# Acquisition Assessment and Remediation

## Our Client

The RND Group recently partnered with a leading medical device company who filled a portfolio gap by purchasing a niche software company in Europe. Their acquisition of this company included a large laboratory management software package.

The RND Group performed a GAP Analysis on their software development documentation to identify where their software was at, where it needed to be, and determine compliance with FDA regulations.

## Let's Talk About It

The Risk Assessment was leveraged to assure the testing methods were effective as well as efficient.

The RND Group leveraged the client's quality management system allowing for a seamless handover at the end of the project. All user needs, requirements and verification test cases were written and managed in JAMA allowing for efficient collaboration with a distributed team (Chicago, Indianapolis, Dallas and Milan Italy).

The project demonstrated that an existing product can be brought into line with the FDA documentation requirements. The RND Group's extensive knowledge of medical device standards allowed us to assess the gaps, develop a plan to address the deficiencies and execute the plan to bring the product into compliance.

With over 20 years of experience in regulated software engineering, we've built a heritage and reputation for building specialized software with precision and care. The RND Group can point with pride to products that have been successfully introduced into the medical device marketplace.

## SoftwareTechnologies

- Microsoft Windows 2012 Server — Target OS
- JAMA — Requirement, Test Case & Test Execution
- Oracle 11.2 — Target Database
- LIS2-A2 / ASTM 1394 — Laboratory Communications
- Oracle Virtual Box — Test Environments

## Capabilities Applied

- FDA Part 820, Part 11
- Requirements development and management
- ISO 13485, HIPAA, IEC 62304
- Software risk analysis and management
- Software life cycle processes
- Project management
- Software verification