Clinical Research · Regulatory Affairs · Quality Systems · Biomedical Engineering

Joy L Frestedt, PhD, CPI, RAC, FRAPS

Strong reputation for building cohesive, results-oriented teams and for developing and implementing strategic business plans. Over 35 years in regulatory, scientific, clinical and quality affairs as well as project and program management, staff development, grants administration and operations. Outstanding abilities include planning, prioritizing and facilitating business growth. Expertise in initiating, developing and reviewing clinical, regulatory and quality operations. Extensive written and oral communications with teaching and training experience for many different teams including platform presentations, writing and editing manuscripts, study reports, clinical and regulatory documents, market research, literature reviews, safety summaries, and brochures. Author of *FDA Warning Letters about Food Products: How to Avoid or Respond to Citations* (Elsevier, in press, August 2017) and *Warning Letters: 2016 Reference Guide* (Barnett International, 2016).

MAJOR CAREER RESPONSIBILITES

Clinical

- Create and develop 100s of clinical trial protocols/ICFs/CRFs/IBs/other documents
- Serve as principal investigator
- Facilitate communication between investigators, sites, sponsors, CROs, data management and statistical analysis teams
- Design data management and stats systems
- Provide PI/CRC/CRA/Monitor Functions

Regulatory

- Facilitate US FDA regulatory negotiations
  - IND, NDA, 505(b)(2)
  - IDE, 510(k), PMA, De Novo
  - FDA meetings
- Facilitate international compliance
  - Regulatory submissions/negotiations
  - Clinical Evaluation Reports (100s)
  - Risk Management Reports and FMEAs
  - Technical Files and Design History Files

Quality

- Provide acquisition and divestment services
- Design quality systems/policies/procedures
- Partner with sales and marketing teams
- Select vendors and negotiate contracts
- Guide bid/budget administration

Design/Engineering

- Develop proprietary drugs/devices/foods
- Optimize engineering strategies
- Implement Risk Management Reviews
- Consolidate Post Market Surveillance steps
- Provide Unique Device Identifier strategies

Training

- Deliver customized corporate training
- Hire, train and motivate staff
- Implement operational and strategic plans
- Develop curricula and write test materials
- Conduct lectures and direct projects

HONORS

2016 Frestedt Inc. Awarded Best Biotechnology Clinical Research - Minnesota (GHP Magazine)
2015 Appointed to NSF Publicly Available Statement (PAS) Generally Regarded as Safe (GRAS) panel
2011 "100 Most Inspiring People in the Life Science Industry" (PhamraVOICE)
2011 Top 25 "Industry Leaders" a "Women in Business Award" (MSP Business Journal)

CAREER HISTORY

2012-present Founder, Alimentix, Minnesota Diet Research Center, Saint Louis Park, MN
2008-present President and CEO, Frestedt Incorporated, Saint Louis Park, MN

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Digitally signed by Joy Frestedt, PhD, CPI, RAC, FRAPS
DN: cn=Joy Frestedt, PhD, CPI, RAC, FRAPS, o=Frestedt Incorporated, ou, email=jf@frestedt.com, c=US
Date: 2017.05.08 13:09:55 -05'00'

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1994-present	Independent Consultant, Sole Proprietor, Saint Louis Park, MN
2012-2012	Interim Regulatory Director, University of Minnesota AHC, Minneapolis, MN
2007-2008	Vice President of Clinical Affairs, BridgePoint Medical, Plymouth, MN
2007-2007	Contract Research Organization Liaison, CRDM, Medtronic, Fridley, MN
2005-2006	Adjunct Faculty (Biol/Business), College of Saint Catherine, Saint Paul, MN
2004-2007	Vice President, Scientific/Clinical Affairs, Humanetics, Eden Prairie, MN
2002-2004	Manager of Clinical Affairs, Ortho Biotech/J&J, Saint Louis Park, MN
2001-2002	Operations Manager, Mayo Clinical Trial Services, Rochester, MN
2000-2001	Medical Information Scientist, AstraZeneca Pharmaceuticals, Saint Louis Park, MN
1999-2000	Manager of Busulfex Clinical Development, Orphan Medical Inc., Minneapolis, MN
1996-1999	Adjunct Faculty (Biol/Chem), Minnesota State Colleges and Universities, Saint Paul, MN
1996-1997	Research Scientist, Saint Jude Medical, Inc., Saint Paul, MN
1981-1996	Med Tech/Res Asst/Lab Director, University of Minnesota, Minneapolis, MN

Other Med Tech/Res Roles: Minneapolis Children's Medical Center (Minneapolis, MN), Roswell Park Cancer Institute (Buffalo, New York), Illinois Masonic Medical Center (Chicago, IL), Lutheran General Hospital (Chicago, IL), Knox College (Galesburg, IL)

SELECTED CAREER ACCOMPLISHMENTS

For Frestedt Incorporated

Founded **Frestedt Incorporated** (S Corporation 2/26/2008), purchased building (3/2014) and relocated to 9445 Minnetonka Boulevard (4/2014) to provide services to drug, device & food companies in the broad areas of clinical, regulatory, quality & engineering with six full time staff and 70+ consultants. Services included Regulatory/Quality/Director/staff, Interim Regulatory Director/Executive Director of Research/Clinical Coordinator Staff/Monitor/Advisor (UMN AHC/MARC/MAPS), Clinical/Regulatory Lead for CER/Labeling, Regulatory Site Transfer Team Lead: site transfer from Dayton, OH to Andover, MN including oversight/management of regulatory compliance issues, managed budgets (~$250K/year) for device testing, labeling, regulatory strategies including pre-amendment and 510(k) devices, clinical/regulatory advisor for global new product development including regulatory, clinical and quality negotiation strategies.

For Alimentix

Founded Alimentix (wholly owned subsidiary or Frestedt Inc.) with services including: clinical trials, monitoring/auditing and management/consulting services to pain clinics as well as diet/food/device/drug companies, especially for claim support.

Independent Consultant, Sole Proprietor, St, Louis Park, MN

Consulting for investment bankers (IPOs, etc.), biomedical establishments, and CROs. Served as Contract Compliance Auditor, Senior Scientist/Safety Expert (Science Museum of Minnesota), Research Scientist (VAMC, St. Jude Medical, Inc.), advisor/writer regarding CRO evaluations and NIH/NCI/SBIR grants, regulatory/business/marketing strategies/plans, as well as regulatory advisor/clinical monitor and member of Gerson Lehrman Group and Guidepoint Global (2006-present).

For Medtronic CRDM

Senior management team member responsible for CRO contracting, planning & execution/interpretation of outsourced clinical research projects. Provided strategic direction, managed/developed CRO staff, Medtronic Clinical Trial Leaders, Clinical Research Associates, and directed budgets to $50M.

For Bridgepoint Medical

Senior management member responsible for developing clinical research in the US, EU, Chile, including 510(k), CE Mark and other regulatory submissions for three vascular devices (StingRay, CrossBoss, GW).

For Humanetics
Negotiated NCI5-15 development at Mount Sinai Medical Center including Sponsor/Investigator IND, press releases & program/project grant submissions: NIH (NCAAM) and MA (MERIT). Managed BIO 300 writing staff, FDA submissions and IND discussions with the FDA, Armed Forces Radiobiological Institute and third party vendors. Supervised company/contract staff, clinical sites and new business development, authored manuscripts/reports, presented research findings, interfaced with monitoring boards, trade associations, advisory committees, subjects, customers, vendors, opinion leaders, trade associations, business directors and key regulatory officials. Grew Minnesota Applied Research Center (MARC) by developing and managing business and staff including principal investigator duties, safety reporting and trending, budgets and accounting. Wrote clinical trial protocols and RFPs, led clinical team, managed direct reports and consultants including performance reviews, development/succession planning, policies, SOP's and training; increased revenue 5-fold ($200k-$1M), relocated clinic, tripled staff and expanded capabilities with capital equipment purchases. Evolved and assisted sale of MARC to MAPS (including transition to new Executive Director of Research and retention of past employees/business partnerships).

For Ortho Biotech/Johnson and Johnson (J&J)
Developed clinical trials; managed physician networks, cooperative groups, CRO relationships, dozens of company-sponsored, cooperative group and investigator-initiated research programs and FDA discussions; identified/developed thought leaders, protocols, conferences and advisory boards, and provided consultation/education to regional sales force. National field co-chair for scientific review of pre-clinical concepts and national field leader for company-sponsored trials and development of new clinical trials. Awarded Biovision Peer (2003), Horizon (2004), and two Sighting (2004) Awards; budgets to $1M.

For Mayo Clinical Trial Services
Developed staff, clinical site networks, new business relationships, and programs on protocol design, budget development, monitoring, and site training. Responsible for 100 staff and 200 active trials (budgets to $1.5M). Results included new policies, procedures and metrics for business growth and capabilities expansion, reduced risk and increased revenues by implementing new monitoring and auditing programs.

For AstraZeneca Pharmaceuticals
Identified/developed physician/thought leaders and new business relationships. Managed investigator initiated research, IND submissions and national grant funding requests. Served on IIRIS, Compass, and Training Creation working groups. Partnered with CROs and sales to improve clinical trials. Developed protocols, conferences, symposia, advisory boards and new programs database about customer interactions.

CERTIFICATIONS AND FELLOWSHIPS

2011 FRAPS	Fellow of the Regulatory Affairs Professionals Society
2007 RAC	Regulatory Affairs Certified, Regulatory Affairs Professional Society
2007 CPI	Certified Principal Investigator, Association of Clinical Research Professionals

LICENSES AND DEGREES

2005 X-Ray License	State of MN, X-ray Operator
1996 PhD Pathobiology	University of MN, Minneapolis, MN
1984 CLSp(CG)	NCCLS, Clinical Laboratory Specialist in Cytogenetics (retired)
1980 BA Biology	Knox College, Galesburg, IL