

Designing a CMC Technology Strategy for Cell Therapy

THE SITUATION

A biotech company specializing in cell therapy was growing rapidly with a critical need to scale its IT infrastructure to support the business. The personalized medicine immunotherapy space is delivering a relatively new therapy platform. Manufacturing processes are rapidly evolving and the process has some unique characteristics and challenges. The concept of one batch being made to order for one patient means one set of batch records for each patient. The number of batch records and data needing to be managed can multiply rapidly even during the clinical trials phase when trials of only 50 to 100 patients are being run. There is also an imperative to ensure ironclad chain of custody (CoC) and chain of identity (CoI) tracking throughout the supply chain to ensure the manufactured product is transfused to the right patient. Since many of the business processes were evolving, technology solutions were difficult to plan. As a result, much of the CMC area was running on paper and spreadsheet stop-gap methods. The leadership team knew that they could not keep pace with so much of the business dependent on time-consuming and error-prone manual processes. They needed technology solutions across the enterprise and they needed to invest in the highest priority areas on a “first-things-first” basis. That is, they needed a strategy that they could execute against in a pragmatic way gated by the progression of the business.

“I wasn’t really sure what I was expecting to see today, but I wasn’t expecting this...This is awesome!”

– Global VP of IT

THE SOLUTION

The company turned to ResultWorks to create a strategy to outline the high-level business processes and to capture required business capabilities from the minds of the senior leaders who knew their issues and gaps, but just didn’t have the time to design, organize and drive a

program structured to scale the business. With limited documentation to rely on, ResultWorks met with leadership to gain further insight into their challenges and needs across the CMC area. The focus was on: demand forecasting, capacity and supply planning, order scheduling and management, inventory and warehouse management, manufacturing execution and critical production and quality parameters, end-to-end patient/product supply chain management and CoC/Col sample tracking, and overall integration of data for process development purposes. ResultWorks then documented a strawman future state environment with foundational CMC processes and key business capabilities.

The resulting high-level business process (generalized from the client environment) is shown in the Figure below. Each of these high-level process steps were detailed in successive layers of swimlane diagrams.



High Level Cell Therapy CMC Business Flow

Based on the definition of the future state business flows and capabilities, the company also needed an information management strategy to support the envisioned scale and to better leverage data generated throughout the cell therapy lifecycle. They needed to balance the need for significant short-term business improvement and ability to support near term milestones while providing a foundation for long-term business growth and success. To facilitate this, a high-level conceptual information architecture and data flow was designed to support the agreed business processes. This led to a prioritization of technical capabilities captured in an information management roadmap used to guide investments over the ensuing two to three years.

Subsequent efforts, based on the roadmap, focused on year-one technology projects commencing with detailed definition of requirements and conduct of corresponding solution selection activities.

KEY BENEFITS

Articulated Business Process: For the first time, the CMC business processes and data flows were cohesively articulated and documented. This provided a common reference for decision-making as well as a foundational training tool for consistent employee on-boarding.

Technology Strategy and Focus: The designed information flow, information architecture, and roadmap allowed for clear prioritization and alignment of technology projects to be undertaken. Follow-on projects were quickly mobilized to define detailed requirements, to conduct solution selections, and to implement those solutions.

Alignment: Gained alignment across the leadership team for a CMC vision and strategy supported by a pragmatic roadmap to make it happen.

"This is a damn good piece of work ...A
DAMN good piece of work!"
– VP of QA

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