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From Revvity

Interview - Sven Bajorat
Head of Division Quality Management and Regulatory Affairs EUROIMMUN AG

“Quality You Can Trust — Made in Germany at Euroimmun”

How does Euroimmun ensure compliance with strict EU IVDR regulations?

At Euroimmun, compliance with the EU In Vitro Diagnostic Regulation (IVDR) is not just a checkbox — it is embedded in our DNA. We’ve built a robust quality management system that complies with ISO 13485, MDSAP (Medical Device Single Audit Program) and other standards and is continuously audited by notified bodies and authorities. From product development to post-market surveillance, every step is carefully documented and validated. Our interdisciplinary teams work closely to ensure that all products meet the highest safety, performance, and transparency standards required by IVDR.

Why is compliance not just a legal requirement, but also a trust factor for laboratories and patients?

Compliance is the foundation of trust. Laboratories and clinicians rely on our diagnostics to make critical decisions, and patients deserve results they can depend on. By adhering to stringent regulatory standards, we demonstrate our commitment to reliability, safety, and ethical responsibility. It’s not just about meeting legal obligations — it’s about earning and maintaining the confidence of healthcare professionals and the public.

From your perspective, how does producing in Europe — under EU regulations and strict quality controls — strengthen trust in diagnostics and support the future of healthcare in Europe?

Producing in Europe means operating under some of the world’s most rigorous regulatory frameworks. This ensures transparency, traceability, and accountability throughout the entire value chain. At Euroimmun, our “Made in Germany” label stands for precision, innovation, and integrity. It’s a promise to our partners and customers that we prioritize quality over shortcuts. In a global market increasingly flooded with low-cost alternatives, our European production reinforces the value of sustainable, high-quality diagnostics that support better patient outcomes and a resilient healthcare system.

What sets Euroimmun apart from competitors, especially those outside the EU?

What truly sets us apart is our holistic approach to quality. We don't just manufacture tests — we build trust. Our products are developed in close collaboration with leading research institutions, and every assay is rigorously validated. Unlike many manufacturers outside the EU, we offer full regulatory transparency and comprehensive post-market support. Our commitment to continuous improvement and innovation ensures that we stay ahead of both scientific and regulatory developments.

What does "Made in Germany" mean to you personally, as Head of Division Quality Management and Regulatory Affairs?

To me, "Made in Germany" means responsibility. It means standing for excellence, precision, and ethical standards. It's about delivering diagnostics that healthcare professionals can rely on, and that patients can trust. At Euroimmun, we take that responsibility seriously, — every single day.

Meta Description
How does Euroimmun ensure compliance with IVDR regulations and build trust among laboratories and patients?
Read the interview with Sven Bajorat about the importance of "Made in Germany" quality in laboratory diagnostics and why European production is a guarantee of safety and reliability.

Keywords

- Euroimmun
- Made in Germany
- IVDR
- In vitro diagnostics
- Quality in diagnostics
- Quality management
- Medical device safety
- European Union regulations
- Production in Europe
- Trust in diagnostics