AlfaNordic

MEDICAL DEVICE

FROM IDEA TO PATIENT AND STAYING IN COMPLIANCE

OUR INSIGHTS

- ✓ Compliance with ISO 13485
- ✓ Compliance with FDA 21 CFR Part 820
- ✓ Compliance with MDD, MDR, IVD & IVDR
- ✓ Combination products
- ✓ Regulatory Strategy
- ✓ Marked approval incl. CE Marking and 510K
- ✓ Clinical evaluation
- ✓ Design Control
- ✓ Unique Device Identification (UDI)
- ✓ Risk Management / ISO 14971
- ✓ Product & Process Validation (IQ, OQ, PQ)
- ✓ Software validation
- ✓ Change Control
- ✓ Internal & External Quality Audits
- ✓ Complaint handling & NC & CAPA
- ✓ QP – Qualified Person(s)

YOUR BUSINESS PARTNER THROUGH THE ENTIRE LIFE CYCLE OF YOUR MEDICAL DEVICE.

CLIENT ADVANTAGE

AlfaNordic delivers first class quality through educated people with experience within the Medical Device area.

Medical Device consultants who have the competences needed for the specific challenge through the entire product life cycle.

WHY US?

- Specialists in all MD classes (I, II and III).
- Ensure up-to-date knowledge with regulations and guidelines.
- Large professional network.
- Consultants with different professional backgrounds ensures the right people for the right job.
- Experienced quality auditors.

OUR TRACK RECORD

- QA track lead.
- Implementation and application of QMS.
- Interpretation of ISO13485, ISO14971, MDD and FDA 21 CFR Part 820 -> Securing compliance.
- GMP training and compliance analysis.
- Process analysis incl. validation, mapping and monitoring.
- Analysis of existing root causes and CAPA's.

LEARN MORE FROM

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