

THE CHALLENGE

WebOps needed to complete the initial software validation testing for their medical device logistics software product in under five months. The effort included the development of related validation procedures and all software validation documentation.

Time was a critical factor, so WebOps looked to Indigeny to:

- Develop Quality and compliance procedures for a software validation program
- Perform full life-cycle software validation execution in under five months
- Prepare for top-tier customer vendor audit of the validation effort

APPROACH

Indigeny's Validation Execution Onsite-Offshore service brought computer system validation expertise as well as industry compliance expertise and partnered with WebOps to:

- Develop internal Quality procedures: Quality policy, software development life cycle(SDLC), validation, document management, and change control in less than 8 weeks
- Author validation deliverables: Validation Plan, Installation Qualification(IQ), Operational Qualification(OQ) tests, and Performance Qualification(PQ) tests including both web and PDA platforms
- Execute OQ testing, including all reviews for both web and PDA platforms in an onsite-offshore model that lowered costs and increased efficiencies in the process Performed key internal quality reviews of validation deliverables and WebOps processes to prepare for top-tier customer vendor audit

RESULTS

In less than five months, Indigeny delivered:

All software validation deliverables (Validation Plan, IQ, OQ, PQ) for both the PDA and web platforms Over an estimated 60% cost savings for software validation compared to U.S. only resources High-quality WebOps validation deliverables and Quality procedures that successfully passed a top-tier WebOps customer vendor audit