

Ranier Technology Revolutionizes Product Development for Revolutionary Product (CAdisc)

PTC's Windchill® Medical Device Template improves project management, design control and regulatory compliance

Ranier Technology Limited, Cambridge, UK

Ranier Technology Limited is a medical device development company engaged in the research and development of polymer based medical devices, utilising proprietary Precision Polyurethane Manufacture (PPM) materials technology, with a primary focus on motion preserving spinal implants.

The Challenge: Achieve Regulatory Certification for its Lead Product on Time

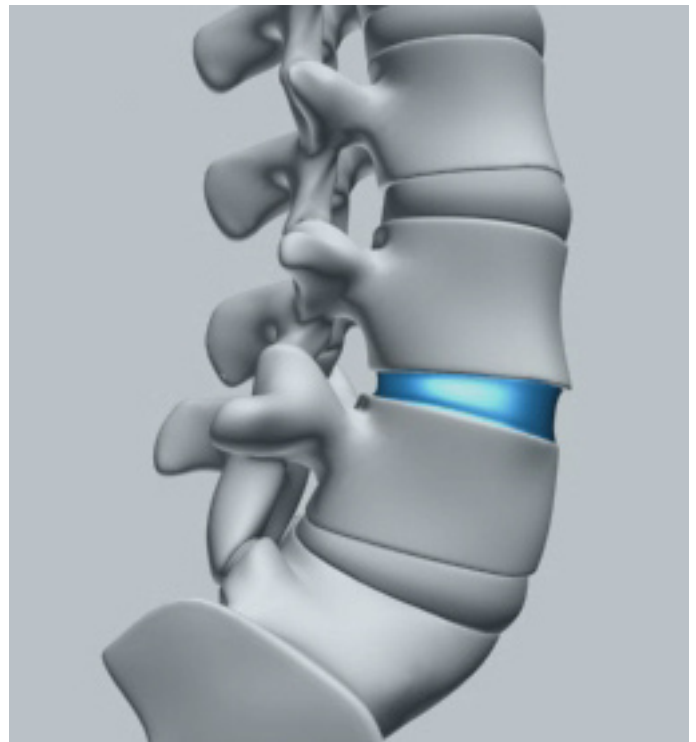
Ranier Technology's primary objective is to achieve regulatory certification of its lead product to a planned timescale and on budget. Delays in product development endanger project timelines which result in costly delays in releasing products to the marketplace. Therefore, the ability to efficiently manage product data, design history documentation and certification processes is essential. "Meeting critical project milestones and regulatory requirements is of utmost importance to Ranier Technology," says Rob Snell, Technical Director of Ranier Technology.

The Solution: Improve Project Execution with Windchill and the PTC Medical Device Template

Ranier Technology chose PTC solutions as its PLM backbone after an extensive competitive benchmark. PTC Medical Device Template combines leading industry-specific capabilities and consulting experience to effectively support the company's product development processes. With Windchill PDMLink™ and Windchill ProjectLink™, Ranier Technology can improve project management execution and manage design control and regulatory compliance of its patented Compliant Artificial spinal disc (CAdisc) replacement spinal disc implant.

The Results: Automated Processes Save Time, Improve Data Quality, and Ensure Regulatory Compliance

PTC Windchill technology enabled Ranier Technology to control regulatory compliance; improve communication and employee productivity; simplify the filing, tracking and finding of critical information; and use their PLM system as a 'Change Agent.' In addition, the system enables an effective and sophisticated means of transferring and integrating data with vendors and partners.



Ranier's Compliant Artificial spinal disc (CAdisc) is a next generation total disc replacement device which will offer significant improvements in biomechanics and durability.

“With PTC’s leading solutions supporting our extended product development team, we expect to enhance the opportunity for CAdisc to become a leading contender for the next generation artificial lumbar disc.”

- Dr. Geoffrey Andrews, CEO
Ranier Technology Limited

Ranier Outgrows its Existing System

Ranier Technology's manual homegrown system, built on a Microsoft platform that utilised file folders for storage, couldn't keep up with the project requirements of a complex regulatory environment. As a result, the company relied on extensive meetings to keep people informed, which was further complicated by increasing involvement from external partners in their critical path activities. Furthermore, as data capture requirements increased in later stages of the project, the old file folder system was beginning to become unmanageable.

Why PLM?

Primarily, Ranier Technology felt that a PLM system would help them create a solid infrastructure for optimising their CADisc development programme and their proprietary technology used in manufacturing processes. It would also help minimise risks that were introduced by the bottlenecks and other constraints of their existing system.

"We wanted to automate regulatory compliance, improve communications, and simplify filing, tracking and finding critical information," says Rob Snell, Technical Director of Ranier Technology. "We needed to organise the workflow and use the system to assist in the cultural evolution of the company as it progressed from a technology developer into a manufacturing and sales organisation. We felt PLM would provide the necessary infrastructure to change the way people performed their jobs, allowing us to become a more structured and controlled organisation as we commence product manufacturing in the highly regulated medical device environment."

Why PTC?

"Meeting critical project milestones and regulatory requirements is of the utmost importance to Ranier Technology," said Snell. "We believe that the combination of Windchill with the PTC Medical Device Template will improve the project execution for our CADisc product development programme both internally and with external suppliers. It is the best solution to help us meet the requirements for compliance to strict design controls, device history file and regulatory requirements within the medical device industry."

The New System

Ranier Technology began with an implementation project for Windchill that enabled them to prove Windchill could comply with both European and U.S. regulatory requirements, automate workflows, improve management visibility and oversight, and enhance collaboration with external partners. They expect to achieve a 10 to 20% improvement in employee productivity and a complete audit trail for design development and documentation. They will also gain proficiency on the new system and capture data early enough to demonstrate full compliance to regulatory bodies by mid-2007.

Windchill PDMLink™ is used to store fixed data and ProjectLink™ handles data in the pre-approval stages. All of the project activity that was previously managed with the Microsoft folder structure is now managed in ProjectLink™. When specifications are finalised, the data is transferred to PDMLink™, which is the control mechanism for the quality system and Ranier Technology's design history.

The Medical Device Template in PDMLink™ adds critical capabilities to support the security, traceability, and automation requirements established by FDA regulatory codes including 21 CFR Part 11, which specifies how electronic data and electronic signatures must be handled. In addition, Ranier Technology customised some of the document templates in the implementation to suit their specific business processes.

Results to Date

Although the project is still in the implementation stage, Ranier Technology has already seen significant improvements in some of their processes and the way they interact with clients. The company is evolving in parallel with the system.

Windchill has played a major part in the company's evolution into a high tech manufacturing company, developing novel products in a highly regulated environment. "Windchill and our quality management system have really allowed us to build on a foundation, which has given us the main development and regulatory infrastructure out-of-the-box," says Snell. "It has accelerated the company's transition into a cutting edge manufacturing and regulated development organisation."

The Present Affects the Future

Another benefit of the Windchill implementation for CADisc is that it becomes a foundation for future projects. Most, if not all, future projects will be similar in their requirements for data management, workflow and regulatory approval.

The development of future projects will be accelerated significantly due to the Windchill infrastructure. Common data will be available to be shared among projects. Some manufacturing and test data are directly transferable so significant time savings are possible. Rather than creating a whole new document repository from scratch for each new project, they can link the new project to the common data, saving significant time and minimizing the possibility for transcription errors.

"By virtue of this project-to-project synergy, overall productivity improvements and time savings of 20 to 30% should be the absolute minimum achievable," concludes Snell.

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