



Clinical Research · Regulatory Affairs · Quality Systems · Biomedical Engineering

Lindsay R. Young



Highly organized and articulate professional with advanced technical and business training and significant experience leading and managing projects. Diverse experience in the planning, execution, management, and reporting of clinical research studies. Deep technical agility and aptitude, allowing for the quick integration of new technologies, techniques, and medical indications. Recognized as a leader and influencer whose style and communication skills promote cooperation and the optimization of individual capabilities and talent.

Professional Experience

FRESTEDT, INCORPORATED – Minneapolis, MN

October 2016 – present

Consulting agency focused on clinical, regulatory affairs, quality and biomedical engineering support for the pharmaceutical, medical device, and food industries.

CRQ Specialist

- Conduct literature searches and draft literature review documents
- Draft Clinical Evaluation Reports according to European Essential Requirements
- Draft research reports, white papers and manuscripts on regulatory and clinical trials topics
- Develop internal and external SOPs, work instructions and template documents
- Assist with Design History File remediation projects

FREELANCE CLINICAL RESEARCH/REGULATORY CONSULTANT

2009 - 2016

- Created trainings on new regulations, standards, and guidance documents (e.g., MEDDEV 2.7.1, ISO 14155, etc.)
- Drafted clinical trial protocols, institutional review board documents, clinical study reports and manuscripts for medical device, pharmaceutical and food industry clients
- Developed presentations for webinars on U.S. and European regulatory affairs for medical devices
- Abstracted and synthesized clinical data for the development of clinical evaluation reports for medical devices

SILK TECHNOLOGIES – Plymouth, MN

June – November 2015

A start-up company focused on developing silk-based protein products for a variety of industries and applications. During my time at Silk Technologies, they were scaling-up production of silk-derived protein for ophthalmic applications.

Project Manager

- Partnered with CEO and other executives on the timing and strategic rollout of new products and offerings

- Managed concurrent R&D, regulatory, quality, and business development projects to ensure alignment of timelines and deliverables for the development of new products and offerings in a highly regulated industry
- Coordinated and contributed to grant submissions resulting in continued grant support and \$1.5 million in new funding

LIFESCIENCE ALLEY – St Louis Park, MN

2013 –2015

A non-profit trade organization that serves individuals and organizations that comprise Minnesota's health industry by influencing policy, fostering connections and providing critical intelligence to improve the quality of health around the world. I was awarded a fellowship to obtain an MBA and apply my training to support medical technology companies.

Applied Business Training Fellow

- Developed technical reports on market feasibility of early stage medical devices and pharmaceutical innovations
- Conducted a marketing research study involving supply chain leaders in medical device companies that contributed to executive level programming recommendations for LifeScience Alley
- Directed and contributed to the research, drafting, and submission of a federal Small Business Innovation Research grant for a start-up company to support a high risk preventative medical treatment
- Completed a Masters Degree in Business Administration (MBA) at the University of St. Thomas

M.A.P.S. APPLIED RESEARCH CENTER (MARC) – Edina, MN

2011 – 2012

A privately-owned clinical research site that conducted outpatient Phase I – IV clinical trials. MARC was undergoing extensive restructuring and downsizing during my time at the organization.

Manager of Clinical Research

- Operated as Study Coordinator for seven clinical trials, performing clinic visits and managing data collection
- Coached site staff (i.e., physicians, nurses, and coordinators) on clinical trial protocol and data collection methodology
- Fostered cross-functional communication between strained clinician and research teams, improving trial outcomes
- Abstracted adverse event information from electronic medical records and reported events
- Drafted institutional review board submissions and reports

UNIVERSITY OF MINNESOTA – St Paul, MN

2004 – 2011

Post-Doctoral Fellow, *Department of Food Science and Nutrition*

2010 – 2011

- Directed a human clinical trial on the effects of vegetable consumption on cancer endpoints
- Recruited participants, developed IRB documents and data capture instruments, published manuscripts
- Data from the study was used to develop a bio-marker for vegetable consumption for future cancer prevention studies

Doctoral Student, Departments of Medicine and Food Science and Nutrition

- Managed and conducted clinic visits for a human clinical trial on omega-3 fatty acids and breast cancer
- Analyzed cancer markers in biological samples and ran statistical analysis using SAS
- Published six manuscripts from the study's results to clarify the impact of omega-3 fatty acids on breast cancer
- Completed requirements for a PhD in Nutritional Biochemistry

Selected Publications

Frestedt J.L., **Young L.R.**, Bell M. Meal Replacement Beverage Twice a Day in Overweight and Obese Adults (MDRC2012-001). *Current Nutrition & Food Science*, 2012; 8: 320-329.

Young L.R., Kurzer M.S., Thomas W., Redmon J.B., and Raatz S.K. Effects of Dietary Fat and Omega-3 Fatty Acids on Urinary Eicosanoids and Sex Hormone Concentrations in Postmenopausal Women: A Randomized Controlled Feeding Trial. *Nutrition and Cancer*, 2011; 63(6): 930-939.

Kang A.Y., **Young L.R.**, Dingfelder C., Peterson S. Effects of Furanocoumarins from Apiaceous Vegetables on the Catalytic Activity of Recombinant Human Cytochrome P-450 1A2. *Protein J*, 2011; 30(7): 447-456.

Awards and Fellowships

Compelling and persuasive passion, goals and purpose contributed to obtaining over \$350,000 in awards and fellowships that directly supported my medical research and business training.

LifeScience Alley/University of St Thomas Applied Business Training Fellowship	2013
National Cancer Institute Postdoctoral Fellowship	2011
Buckman Fellowship for Leadership and Philanthropy	2008
Department of Defense (DOD) Breast Cancer Research Predoctoral Award	2006
NIH Minnesota Complementary and Alternative Medicine Clinical Research Internship	2005
University of Minnesota Graduate School Fellowship	2004
NIH Center for Structural and Functional Neuroscience Fellowship	2003
National Science Foundation Fellowship	2002

Education and Certifications

CAPM, Certified Associate in Project Management – Project Management Institute	2016
MBA, Business Administration – University of St. Thomas, Minneapolis, MN	2015
PhD, Nutritional Biochemistry – University of Minnesota, Minneapolis/St Paul, MN	2010
BA, Biology, Summa Cum Laude – University of Montana, Missoula, MT	2004

Key Skills

Clinical Trial Management	Medical Writing	Project Management
FDA Regulations	Medical Terminology	Cross-functional Communication
Good Clinical Practice	Adverse Event Reporting	Data Presentation
ISO 14155	Microsoft Office	Medical Literature Reviews