Medical Device Compliance

Validation of Medical Device Software

Technology and digitalization in the healthcare industry are advancing rapidly. Combined with current IT trends such as AI, mobile apps and smart devices, cloud systems, etc., there are huge opportunities for **medical software** developers (medical device software and stand-alone software). At the same time, regulatory requirements and standards are constantly evolving **(MDR, IVDR, ISO 14971, ISO 13485, IEC 60601, IEC 62304, IEC 62366)**. Developing software that is compliant with medical device regulations is an increasing challenge.

We support you through the software lifecycle with our expertise in the regulatory field, allowing you to concentrate on your expertise in medical software development. You benefit from our extensive knowledge in IT and regulatory processes in life science on the way to the release of your certified medical device software.

We Offer:

- Compliance assessment/gap analysis of existing Quality Management and Software Development processes versus regulatory requirements
  - Requirements Management
  - Risk Management
  - Continuous Integration / Continuous Deployment
  - Test Management incl. Test Execution, Bug Management
  - Release Management / Change Management
- Establishment and/or orchestration of a quality management system according to ISO 13485
- Creation of a risk management process and moderation of the risk analysis according to ISO 14971
- Adaptation or creation of documentation templates
- Verification and Validation of Medical Device Software
- Validation of tools supporting the development lifecycle

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