

case study: Randstad Engineering develops “safety critical” medical device

results at a glance:

problem: The client needed an experienced partner to develop the “safety critical” software for a new version of a therapeutic medical device they had been contracted to design and manufacture.

solution: They turned to the Randstad Engineering Services group’s extensive experience in designing, managing, and producing “safety critical” applications for a number of high-risk, regulated industries — including the medical device industry.

results: Even though the software for this project was recognized as the riskiest component of the project, an audit of the project gave the software team the highest possible score.

client profile:

Jabil is a manufacturing product solutions company that provides electronics design, manufacturing, and product management services. With over \$16 billion in revenues and 100,000 employees in more than 60 facilities in 22 countries, the firm’s customers span a variety of industries. This project was performed for the Engineering & Design Division, which is headquartered in St. Petersburg, Florida.

business problem:

Jabil was contracted for both hardware and software development for a new version of a life-sustaining, sophisticated therapeutic medical device. The type of medical device under development placed an emphasis on patient safety. The machine relies on “safety critical” software for all of its functionality — to manage the machine’s operations and, through a user interface, to provide information to the technician or physician operating the machine so that they might modify certain functionality during its use. Categorized as a “safety critical” product, Jabil’s customer had identified the embedded software as the highest risk component since the smallest error could result in a patient’s death.

In this highly regulated industry, Jabil needed a partner that understood the risks and knew how to manage the software development process. The Randstad Engineering Services group to which Jabil turned to for help, specializes in developing software for heavily regulated industries such as healthcare.

the Randstad Engineering solution:

Randstad Engineering resource based solution had a two-phased approach. In Phase I, The Discovery phase, Randstad Engineering software engineers worked side-by-side with Jabil’s project team to map out the scope of this effort. The Randstad Engineering team gathered extensive information such as the project’s requirements, the number of

existing lines of code, what had been tested to-date, and the status of FDA approval. Randstad Engineering then assisted with a comprehensive project plan.

In Phase II, Randstad Engineering's software engineering team worked collaboratively with Jabil's team in writing the machine's software. The project remained on schedule with a second software release and the machine went into production 6 months later.

After completing their first comprehensive audit evaluating all aspects of the project (hardware, software, manufacturing, Quality Assurance, etc.), grading each team with a score between 1, the lowest score possible, and 5 the highest, the software team, 80% of which is comprised of Randstad Engineering software engineers, was awarded a 5. Scott Boring, Jabil's project manager, took pride in the software team's score. "This is a great team and that is apparent to our customer. Their hard work, attention to detail, clear and frequent communication, and commitment to deadlines sets a high standard of achievement."

benefits delivered:

Jabil chose Randstad Engineering because of their proven expertise with "safety critical" software development, and their flexibility and scalability. Randstad Engineering was able to provide a significant number of experienced engineers to mitigate the client's aggressive schedule. The ability to quickly put together a team with precisely the skills demanded — and deploy them both on-site and in their own facility — has been invaluable to Jabil and their customer.

Working collaboratively with the Randstad Engineering team, Jabil can leverage this knowledge and expertise to further expand into the rapidly growing, medical device industry.

The Randstad Engineering software engineers provided a level of service that transformed what was the riskiest component of this project — into the highest rated — in just a matter of a few months.

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