

Annual Reporting: Process Transformation

Building consistent, complete, and compliant reporting for a multi-national conglomerate.

Our client, a medical device, pharmaceutical, and consumer packaged goods company with operations in more than 60 countries, was facing significant challenges meeting regulatory and legal expectations related to annual reporting.

With products in over 160 countries and more than 400 different regulating bodies, our client was on track to spend well over \$100M annually in reporting costs, leaving much opportunity for improvement, including:

1. Create standardized, holistic, regulatory-compliant reporting across matrixed business units
2. Simplify processes and governance for reporting functions

We analyzed the current state processes and quantified the business impact, including:

- Annual volumes with labor estimates
- Detailed analysis of regulatory requirements, synergies, and gaps
- Comprehensive SWOT analysis (Stakeholder 360)
- Systems and data mapping and analysis

Using these data, we grouped products, and then simulated and evaluated multiple process scenarios.

Ultimately, we designed a comparatively simple, standard, highly efficient, and robust process for creating regulatory compliant annual reports using existing systems and infrastructure. Worldwide implementation is gaining recognition as a potential industry best practice.



Success Measures

- \$21M reduction in resource allocation (annual)
- \$58M cost avoidance - people and systems (annual)
- 40% reduction in Pharmaceutical sector reports
- 60% reduction in Consumer sector reports
- 90% reduction in Medical Device sector reports
- 76% simplification of systems & software

The Challenges

- 1) With regulatory expectations evolving, our client was struggling with compliance under increased scrutiny.
- 2) Reporting was inconsistent, with varying levels of quality, and provided marginal business value.
- 3) The associated costs of data maintenance and report development had grown exponentially and was continuing upward.

The Solutions

1 Develop a simple, standard process built on the principles of effective, efficient value streams.

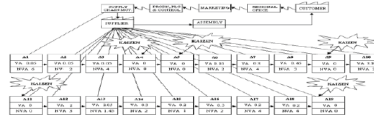


Figure 10: Future State Map

2 Identify the opportunity to group products within the parameters allowable by regulators to reduce the number of reports by more than 50%.



3 Redesign the content and format of the reports, setting specific standards that better-align to expectations and reduce complexity by as much as 93%.



4 By eliminating the need for more than \$20M of capital investment to deliver a workable solution, we minimized the cost of future automation through process improvement.

\$21M

Annual Report Volume & Cost

