Consulting™

Expert Advice for Medical Device Research

Experienced Quality Assurance Services for Clinical Trials

The complexities involved in launching a new medical device clinical trial require a diligent and comprehensive approach to quality assurance. The medical device experts at Advarra® can help you navigate the regulatory environment to ensure compliant, high-quality clinical study conduct.

Comprehensive Services

- Audits of investigative sites and clinical vendors
- Inspection readiness support and mock inspections
- Clinical development process mapping and gap analysis creation and evaluation
- Standard operating procedure (SOP) development, evaluation, and consultation
- Unanticipated adverse device effect (UADE) reporting requirement guidance
- Training for investigative sites and monitors
- Monitoring plan evaluation and compliance review
- Vendor quality plan development, evaluation, and consulting
- Regulatory pathway planning
- Agency submissions (510[k], PMA, HDE)
- Computer software validation
- Part 11 compliance plans
- Support for CE marking in EU
- Clinical trial development

Demonstrated Expertise with Global Capabilities

50+ auditors

worldwide experienced in medical device research

- Support in determining the **appropriate regulatory path** for device approval and marketing in the US, EU, UK, and other jurisdictions

ISO expertise

International Organization of Standardization expertise (9000, 13485:2016, 14155:2011)

- **Expert guidance** in navigating the ever-changing national and international medical device regulatory landscape

Ready to make your research altogether better?

Contact Consulting@advarra.com to get started.

ADVARRA

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