
episKey
MEDICAL CONSULTING
Service catalogue

Software as Medical Device

Software development plans, usability and validation

Commerce y registration

- Marketing in other markets
- Device registration
- Entry strategies in third countries

Clinical evaluation plan

- Clinical evaluation plan and performance assessment.
- Own methodology for the search for scientific evidence.
- Search for the best clinical strategy for market launch

Administrative formalities for medical devices

- Administrative management of dossiers with Health Authorities, EU and other actors
- Actors registration at EUDAMED
- Review of contracts with suppliers, critical subcontractors or Authorised Representatives

Quality management systems

- Quality management system tailored to your circumstances
- Internal audits
- Initial status analysis
- Accompaniment in audits

Tecnhical Files

- Complete technical documentation
- Post market surveillance

Clinical research

- Supervision and Management of Clinical Investigations with Medical Devices
- Supervision and Management of Clinical Performance Investigations for IVDs
- PMCF
- Preclinical research: BER, identification of evidence and trials
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Annex XVIDevice

- Trial identifications
- Preparation of technical and quality documentation

Regulatory strategy

- Regulatory feasibility studies
- Cost studies
- Entry strategies in third countries
- Commercialisation in other markets
- (FDA, TGA...)
- Device registration

Our mission

We help medical device manufacturers and their supply chain to understand and comply with all health regulations applicable to their products.

Ours values

- Quality
- Rigour
- Integrity
- Work rsponsibility
- Competitiveness and innovation
- Continuous improvement

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