Traceable by Design: RONNA's Compliance-Driven Innovation

How RONNA Medical is building an institutional-grade engineering backbone to support global growth, regulatory readiness and the future of surgical robotics.

RONNA Medical is a pioneering medical technology company headquartered in Zagreb, Croatia, dedicated to transforming surgery through advanced robotic systems. Founded in 2022, the company focuses on delivering submillimeter accuracy, safety and efficiency in minimally invasive procedures. Its mission is to empower surgeons with innovative tools that enable precise image-guided navigation across multiple clinical fields, helping healthcare providers elevate patient care and improve surgical outcomes.

Driven by a culture of innovation and collaboration, the company specializes in robotic surgical systems for neurosurgery and other high-precision interventions to meet the evolving needs of modern operating rooms. RONNA's multidisciplinary team comprises engineers and medical professionals committed to advancing neurosurgery in hospitals, surgical centers and medical research institutions across Europe. By pushing the boundaries of technology and human-centered design, RONNA strives to make precision surgery more accessible and impactful across all surgical fields.

Challenge: Laying the Foundations for a Scalable, Regulatory-Ready Organization

RONNA Medical made a deliberate, forward-looking decision to establish a globally scalable engineering foundation early in its growth. Rather than waiting for legacy systems to become limiting, the leadership team proactively invested in enterprise-grade product lifecycle management (PLM) and computer aided design (CAD) capabilities at the outset.

This early investment ensures long-term regulatory and organizational readiness, supports global expansion and creates a unified engineering environment built for scale. Central to this strategy is a robust design history and full traceability framework, which are essential for medical device certification and future regulatory submissions.

"We are building a globally scalable surgical robotics company, and that requires an institutional-grade engineering infrastructure," explained Dr. Bojan Šekoranja, Co-founder of RONNA Medical. "We made a proactive commitment to building the right foundation before rapid expansion introduced wide-scale complexity."

Solution: Building for Scale from Day One

RONNA partnered with EAG Center Technologies to implement PTC Windchill for product lifecycle and data management, and Creo for advanced 3D design of its robotic systems. Together, these platforms create a unified, secure, and traceable environment for managing product structures, design iterations and compliance documentation.

PTC was chosen not for its short-term ROI, but rather as a long term partner to support RONNA's growth and future readiness as it progresses into a much larger global organization.

Windchill provides end-to-end version control, design and development traceability, as well as structured audit trail across engineering decisions.

"Traceability is a huge part in regulatory readiness, and that's an important part of being certified," Dr. Šekoranja explained. "Everything has to be traceable, especially in the medical device industry."

Creo complements this by enabling high-fidelity modelling fully integrated with Windchill, ensuring every design iteration is captured and controlled. Together, these platforms form a long-term digital backbone designed for scale, regulatory rigor and sustained innovation.

Partner Spotlight

EAG Center Technologies – Technology Implementation & Solution Providing Company.

Since 2022, EAG Center Technologies, a trusted PTC Partner, supporting and collaborating with RONNA Medical. From introduction RONNA Medical with huge possibilities of PTC Creators Program till implementation of cutting-edge PTC solutions. With EAG Center Technologies experience in CAD and PLM implementation, RONNA Medical improve design processes and operational performance and as a Partners they created foundations for pushing the boundaries of technology.

With built-in support for regulatory traceability, Windchill allows teams to link design decisions to validation protocols, quality checks and audit trails. This not only ensures internal workflows remain streamlined but also simplifies external reporting for FDA and ISO compliance.

Creo empowers RONNA's design teams to create high-fidelity 3D models with precision and speed, while maintaining full integration with Windchill. Engineers can collaborate in real time, iterate quickly and ensure that every design meets both functional and regulatory requirements. Together, these tools form a digital backbone that proactively connects hardware and software development, reduced risk and accelerated innovation.

Benefits: A Traceability-First Engineering Backbone

Thanks to the leadership's long-term vision for growth and proactive investment in a unified digital backbone, RONNA Medical now maintains continuous traceability across every design iteration, demonstrates compliance readiness with confidence, and builds a regulatory-sound engineering history from day one.

"We invested in Windchill early because traceability is the foundation of a scalable medical device organization. It gives us confidence that every iteration, every change and every decision is captured in a way that supports our long-term regulatory growth," Dr. Šekoranja added. "It's not just about meeting standards or regulation requirements. It's about unlocking agility, accelerating innovation and turning complexity into a competitive advantage."

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> **Dr. Bojan Sekoranja, RONNA Medical Ltd**

This traceability framework is already essential for future certifications, audits and regulatory submissions. Centralized ownership, controlled access and structured versioning minimize friction and risk, ensuring teams operate from a single, authoritative source of truth. Engineers can explore alternatives and compare versions with confidence because traceability is embedded into every stage of development.

The digital backbone also reduces unnecessary rework and lowers the likelihood of errors, contributing to smoother, more predictable engineering cycles.

Looking Ahead: Scaling with Confidence

RONNA's Medical's investment in Windchill and Creo has laid the foundation for long-term scalability and resilience. As the company expands its product lines and enters new markets, this engineering backbone will support increasingly complex development cycles, regulatory requirements and global collaboration.

Looking ahead, RONNA plans to implement Windchill's advanced regulatory models as part of its deliberate phased adoption to leverage even deeper compliance and audit automation as the business scales.

The company is also investing in training and change management to ensure that teams across departments can fully leverage tools and workflows.

"Ultimately, our investment in our infrastructure is so much more than technology," Dr Sekoranja concluded. "It's about delivering better results for patients and providers while raising the standard of medical care."

By aligning engineering excellence with regulatory rigor, RONNA Medical continues to set new standards for quality, innovation and trust in the medical device industry.

Benefits

- **Compliance Readiness** - Supported by a complete, auditable design history
- **Regulatory Engineering Record** – Day one records for future certifications and submissions
- **Centralized Data Ownership and Access Control** - Reduces friction and operational risk
- **Structured Versioning** - Teams work from a single, authoritative source of truth
- **Unified Digital Backbone** - High-fidelity, fully traceable design workflows through Creo/ Windchill integration, connecting hardware and software development
- **Real-Time Collaboration** - Engineering teams have consistent, controlled data
- **Reduced Rework, Fewer Errors** - Smoother, more predictable engineering cycles
- **Scalable Engineering Infrastructure** - Supports global growth and increasing product complexity
- **End-to-End Traceability** - Traceability foundation across design and development that supports deeper compliance automation as the company expands
- **Long-term Platform for Innovation** - Enables model-based design, advanced simulation, and continuous improvement

Customer Overview | RONNA Medical d.o.o.

Headquarters	Zagreb, Croatia
Industry	Medical Technology
PTC Products	Windchill, Creo
Website	www.RONNA-medical.hr