Medical Device Compliance

Validation of Medical Device Software

Technological and digital advances such as AI, mobile apps, smart devices and cloud solutions are transforming healthcare, creating significant opportunities for medical software developers (medical device software and stand-alone software). However, evolving regulatory requirements and standards such as the **MDR, IVDR, ISO 14791, ISO 13485, IEC 62304** and **IEC 62366** present increasing challenges.

Know more about our offering :

Software Life Cycle Management

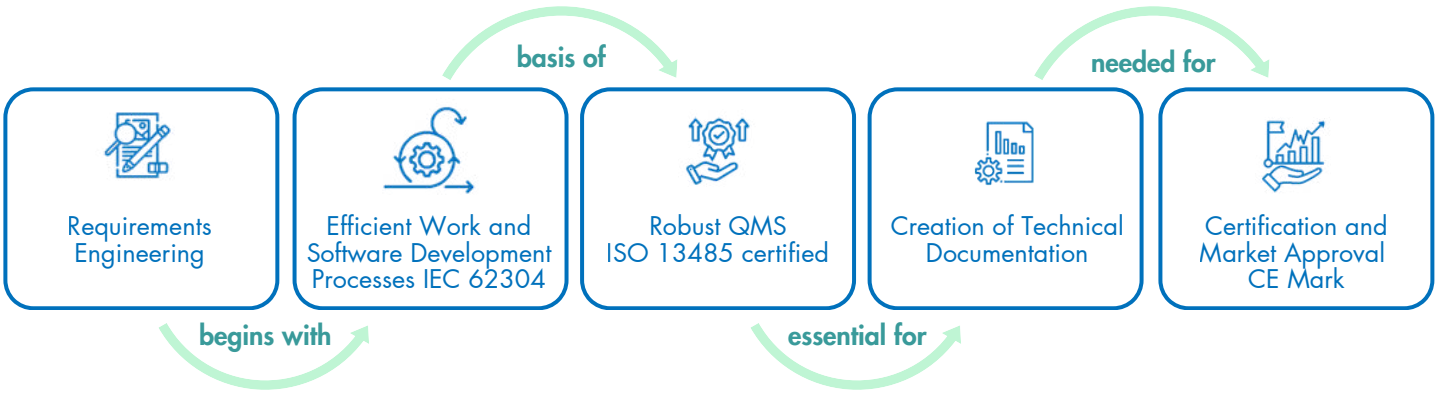
Quality Management System

Risk Management for SaMD/MDSW

Medical Device Cybersecurity

AI/ML Compliance

We support you throughout the software lifecycle with our regulatory expertise, allowing you to focus on developing medical software. Achieve CE marking for your medical device software by leveraging our in-depth knowledge of IT and regulatory processes in life sciences.



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360° Services in Life Science, Pharma, and Healthcare Informatics