

Bridging Data from Pharmaceutical Development to Manufacturing

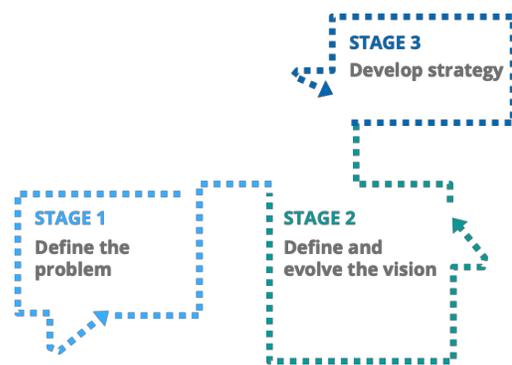
THE SITUATION

Traditional means of transferring a drug product from development to manufacturing along with the requisite information, involves significant formal, informal, and iterative communications. Business processes are not optimized to make the transfer straightforward. Neither development nor manufacturing systems are designed to support the transition. Information requires bi-directional translation rather than flowing in a smooth fashion. One global pharmaceutical company decided to prioritize this area, go after the problems, implement solutions, and turn deficiencies into a strategic advantage.

THE SOLUTION

The client engaged ResultWorks to help frame the problem, shape a shared vision, and develop a strategy that could be adopted and implemented across functional areas. First, the problem is not a new one. It is a challenge across the industry and often viewed as tech transfer issue. This thinking has led to an increase in focus on tech transfer without looking at the root cause issues. At the same time, most product teams are operating with “green lights” to move the product along as quickly as possible, usually with little consideration for how information will be used beyond the immediate need. This invariably leads to rework in the further use of the same data for different processes. So, in the first stage, a common definition of the problem was defined.

The second stage focused on defining and evolving a shared vision – that is, getting everyone on the same page. Too many previous attempts had been undertaken with bridges started from both sides never to meet. One vision; one bridge; one architecture was needed without the anchors of each



organization's current structures. The vision needed to transcend those current states.

In the third stage a strategy was developed which defined information-centric capabilities required by the business units with an architectural framework to deliver those capabilities in a concerted way. This approach considered a progression of needs and capabilities from data generation to information integration to business intelligence and analytics and decision making. Current technologies were accounted for in the architecture, while recognizing gaps in meeting future needs.

KEY BENEFITS

Characterized the Problem: Consolidated perspectives on the problems to be solved to get everyone on the same page with executive level support.

Shared the Vision: Developed a shared vision working across stakeholders was key to alignment of the organization leading to the change management focus necessary to solve the problem.

Defined the Strategy: The strategy accounted for gaps between the current state and where the organization wanted to go. Recognizing that nothing happens overnight, capabilities were planned incrementally in concert with an architectural framework with limited disruption to the business.

"ResultWorks has done a really fantastic job of helping us tell a coherent story and develop a strategy around issues that we have been grappling with for years. For the first time we can communicate what is needed in a way that is understandable."

- Global IT Leader

For more information, visit our website www.resultworksllc.com or contact us at marketing@resultworksllc.com.