CYIENT

MEDTECH REMEDIATION SOLUTIONS

Achieve Long-term Compliance and Improve Quality Performance

Overview

MedTech companies around the world are facing numerous challenges due to stringent regulatory requirements of FDA and other authorities and complexities related to warning letter preparation, handling, and quality reviews. Given the tighter budgets and lack of bandwidth companies today struggle to manage quality and remediation for DMR, DHR, and RMF. In addition, limited experience in managing untimely challenges interrupts the product development process and upsets the business.

Organizations need better remediation solutions across the product life cycle to ensure product success and growth. Cyient offers end-to-end remediation-quality system services to help clients improve regulatory compliance. With deep expertise and knowledge of US FDA regulations, ISO13485, and 14971, CE mark, and complementary systems across geographies we empower clients to rapidly solve remediation issues cost-effectively.

Our Portfolio: Remediation-Quality System Offerings

Remediation Services

- FDA warning letter handling
- Remediation planning
- Total compliance assurance
- Remediation and rewriting for DMR, DHF, RMF
- Updating DHF and RMF for products from acquisition

Quality System Compliance

- Quality system implementation
- Gap analysis
- Quality system process management
- Corrective and preventive action planning and implementation

Audit Preparation

- FDA audit preparation
- Supplier audit preparation
- Conduct gap analysis
- Manage ISO audits

Tangible Benefits

Our remediation-quality system services help clients achieve exceptional benefits, enabling them to:

- Successfully handle FDA audits and review process
- Accelerate compliance and product innovation with robust remediation-quality system support

What Sets Us Apart

We leverage our strong experience of working with leading diagnostic imaging, in-vitro diagnostics, cardiology, and orthopedic original equipment manufacturers. Our team of domain experts and ready-to-use methods and processes ensures seamless service delivery that is aligned with your business remediation needs. Some of our other key differentiators include:

- Extensive experience in design and manufacturing of complex electro mechanical systems
- Deep knowledge of medical device regulatory and quality requirements

Contact Us

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