Industry: Bio-Pharmaceuticals

Service: IT Compliance and Software Testing Validation and Verification

Background: A global bio-pharmaceutical manufacturer planned to streamline and harmonize their IT Compliance and Computer System Validation (CSV) services across the plants. The Compliance Management of GxP IT Systems, was being performed using non-integrated manual processes.

Business Issue: Manufacturing capacity growth required a cost-effective and speedy completion of CSV of the Process equipment, Laboratory Instruments and Enterprise applications in line with various regulatory requirements. The team was not ready for audit and many processes were not harmonized across the plants.

The Objective: Implement a harmonized CSV approach that reduces the turnaround time and meets the requirements of regulatory agencies including the U.S. Food and Drug Administration (FDA), Medicine and Healthcare Products Regulatory Agency (MHRA), World Health Organization (WHO) and European Medicines Agency (EMA).

The Solution: Qforce ensured the IT compliance through (1) Harmonized IT Compliance policies, SOPs and templates across the plants to ensure adequate controls were in place for CSV planning, Risk Assessment, Testing , Release and change control as well as data center security and operational controls. (2) Consolidated GxP IT System Inventory, which was maintained manually earlier, now made system driven. (3) Carving out the Network for protecting critical instruments from cyber-attack. (4) Implementing the procedures and controls necessary to assure an ongoing state of compliance. (5) Action on the equipment / applications which non-compliance to ER/ES and also pose cyber threat. (6) Creating culture of Quality and Compliance across the Organization

The validation deliverables included:

- Validation Plan
- User Requirements/Functional Specifications
- Risk Assessment (RA)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Requirements Traceability Matrix
- Validation Summary Report
- Vendor Audit Report
- Policies, Standard Operating Procedures, Formats/Templates/Checklists