

Regulatory Compliance QA



Implementation of smart test practices improves test coverage by 50% and adherence to regulatory compliance in all product releases enables STAG to gain the trust and assist in all FDA audit of a leading compliance eLearning solutions provider.



Domain - e-Learning/FDA and CFR Part 11 Compliance



Technology - ASP.Net, SQL Server 2008, IIS, IE5.0 - 8.0, FF1.5 - 3.0, Safari2.0 - 3.0, Chrome, XP, Mac, Windows 2000/Win XP/Vista/Mac/Windows 7

CUSTOMER AND PRODUCT BACKGROUND

The customer, based out of the USA, is a pioneer in enterprise-wide compliance learning management solutions for companies in the pharmaceutical, medical device, healthcare, energy/manufacturing, and retail/service industries.

The product in question is eLearning software that leverages the SaaS/Cloud delivery model and is designed for the life science industry. Designed to meet 21 CFR Part 11 and Annex 11 requirements, the product serves as the one-stop learning repository for all FDA-regulated enterprises. The product readily integrates with critical compliance and business systems like EDMS, HRIS, and MES. It also supports different types of training: Computer-Based Training (CBT) that is SCORM and AICC compliant and includes 700 off-the-shelf modules, Instructor Led Training (ILT) that includes 200 instructor-led classes, and 5,000 custom courses. The product has more than 1 million users and is available in over 30 different languages. It is also available for mobile devices.

PROBLEM STATEMENT

The customer's two-member QA team was severely stretched in terms of meeting business demand and serving the clients better in deployment. The customer preferred the offshore testing option to increasing their internal QA team; however, the first attempt at using an offshore partner was not successful – the partner was unable to meet the customer's expectations in terms of FDA compliances and had to exit. The customer began to look for another offshore partner who could support their quality initiatives within the framework of regulatory compliance thereby enabling them to focus on product development.

SOLUTION

The initial scope was to execute all customer-designed test cases while adhering to the CFR compliances and then prepare and share a report. Since the product release cycle was fixed, we set up an internal knowledge transfer system that included structured learning for easy assimilation by new members. A 4-member team used the Interaction Matrix technique to prioritize test cases for execution, ensuring compliance and enabling scheduled product release by completing the QA cycle within the one-month cycle. Initially the client insisted on regular interactions with the STAG team; however, with the team's deliverables meeting all customer expectations, there was a gradual reduction in the number of interactions during the year, from daily conference calls during the first four months to weekly conference calls during the next four months, to calls purely on a need-basis during the last four months. At the end of the first year of engagement, there was a reduction in the number of non-conformance issues, detected during the FDA audit, from a pre-engagement number of 20 to just 7.

The second year of engagement saw an expansion in the scope of work to include designing of test cases for new product features and test execution, including regression testing. This led to identification of gaps in test cases and scenarios, which were then presented to the customer for coverage improvement. The team also provided support in four product releases during the year, and there was further reduction in the non-conformance issues detected during the FDA audit, from 7 in the previous year to 5.

The third year saw further expansion in the scope of work for the STAG team because of the increase in the customer's trust in our delivery capabilities. The team took complete ownership of all QA activities, including feature-specific releases (3 per year) as well as customer-specific releases (2 per year), re-adjustment of test cases, and testing of e-learning courses (120 of them) in addition to platform/customization-based needs. The team size was increased from 4 to 12. The reduction in the number of non-conformance issues detected during the FDA audit continued, from 5 in the previous year to 1.

During the fourth and fifth years, the scope of work for the team expanded further to include performance testing. The team automated 100 test cases using the RFT tool. Importantly, the team now began to extend FDA audit assistance to the customer by supporting them in furnishing audit-related documents. The team also designed customer acceptance test cases and supported the customer in interactions with their clients on quality-related issues. Non-conformance issues during this period remained at 1 and customer trust was strong.

The sixth year saw the team achieve customer buy-in on resource proposal issues provided there was no compromise on the quality of deliverables. The team's prompt response on all FDA audit-related issues left a strong impression on the customer.


OUTCOME AND VALUE ADDITIONS

There was a gradual progression in the customer's level of trust and confidence in the STAG team. This resulted in expansion of the scope of work and an increase in the length of the engagement – from merely executing test cases to becoming the extended QA team of the customer with the freedom to strategize, design, and execute test cases, and with complete customer backing in resource ramp-up, assistance in the FDA audit and ensuring complete FDA compliance of the product and making it highly audit-worthy. This resulted finally in a transition of roles for STAG, from just a vendor to QA partner.

The team set up an efficient internal knowledge transfer system that readied a new team member within two weeks. It strictly adhered to compliances and ensured the first scheduled release was on time, despite a 15-day handicap we inherited with the engagement. We have supported 18 product releases in all, 5 of them major.

By re-engineering test cases, it was able to improve the overall test coverage by 50%, bringing down the number of non-conformance issues from a pre-engagement high of 20 to a healthy 1 by the fifth year.


The customer was also able to monetize with their clients the customer acceptance tests that we designed. The team also assisted in all FDA audits and in customer buy-in for all quality issues, which resulted in new customer acquisition. Finally, the team also helped the customer support team in training their clients.


 # Test scenarios – added 3608

 #Defects – 970

 #Releases – 18
- # Feature updates: 7
- # Customer release: 11

 # Courses validated – 120

 # Languages tested – 2
(Arabic and Hebrew)

 # Documents created to support in client audits: 6