Medical Devices

Scientific and Regulatory Services

Asphalion provides comprehensive support during development, certification and registration of Medical Devices in Europe, US as well as other selected regions.

- Medical Device Regulatory Roadmaps and Feasibility Assessments for Europe and US
- Medical Devices EU & US Classification Strategy
- Medical Device EU Certification Procedure assistance: CE Marking (including management of communication with Notified Bodies)
- Medical Device EU Technical File preparation, compilation and maintenance (Essential Requirements Checklist, Risk Analysis, Clinical Evaluation Reports, Pre-Clinical Testing activities, Labelling, Post-Market Surveillance and other Technical File 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.)
- Medical Device EU electronic submissions for certified devices
- Assessment and training on new 2017 EU Medical Device Regulation requirements and its regulatory impact

Regulatory Roadmaps & Feasibility Assessments (EU & US)

Classification Strategy

Country Specific Regulatory Support

Conformity Assessment & CE Mark

Technical Documentation

Assessment & Training

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