MedTech

MD, IVDs, Combination Products

Asphalion provides comprehensive support during development, certification, registration and post marketing of Medical Devices, IVDs and Combination Products in Europe, US as well as other regions.

- MedTech Regulatory Roadmaps and Feasibility Assessments for Europe & US
- MedTech EU & US Classification Strategy
- MedTech EU Certification Procedure assistance: CE Marking (including selection and management of communication with Notified Bodies and Technical Documentation submission)
- MedTech EU Technical Documentation preparation, compilation and maintenance (General Safety and Performance Requirements Checklist, Benefit-Risk Analysis and Risk Management activities, Clinical Evaluation Reports, Performance Evaluation Reports, Pre-Clinical Testing activities, Labelling, Post-Market Surveillance and other Technical Documentation core-parts preparation and/or evaluation)
- Support for EU country-specific regulatory requirements (including assistance with local Competent Authorities communication, product registration, facilities licenses, etc.)
- Support in Eudamed registration (economic operators, UDI and devices)
- Assessment and training on 2017 EU Medical Device and In-Vitro Diagnostics Regulations requirements and regulatory impact
- Definition, development and implementation of Quality Management System (QMS) according to ISO 13485, US 21 CFR 820 and MDSAP
- Maintenance of QMS and annual audits programme (including ISO 13485, US 21 CFR 820, UK Medical Device Regulation and MDSAP)

Regulatory Roadmaps & Feasibility Assessments (EU & US)

Classification Strategy

Country Specific Regulatory Support

Conformity Assessment & CE Mark

Technical Documentation

Assessment & Training