



## Matthias Bissig

Function	CEO / Senior Consultant
Education	Dipl. Masch. Ing. FH / NDS ETHZ BW
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### About me

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From 1998 to 2009 I worked as an Engineer and Project Manager for various companies in the medical device industry.

Since 2009, as a Senior Consultant, I have been supporting MedTech companies in setting up quality management systems, conducting audits, preparing technical documentations, implementing and carrying out post-market surveillance activities and communicating with international regulatory authorities for registrations and in vigilance cases, for example:

- Taking over the PRRC and RP (fvP) role at an importer, CH-Rep and distributor of medical devices and transplants.
- Implementation and maintenance of an ISO 13485 quality management system on SharePoint for a startup company, from scratch to certification.
- Evaluation and implementation of IT solutions for regulatory knowledge management including AI tools.
- Negotiations with Notified Bodies and authorities for a micro-enterprise regarding the classification and approval of a medical device.
- Supervision of a product development project of a class IIb device from the first idea up to the creation of the technical documentation and the successful CE registration.
- Remediation of the biocompatibility evidence for the entire product portfolios of international companies in the field of dental implants, wound treatment and medical equipment.

## Previous positions

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- CEO / Senior Consultant, inteQRA GmbH, Altdorf (2025 – today)
- Senior Consultant, Member of the Executive Board, inmedis GmbH, Zug (2009 - 2024)
- Senior System Engineer / Project Manager, Qiagen Instruments AG, Zürich (2005 - 2009)
- Project Leader, Mixpac Systems AG, Rotkreuz (2004 - 2005)
- CFD Engineer, Helbling Technik AG, Aarau (2002 - 2004)
- Research Associate, HTA Luzern, Luzern (1998 - 2002)

## Further education

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Continuous training in quality management and regulatory affairs, for example:

- Person responsible for regulatory compliance (TÜV Süd)
- Manager regulatory affairs international (TÜV Süd)
- Environmental management officer (Vorest)

## Expertise

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- Quality management systems ISO 13485 / 14001 / FDA QSR
- Technical documentations according to MDR
- Design and process verifications and validations
- Sterile packaging
- Risk management ISO 14971
- Biocompatibility ISO 10993
- Internal audits and supplier audits
- Person responsible for regulatory compliance (PRRC)
- Post-market surveillance and vigilance

## Languages

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- German mother tongue
- English fluent in spoken and written

## Strengths

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- In-depth understanding of all phases of product development including post-market surveillance
- Provides concrete and practical solutions
- Is versed with Office 365 and regulatory AI
- Well organized, works in a structured and reliable manner