ReliSource

Case Study

Cross Platform Enterprise Mobile Application

Background

ReliSource worked with a leading Pharmaceutical service provider to Develop a Cross Platform Enterprise Mobile Application and Lead the Qualification & Validation Efforts prior Launching in the market.

Return on Investment (ROI)

Actions

- FDA Regulations on Electronic Systems
- Prepared Validation & Qualification plan
- Conducted Verification alongside Product, Development & Test Team
- Performed both Device Qualification as well as Validation of Customized and COTS applications

Results

- **Faster Tiome to Market:** Product launch was possible in less than 8 months
- **Implementation of Industry Standard Tools:** Finished product contained industry verified tools than custom made tools
- **Better Document Control:** The internal regulatory team had better visibility in terms of Validation

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Validation & Qualification

Documentation

* Validation Plan (VP)
* Business Process Description (BPD)
* Functional Requirement Specification
* System Design Specification
* Configuration Specification
* Installation Specification
* System Test Plan
* User Acceptance Test (UAT) Plan
* IQ/OQ Results (Test Environment)
* System Test Scripts (AST/MST)
* Incident Report Forms (IRF)
* UAT Scripts
* System Test Results + Evidences
* UAT Results + Evidences
* Test Summary Report (TSR)
* Release Notes
* Release-to-Production Memo
* IQ/OQ Results (Product) & IRFs
* Validation Summary Report (VSR)
* Qualification Summary Report (QSR)
* Design/Installation/Operation /Perfomance Qualification (DQ/IQ/OQ/PQ) Scripts