EU-MDR 2017/745

The marketing of your Medical Devices requires control of your Technical File, and Quality Management System. We propose:

SOLUTIONS ADAPTED to EU requirements for a CE mark:

Compliance with current ISO standards including 13485, 14971, 10993 and other guidelines MDGG

Transition to compliance with the European Regulation MDR 2017/745

SUPPORT throughout the lifecycle: from the development to the marketing of your medical device, as well as all maintenance activities and post-market surveillance:

Positioning of your medical device: rules, classification

Strategy and regulatory/normative monitoring

Assistance to development: *Product Spec Design*, specifications, audit, coordination with your subcontractors

Preparation/maintenance of Technical File documentation : product life cycle, plan/risks management report, Clinical Evaluation Plan/Report (CEP/CER), Biological Evaluation Plan/Report (BEP/BER), Post-Market Surveillance (PMS/PMCF) Plan/Report, PSURs, Documentation for Price/Reimbursement for France with *HAS.*

Support for the Implementation / Compliance of your Quality Management System: document management, training, audits, management of complaints, change controls and other non-conformities.

We work alongside our clients in the development of their QMS and the CE-mark registration of their devices; we liaise with the Notified Bodies during audits and any follow-up procedures.

PHARMACONSULT
PART OF A-CONSULT GROUP

CRÉDIT IMPÔT RECHERCHE AGRÉMENT CIR

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