TekNirvana
Making technology bliss a reality

Case Study

Health IT Enterprise Architecture & Systems Integration

End Client

An innovative and leading Telemedicine Solution Company

The Challenge

Our client needed to detailed system architecture documentation in order to get their flagship Telemedicine solution through the FDA 510K approval process. Without this approval, our client would not be able to expand its market reach to hospital and care providers across the nation.

Our Services

- ✓ Strategy and IT Enablement → IT Program and Project Management
- ✓ IT Advisory Services → IT Infrastructure & Architecture Assessment
- ✓ Operational Excellence→ Process Analysis, Design, & Improvement

Our Approach and the Results Achieved

TekNirvana, as the prime vendor, provided the client assistance in performing systems analysis and documentation related to the Telemedicine System, an object-oriented, hosted system comprising of a Java codebase and associated data models. The analysis and documentation were done in accordance with the requirements outlined by the Food and Drug Administration (FDA) for the 510(k) submission and included requirements specifications and detailed design documentation for the entire system and code level documentation identified high risk areas. We implemented an architecture analysis methodology/approach based on the "4+1" Rational Model to analyze and document the architectural, design, and implementation details of the Telemedicine System. The "4+1" model is an industry standard, best practices based approach for describing a software architecture using five different views or perspectives of the system. TekNirvana worked with the client to ensure that the artifacts mapped to FDA required documentation. We also worked with the client to identify and create additional documentation required by the FDA, which was not appropriately covered by the "4+1" model. We managed the project in accordance with project management best practices based on PMI's PMBOK. All project deliverables were produced in accordance with the FDA guidance on software validation for the 510(k) submission. We fully and consistently delivered services on-time, within budget, and to the expectation of the client, which is why the client increased the initial scope of the contract by almost two months to provide additional documentation. In fact, on several occasions, the CTO of the client organization complimented us on the quality and thoroughness of our deliverables. All deliverables were on time and there were no delays in submission.