Development of Next Generation Sequencing (NGS) Companion Diagnostic Device

Our Client

The RND Group recently completed a project with an industry-leading genomics company to develop an FDA-regulated Companion Diagnostic Device to aid in the identification of cancer patients who qualify for acceptance into clinical trials. The clinical trial's purpose was to test the effectiveness of a specific pharmaceutical drug in treating Diffuse Large B-Cell Lymphoma.

RND Group assisted its client in requirements defintion, software development, software verification, validation of software tools used for development, and provided guidance on QMS and Design History set up and usage. The project involved developing bioinformatics software on a Linux platform to process the geneomics data output produced by an Illumina MiSeqDx sequencer. RND Group wrote new software for results calculation algorithms, wrote formal automated tests for the results calculations, wrote a web-based user interface for managing sample preparation and results data, and verified the overall software solution.

Choosing RND

The RND Group was recommended to this genomics company by the sequencer hardware vendor, based on completing several previous successful projects for the hardware vendor

Full Lifecycle Services

The RND Group provided full life cycle software services for the project, including:

- Analysis
- Requirements definition
- Software design
- Software implementation
- Software unit and integration testing
- Software verification
- Software tool validation

Accelerating the Timeline

This solution leveraged RND Group's QMS system and 20+ year history of developing FDA-regulated software. RND Group was able to quickly adapt requirements and software architecture concepts from other projects to this project and, most importantly, provide guidance to the client's existing software development and verification teams. The clients existing software development and verification teams had no prior experience in developing regulated software, so the leadership and experience provided by RND Group was critical in getting the project delivered on-time and with all necessary design controls and documentation to accompany the software.

Tools Validation was performed by RND Group on tools used to support the client's Agile software development methodology. The tools validated by RND Group included GitHub and GitHub Issues, which are both cloud-based software tools.

Results

The result of this joint effort was a robust Companion Diagnostic Device that consisted of a combined hardware and software solution. The software project was completed using The RND Group's design control procedures which meet applicable FDA requirements.
With RND Group's assistance, the client completed a successful delivery of its first medical device and has since delivered other medical devices based on the foundation and education provided by RND Group.
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
Your project deserves a specialist.
Contact us to see how we can assist with your project here.

Capabilities Applied

- FDA Part 820, Part 11
- Results algorithm design and development
- Software risk analysis and management
- ISO 13485, HIPAA, IEC 62304
- User Interface design and development
- Project management
- Software validation
- Software life cycle processes
- Requirements development and management
- Software verification

Technologies Used

- Python and Python/Django on CentOS Linux
- Postgres Database
- Illumina MiSeqDx software interface
- VmWare
- GitHub and GitHub Issues for Agile development

Software

- Python language for results algorithms
- Python plus Django for UI development