MARCO MATTIUZZI, PhD

SENIOR MEDICAL DEVICE SOFTWARE ASSOCIATE

Marco Mattiuzzi has a degree and a doctorate in Physics from the Universita' Statale di Milano. Dr. Mattiuzzi has over 20 years of experience in the field of Research and Development, where he developed a rich experience in fundamental and industrial research. In his many roles, he has helped resolve scientific, engineering, and industrialization problems, providing a broad spectrum of technical expertise. He has led multiple software projects and has worked for Medtech and Pharma companies, including the development of firmware and stand-alone software for Class I, Class II and Class III devices.

Dr. Mattiuzzi is able to consult on all engineering and quality aspects of software development: planning, maintenance, configuration, traceability, risk, and usability, together with unit and system integration verification and validation. He also brings knowledge on the practical aspects of IEC 62304, IEC 82304, IEC 80002 in addition to the specific requirements for software related to ISO 13485, ISO 14971, and IEC 62366. He has also worked on quality system development for medical technology companies to help meet the requirements of the US FDA Quality System Regulation (QSR, 21 CFR 820) and the European Medical Devices Directive (MDD 93/42/EEC).

Dr. Mattiuzzi can help you with:.

- Implementing medical device software life cycle processes in accordance with international standards and FDA guidelines
- Adapting your internal software development model (V-model, Agile, Waterfall, etc) to quality management system needs and IEC 62304, IEC 82304, IEC 80002 standards
- Guiding your software engineering choices, taking into account quality and regulatory aspects
- Strengthening your cybersecurity and data privacy solutions for medical device software
- Managing software-related risks in accordance with ISO 14971 and IEC 62366
- Engineering your software to take into account usability requirements in accordance with IEC 62366
- Planning and running software product human factors formative and summative testing in accordance with