

Industry

Manufacturing - Cosmetics

Employees

60,000+

“Trissential has been an integral part of the Data Integrity Program’s success. Our Partnership began in 2016 with the rollout of our Computer System Validation process which has now transitioned to Computer Software Assurance. Their knowledge of the compliance industry along with highly skilled resources has been key to many of our project deployments.”

- Executive Technical Director
of IT Compliance

Increasing Speed to Market and Reducing Costs with Computer Software Assurance (CSA)

Our cosmetics client is a technologically advanced, innovative company that has gained a worldwide reputation for elegance, luxury, and superior quality. The client’s products come with a promise to uphold the finest standards of excellence. This case study outlines how Trissential partnered to dramatically reduce costs and shorten the time it takes to get new products to market.

CHALLENGES

As a regulated organization, the client is responsible for validating and qualifying processes, systems, and equipment to comply with FDA standards for most of their products. After conversations with our client’s global compliance team, we determined the cost of validation and qualification was too high, business decisions were driven by fear rather than risk management, there was an inconsistent approach to validation across the enterprise, and validation and qualification was caught in unnecessary documentation, unclear roles and responsibilities.

SOLUTION

Trissential leveraged our CSA Playbook to launch a transformation effort centered around Validation as a Service (VaaS) within a CSA Competency Center. This strategy complies with the recent FDA guidance favoring a more risk-based, automated approach to validation and qualification. This led to critical thinking and pragmatism over documentation and aligned our client with people, processes, and technology globally. Highlights of Trissential’s solution include:

- Establishing a centralized Competency Center for consistent processes and technology
- Identifying clear roles and responsibilities to remove ambiguity and establish ownership
- Implementing the five foundational pillars of a Competency Center (Leadership, Services, Enablement, Organization Change Leadership, & Global Harmonization). This implementation included:
 - ◇ Overall vision, strategy, and roadmap for the transformation to CSA
 - ◇ Organization Change Leadership (OCL) to lead cultural readiness for implementing, optimizing, and sustaining transformational success
 - ◇ Delivering standards, guidance, governance models, and templates to improve validation control, integrity, and accuracy
 - ◇ Implementation of a value model to assess a project’s risk, scope, cost, and savings before project initiation
 - ◇ Providing training, coaching, and on demand subject matter expertise

RESULTS

The client is already reaping the benefits of the centralized CSA VaaS delivery model. We anticipate a 20% reduction in cost in 2023, and additional 15% in 2024, and 10% in 2025. The client’s savings on validation projects are dropping the regulatory burden on the teams, and increasing quality is due to the decrease of manufacturing risks.

