reach submission status. The U.S. Food and Drug Administration approved only 25 first-of-a-kind drugs in 2009.

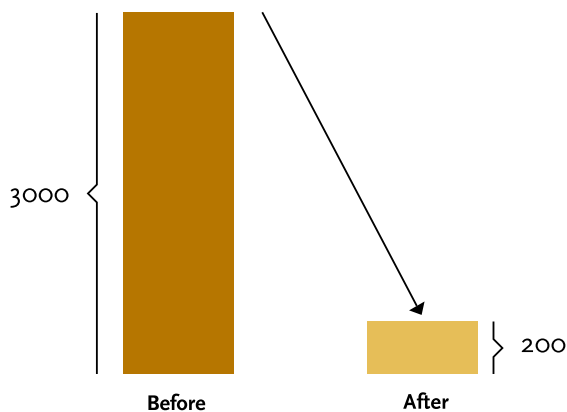
This decline in R&D productivity means that each candidate is increasingly important to the bottom line, so firms must maximize their pipelines' value and optimize portfolio performance. Evidence-based decisions on commercial viability must be made as early as possible, with projects demonstrating proof-of-concept continuing and non-viable projects being allowed to "fail fast."

Challenge: Reduce Complexity and Boost R&D Productivity

Quintiles' customer — a global leader in ophthalmic pharmaceuticals and medical devices — faced significant pipeline productivity challenges coupled with an overly complex quality system. This system handicapped the organization with administrative burden that, in turn, stifled productivity. The customer was looking to simplify processes, conserve resources and stimulate innovation.

Working with the customer, Quintiles launched a transformational initiative to redefine how the organization approached pipeline management, decision making, and the development lifecycle. This involved a top-down alignment of portfolio strategy, intersecting business and scientific processes, proof-of-concept constructs, and close alignment to regulatory requirements, thereby ensuring compliance, quality and risk management. For this customer, development processes, from pre-clinical sciences to commercial transfer, needed to be aligned as a continuous value chain. The focus moved to improving outcomes and ensuring the most judicious use of finite resources.

Streamlined R&D SOPs



Quintiles helped reduce the number of global SOPs for R&D activities from 3,000 to approximately 200, while ensuring regulatory compliance.

The outcome of the project has been a complete transformation of the R&D SOP management process and the streamlining of global SOPs. The customer is also transforming the entire R&D process based on an industry-leading model.

Solution: Novel Approach Accelerates Pipeline Performance

The solution involved reducing the number and complexity of Standard Operating Procedures (SOPs) to those needed to ensure regulatory compliance, while leaving scope for research excellence and innovation. There were two main phases:

Phase 1: Streamlined SOPs

In the first phase of the project, Quintiles provided a plan for SOP optimization to assess and transform the customer's quality system into one that was lean, improved operational efficiency and reduced compliance vulnerability. The number of R&D SOPs was reduced by approximately 90 percent, with the remainder realigned to more closely match regulated activities, improving process-driven compliance.

Phase 2: Reorganized Core Processes

During the second phase, Quintiles helped the customer develop and operationalize a pipeline strategy based on the concepts of "learn and confirm," coupled with solid quantitative measures and fact-based decision criteria. A reorganization of the R&D business architecture was implemented using industry-leading practices to optimize performance. Throughout this project, Quintiles created a global foundation of core business and scientific processes within multiple therapeutic areas and centers of excellence.

"Learn and Confirm" Approach Taken

Quintiles incorporated concepts from Lewis Sheiner's "Learn and Confirm" paradigm to accelerate pipeline performance. The paradigm encompasses a science-driven development focus to maximize medical value and reduce late-stage product failures. This approach served as the basis for a solution to improve the performance of our customer's pipeline.

One promising approach to manage R&D transformation is the use of a "stage-gate" model of governance, defining activities and deliverables required at logical intervals. These are then aligned to milestones, requiring evidence-based, proof-of-science constructs. The stage-gate model incorporates cross-functional components

and examines commercial, regulatory and quality variables. Without threshold evidence, the project should be allowed to "fail fast," freeing precious resources for more viable opportunities.

Results: Transformed R&D Architecture Maximizes Pipeline Value

Quintiles developed an optimized business architecture supporting the client's stage-gate model of governance. We leveraged a top-down approach to define value streams, including detailed activities, sub-tasks and capabilities contributing to deliverables needed for stage-gate decisions. The model tightly aligned regulatory requirements with operating processes, ensuring improved compliance. Major elements included:

- > Detailed analysis of regulatory requirements for written procedures, which allowed the number of global SOPs for R&D activities to be reduced from 3,000 to approximately 200, while ensuring regulatory compliance.
- > R&D process optimization that successfully incorporated tenets of "learn and confirm" into an optimized process model supporting our client's stage-gate model strategy.
- > Over 750 optimized processes were designed in the areas of research, pre-clinical sciences, Chemistry Manufacturing and Controls, manufacturing scale up, medical safety, medical affairs and regulatory affairs.
- > Development of this future state model comes from industry-leading practices that Quintiles brings to the customer, plus the customer's own current best practices, to yield a model that capitalizes on the strengths of both.

Our ultimate goal was to provide the customer's R&D with tools that minimized inefficiencies, while maximizing efforts to bring innovative products to market.

The outcome of the project has been a complete transformation of the R&D SOP management process and the streamlining of global SOPs. The customer is also transforming the entire R&D process based on an industry-leading model. This will dramatically improve efficiency, reduce complexity and enhance the overall success of their R&D pipeline.

1 Lewis B. Sheiner, M.D. UCSF. Learning versus Confirming in Clinical Development. *Clinical Pharmacology & Therapeutics* (1997) Volume 61; pages 275-291. Posted at <http://www.nature.com/clpt/journal/v61/n3/abs/clpt199717a.html>

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