



Full Lifecycle Software Development of IHC Slide Staining Instrument

At A Glance

Client / Summary

The RND Group has been working with an industry-leading testing company that provides lab automation solutions for immunohistochemistry (IHC) slide staining for pathology and research labs. The client engaged with RND Group to create the user interface and instrument control software for their latest sample preparation platform. The slide stainer allows high throughput slide processing, continuous loading, and minimal user interaction for a high degree of lab automation. These features enable labs to operate efficiently.

Challenge

RND Group was tasked with creating new slide staining software combining the features of two separately existing solutions, one each for IVD and RUO. The project included integration with a new lab automation platform with expanded capabilities. The project was a precise fit with RND Group's extensive experience with lab automation, including robotics, liquid handling, and sample chain of custody.

Lab automation of the IHC process provides a significant improvement over using a manual process. In this system, slides are introduced in a few minutes, leading to a walkaway time of 4 to 5 hours. The system supports continuous loading to allow optimal workflow for the lab. Barcodes are used throughout to reduce manual entry errors and track consumables.

The existing documentation for the predecessor designs lacked critical details. Therefore, significant reverse engineering was required to elicit the requirements. RND Group assessed, planned, and documented the new design as an initial engagement. The planning and design were done using processes that comply with IEC 62304, a key component in meeting the FDA's 21 CFR Part 820 requirements. The final design was refined using an Agile process during the implementation phase.



Methods Employed

RND Group provided turnkey software development for the client, including requirements definition, software development, software verification, and project management.

RND Group designed and developed the lab automation software with the functionality for scheduling, operations multitasking, sample management, protocol management, label printing, HL7/LIS2-A2, and reports. The software development, including verification, followed RND Group's Quality Management System, which complies with IEC 62304.

With both IVD and RUO features merged into a single solution, the new sample preparation software provides better maintainability and robustness.

Solution

RND Group deployed a cross-functional team of software engineers, quality engineers, a technical leader, and a project manager to provide a complete outsourced software team. The team was staffed dynamically during the project duration with 2 to 10 internal RND resources to account for peaks and valleys in the schedule. The overall project was completed in approximately 14 months, including software verification.

The project completed by RND Group allowed the client to develop a new sample preparation instrument with updated features and higher capacity without staffing an entire software team. The new platform has a complete design history file for regulatory compliance (IEC 62304), increased maintainability, and historical reference.

Expertise Employed

- Software Project Management
- Software Gap Analysis
- Requirements definition
- Project documentation
- Software design
- Software implementation
- Software unit and integration testing
- Software verification
- Software Hazards Analysis
- FDA 21 CFR Part 11
- FDA 21 CFR Part 820
- IEC 62304
- ISO 14971

