February 1, 2026

Hiring Manager
Insulet

Re: Director of Data and Biostatistics

I am writing to express my strong interest in the Director of Data and Biostatistics position within your Clinical Affairs team. With over 10 years of leadership experience in data management, statistical analysis, and regulatory compliance across FDA-regulated pharmaceutical and biotech environments, I am confident I can drive data operations excellence and support your medical device clinical trials program.

Throughout my career, I have built and led data management and analytics functions in highly regulated environments. At Gilead Sciences, I designed and implemented a centralized data lake that served as the single source of truth for Medical Affairs, establishing comprehensive data governance frameworks and validation processes that ensured data integrity across the organization. At Takeda, I led both digital/data science and statistical monitoring groups, developing predictive models for manufacturing and quality decisions while maintaining 21 CFR Part 11 compliance as the Spotfire system administrator. Most recently at Redica Systems, I have designed reference data architectures from scratch, built production machine learning models with rigorous validation, and established data quality assurance processes for pharmaceutical clients including Eli Lilly and Merck.

My technical expertise spans the full data lifecycle, from database design and EDC system experience to advanced statistical methods and regulatory reporting. I have extensive experience with statistical analysis including ensemble methods, PCA, PLS, and risk scoring models, and I consistently apply appropriate statistical rigor to ensure accurate analyses. My background managing cross-functional teams, vendor relationships, and CRO partnerships positions me well to oversee your clinical data systems and biostatistics operations. I have directly managed teams of 3-7 people, mentored technical staff, and collaborated effectively with Clinical Operations, Medical Affairs, Regulatory Affairs, and Quality Assurance stakeholders.

I am particularly drawn to this opportunity to apply my data strategy and statistical analysis expertise to medical device clinical trials. My proven track record of building scalable data systems, establishing best practices, and ensuring regulatory compliance - combined with my experience presenting at industry conferences on AI/ML applications in FDA-regulated industries - aligns directly with your need for a leader who can oversee data operations, support study design, and provide strategic guidance to the Clinical Affairs team.

I would welcome the opportunity to discuss how my experience in data management, biostatistics, and regulatory compliance can contribute to your clinical trials program. Thank you for considering my application.

Sincerely,

Matt Oremland, PhD