Your main responsibilities will include establishing and maintaining a quality system that meets the needs of the company including overall company compliance policies, medical device regulatory requirements of the US FDA, and ensuring coherence with our existing clinical laboratory quality system based on CLIA and CAP guidance.

Responsible for the establishment and maintenance of a quality system that meets the business needs of the company and medical device regulatory requirements of the US FDA

Understand international requirements as applicable to IVD products that the company may develop and distribute as well as clinical regulatory guidance for international collaborations
Facilitate the conduct and documentation of periodic Management Reviews
Coordinate with clinical laboratory QA to ensure that quality system functions are appropriate for LDT/CLIA/CAP regulatory environment: Document control, complaint handling, internal audits, CAPA systems, and training systems

- Provide quality support for Design Control projects
- Interact with external regulatory consultants on the coordination between quality and regulatory for new design projects including what types of analytical and clinical studies and associated data are needed for FDA regulatory submissions
- Facilitate the set up and generation of design control and risk management documents for the Design History File (DHF) and risk management file
- Provide guidance in software development lifecycle policies and regulations
- Lead and manage the QA team
- Collaborate across the company to ensure clinical and FDA compliance is achieved
- Exemplify our core values – Visionary, pioneering, truth seeking, driven, honest and considerate communication, embrace diversity and operate with transparency and integrity.

Requirements

- BS degree or equivalent with 10+ years related experience at an IVD or medical device company or CLIA lab with FDA cleared/approved LDT assays
- Excellent interpersonal, teaming, written and spoken communication skills.
- Strong working knowledge of US regulations including but not limited to 21 CFR 820
- Experience in setting up and maintaining a medical device quality system.
- Experience in building and leading a team.