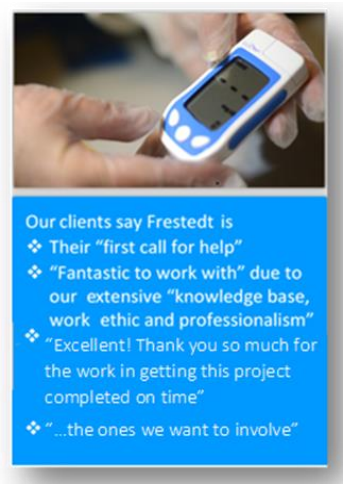
Clinical Research · Regulatory Affairs · Quality Systems · Engineering Affairs

Frestedt is a Comprehensive Science Service Provider

conducting research for drugs, devices and foods. Frestedt creates, revises and trains people to complete clinical research, regulatory, quality and engineering documents. With more and more science required for new products to get to the US market, Frestedt specializes in providing scientific substantiation and independent, third-party reviews of company strategies and work processes along with hands-on work to get the job done!



Frestedt Experience

Frestedt Incorporated delivers expertise to companies within the drug, device and food industries. Frestedt has 100+…

- Clinical Evaluation Reports generated — even *in vitro* devices and software applications!
- Randomized-controlled trials managed
- Regulatory negotiations completed (e.g., US, EU, Japan, Australia, Canada)
- Quality Management Systems (QMS) developed, training provided and quality audited
- Risk-based monitoring services and analyses provided
- Literature reviews conducted and Peer-reviewed articles published
- Presentations developed and presented

Clinical Affairs

Frestedt uses our extensive clinical research management experience to support your clinical affairs strategy. We customize each project to meet timely and high-quality outcomes.

- Literature reviews
- Protocol, informed consent development
- Objective / endpoint evaluation
- Site selection and feasibility assessment
- Personnel training and study monitoring
- Planning, conduct, close-out, reporting
- Site/Data management and analysis
- Statistical analysis and reports
- Safety analyses and reports
- Dietary and clinical risk analyses
- Final study reports
- Post market study reports
- Clinical evaluation reports (CER)
- Justification for Absence of CER

Regulatory Affairs

Whether designing a global regulatory strategy or just helping to complete a few documents, Frestedt has hands-on experience with regulatory bodies worldwide. We provide comprehensive, submission-ready information and documentation to streamline your regulatory approvals.

- Regulatory strategy / Regulatory plan
- Regulatory document creation
- Regulatory submission / negotiation
- Expert panel meeting / report
- Pharmaceutical [IND/NDA/505b2]
- Medical device [IDE/PMA/510(k)]
- Food [NDI/GRAS/Claims]
- Labeling and User information

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Quality Affairs

Every company benefits when they have a robust, user-friendly, Quality Management System (QMS) incorporating high-level standard operating procedures (SOPs) with well used supporting documents. Frestedt stays up-to-date on US and international standards and regulations to better analyze your current system, identify gaps and facilitate creation of the missing components.

- Quality policy and Quality manual
- Auditing and Audit Support
- Feasibility assessments
- Risk management
- Record Review and Gap Analysis
- Standard operating procedures
- Work instructions
- Forms
- US (FDA, GxP compliance)
- OUS (ISO, GHTF, AAM/ASTM)

Engineering Affairs

Frestedt offers a services including engineering project management, development and support for technical files, design history files, verification and validation support and more...

- Unique Device Identification
- Project Management
- Test Method Development
- Product Marking and Labeling
- Process Validation and Verification
- Risk Remediation

CASE STUDIES

Risk-Based Monitoring

An IRB determined a small company's clinical trial did not meet regulatory requirements. Frestedt provided a risk-based monitoring plan, received IRB approval, trained study staff accordingly, completed risk-based monitoring and advised changes to the company's Quality Management System. Clinical trial issues were resolved in a timely manner with Good Clinical Practices (GCP) in place for future clinical endeavors.

Clinical Evaluation Reporting

A large, fast-growing company had engineering-driven clinical risk benefit analyses (CRBA) and separate clinical evaluation reports (CER) which did not link to their risk-monitoring processes. Frestedt recommended combining CRBA with CER and revised separate processes into one risk management process, which led to a broader discussion of reducing the regulatory gap to be compliant with international standards such as, ISO14971 and MEDDEV 2.7.1, Rev 4. Frestedt revised the company's Quality Management System to merge CRBAs and CERs; linking them to the risk-management processes in the engineering department. A streamlined, integrated, interdepartmental system is now in place supported by updated/revised standard operating procedures, work instructions and forms. Frestedt completed dozens of CER/CRBA and trained numerous staff team members.

FRESTEDT, YOUR FIRST CALL FOR HELP
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