



PROJECT MANAGEMENT SOLUTION HELPS DIAGNOSTIC SYSTEMS COMPANY PREPARE FOR FDA APPROVAL

- SITUATION:** We met with the CEO and his management staff at an emerging, entrepreneurial Diagnostic Systems company. They had a concept & prototype of one diagnostic machine, the key component to their system, but did not possess the engineering processes and resources to engineer, design, document, and build an intended use device for FDA clinical trials.
- CRITICAL ISSUE:** Our client company required alliance with a company that could quickly identify, qualify, and provide engineering personnel with superior technical backgrounds and 3-D CAD tools experience.
- REASONS:** In subsequent meetings with the CEO and his staff, it became clear that our client was lacking the resources to quickly identify qualified individuals and also sought the advantages of the variable costs provided by Sterling's Engineering and Staffing Services.
- VISION:** The CEO stated that they wanted an alliance with a company that could deliver a managed solution, including project management, supervision, and reporting. In addition, Sterling was to provide recruitment of support personnel, including thorough background research, fair compensation, and a benefit package to minimize turnover.
- PROVIDED:** Sterling provided a Dedicated Project Manager who reported directly to our client's VP of Engineering. The PM, a hands-on design engineer, was also responsible for managing a group of four Mechanical/Product design engineers during the Engineering and Design Phase of the project. In addition, Sterling provided, on an hourly, contractual basis, a Design Checker, Model makers/machinists, Assemblers, Electricians, a Manufacturing Engineer, a Buyer, a Regulatory Compliance Specialist, a Quality Engineer, and an Incoming Inspector. Sterling also provided ongoing support for CAD, Network, and Desktop issues.
- RESULT:** The medical device has gone through clinical trials and has received FDA approval.
- SEI PROJECT #:** (129-DOC-025-(V1R1-CASE STUDY Project Management FDA))