Center of Excellence & Software Validation Testing

Client

The customer's parent organization is a global safety consulting and certification company that certifies, validates, tests, verifies, inspects, audits, advises, and educates. The company is a leading provider of learning management system (LMS) for all GxP and non GxP trainings and manages and maintains their employee history for compliance.

Business Driver

Our customer's computer system application is used by 500 major companies worldwide leveraging 21 CFR Part 11 fully validated, with hundreds of thousands of employees logging in daily. The application is uniquely designed as a workforce training solution that meets both compliance as well as performance needs of a global workforce in regulated manufacturing environments. Their clients have learning and development programs managed by HR, compliance, quality assurance, sales, and other departments to organize, distribute, and monitor all training and qualification activities.

Scope of Service

- Set up a quality assurance and validation testing COE as the backbone for all validation testing needs of the software and computer system application.
- Set up offshore validation testing team and establish a knowledge base with a core team of lead resources who can further train new resources for ramp ups and downsizing based on varying demands.
- Ensure that validation testing meets the requirements and client's needs.
- Build a common QA framework so that planning/scheduling, monitoring and control, and delivery are streamlined.

Solution Highlights

- Marlabs built a team of highly skilled resources for validation testing.
- Reviewed the validation life cycle and implemented the change control process to move any code change to production.
- Extended the team to offshore with an onsite lead who managed the communication between offshore and onsite for all validation and testing activities.
- Based on Waterfall development methodology, an onshore test lead represented the QA team in requirement reviews, status calls, and other meetings, and conducted daily meetings with all offshore QA members.
- Marlabs validation team participated in all the phases of the development life cycle right from requirements review to product validations including design validation and test plans, design and reviews of validation, qualification and test criteria with business analysts, installation qualification and testing, operational qualification/integration and system testing of the computer application.
- Monitored and measured important efficiency and effective metrics, and also established daily/weekly/monthly status reporting structure.
- Easily ramped up additional offshore team during the major releases of the application supported by existing validation team leads.

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