



Compliance through Business Process Improvement and Agile Innovation

Summary

Through the implementation of a Process Management Discipline, a leading Biologics Company achieved a significant 60% improvement in documentation compliance. This improvement had a substantial impact on revenue, cash flow, and profitability, demonstrating the value of adopting a disciplined approach. The transparency provided by this initiative also facilitated agile innovation, allowing the company to adapt and respond to market demands more effectively.

Organization Background

A leading Biologics Company, known for producing high-quality products for medical lifesaving applications, faced strict compliance requirements for product handling and documentation. However, as the company experienced significant growth, manual processes and strict quality controls became unsustainable.

To address this challenge, the company recognized the need for automated systems and process management disciplines. By embracing technology and implementing a more robust framework, they aimed to enhance operational efficiency, maintain compliance, and sustain their commitment to delivering high-quality medical products.

Business Challenge

The Biologics Company encountered substantial delays in the shipment of their products due to issues with compliance documentation. As a result, the company had to allocate additional storage space to accommodate the delayed items, which had an adverse effect on their cash flow and revenue. Recognizing the detrimental impact of these inefficiencies, the company acknowledged the need for improvements in their compliance-related business processes, which were not only inefficient but also consumed significant amounts of time and resources.

Recognizing the need to enhance their compliance documentation-related business processes, the executives at the Biologics Company sought to standardize, digitalize, and improve these processes. They anticipated that such improvements would lead to a reduction in errors and inefficiencies. To address these challenges, the company reached out to us for guidance and clear directions on how to optimize their business processes.

The Solution

- Identification of Improvement Opportunities**
 Rapid As-is process analysis leveraging the SAP Signavio tool to identify what causes the compliance issues and define actionable improvement opportunities.
- Design of Innovative To-Be Processes**
 To-be processes were defined in Signavio addressing in improvement opportunities. They show in detail how the document-related non-compliance can be significantly reduced.
- Value-Packages as Basis for Pragmatic Realization**
 The required realization initiatives were defined in the form of “value-packages”, describing how the To-be processes were to be implemented. Core was the definition of a simple compliance application digital check lists and its focused use.
- Start of an Agile Innovation Approach**
 A short term To-be process scenario was complemented with a medium-term scenario for further improvement leveraging a combination of workflow and document management systems. This started the ongoing innovation process.

Results

- Process Innovation resulted in reduction of over 60% in document-related compliance issues in less than 3 months.
- Significant improvement of cash flows as well as strong impact on revenue.
- Process governance structure in place the ensures an ongoing improvement and innovation.
- Approach for agile process innovation defined that guides the process governance.
- Generation of “Process Playbook” out of to-bemodel to support change management, especially education about new process.
- Update of Business Process Management Playbook to reflect applied approach and use of the SAP Signavio tools.

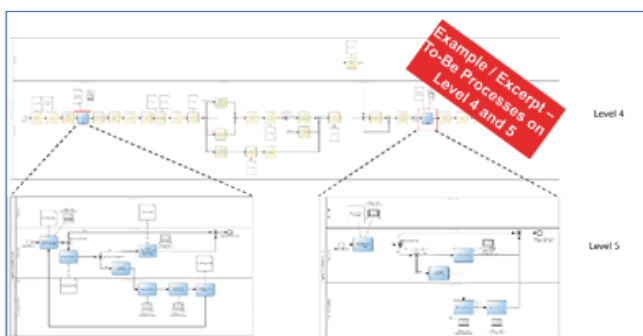


Figure 1: Example of To-Be Process Model in Signavio
 How innovative process components, supported through a new simple digital compliance application, deliver the required compliance

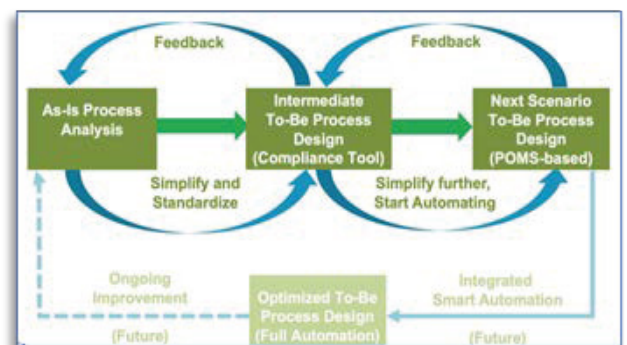


Figure 2: Value-Package Example
 The realization of the To-be process, based on the information from the To-be model.

Do you have questions on these subjects, or would you like to talk with us about specific projects?
 Simply send us an e-mail or give us a call!

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