KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

MEDICAL DEVICE SERVICES:
MDSAP AND EU MDR / IVDR COMPLIANCE

CUSTOMIZED TO MEET YOUR NEEDS

- Choose the level of support you need to meet changing international regulations.
- You will have an assigned Account Manager and direct access to consultants supporting your project.

READINESS SERVICES INCLUDE:

- Development of Site Compliance Plan with consideration of impact to Design, Manufacturing, Suppliers, Sales / Marketing, Distributors and Global Product Registrations
- Leadership and / or support for teams in support of compliance plan
- Gap Assessment to applicable regulations, including, but not limited to (dependent on product and site activities):
  - US - 21 CFR 820, 803, 806, 807
  - EU: ISO13485:2016, EU MDR / IVDR
  - Canada – Food and Drugs Act R.S.C., 1985, c.F-27, CMDR SOR 98-282
  - Australia – Therapeutic Goods Act 1989, Therapeutic Goods (Medical Devices) Regulations 2002
  - Brazil – ANVISA RDC 185/2001, RDC16/2013, RDC 25/2009, RDC 67/2009, RDC 23/2011
  - Japan – MHLW Ministerial Ordinance No. 169
- Assistance with required quality system updates
- Employee Training
- Internal and Supplier Audits
- Mock MDSAP audit
- Verification of product classification to new EU MDR / IVDR
- Technical Documentation gap analysis and updates, including Clinical Evaluation Plan development, Clinical Evaluation Report (CER) development / revision and Summary of Safety and Clinical Performance requirements (SSCP).
- Labelling updates (including UDI requirements)
- Post Market Clinical Follow-up Plan and Reporting (PMCF)
- Post Market Surveillance Plan and Reporting (PSUR / PMSR)
- Support during ISO13485, MDSAP and CE Mark audits
- Assistance with audit follow-up activities / CAPA

EFFICIENCY

COMPLIANCE

EXCELLENCE

Safis
MEDICAL DEVICE SERVICES
A ➤ PHARMALEX Company

Ask us about our other QA /RA Consulting and Outsourcing Solutions

CONTACT US

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