Our company is hiring for a senior design quality engineer. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for senior design quality engineer

- Guide the development of cleanroom construction protocols, reports and evaluate methods in collaboration with intra and inter-departmental teams (e.g., Microbiologists, Quality Engineering, Manufacturing Engineering, Facilities)
- Provide strategic direction and guidance on all global controlled environment projects
- Negotiate and manage contractual agreements with cleanroom construction and/or operations contractors
- Provide expertise for the preparation of risk management plans and documentation for cleanroom and supporting critical utilities including impact assessments, risk analysis, and risk/benefit analysis (e.g., FMEA, FTA, HACCP)
- Standing member of multiple controlled environment standards
- Provide recommendations, identify and gain buy-in from senior management in support of new strategic globalization initiatives, and/or programs involving cleanroom renovation, new construction, and operational best practices
- Using engineering principles, analyze situations or data to identify gaps between project work and the QMS
- Work with product development teams and other QEs to assure compliance to the QMS
- Develop mastery of our products and analyze complaint data, post market

- Lead Corrective and Preventive Actions (CAPA) and QMS continuous improvement projects as they relate to Design Assurance and Complaint Review Board Process

Qualifications for senior design quality engineer

- Familiar with statistical software tools (Minitab, Stat Graphics, Statistical), Desirable
- Stability, Biocompatibility, Sterilization, Ship Testing Knowledge, Desirable
- Familiar with IEC 60601, ISO 5361, ISO 5366 and product specific industry standards
- Prior experience with Regulated software development· Effectively manage multiple tasks and lead execution of change management plans
- Performs work under only general direction
- Bachelor's Degree in Engineering or other similar Technical Discipline