Job Description

Position: **Quality Engineer – Validation**

Updated: 7/12/2022

Job Description:

Quality Engineer – Validation is responsible for supporting validation activities including product qualification and validation for PBS's bioreactor systems, facility, and equipment. This full-time role supports product development, product transfer, manufacturing, and commercialization of bioreactor products. This position incorporates elements of medical device design control, standards for GMP bioprocessing equipment, and single-use medical products to define requirements for testing, qualification, verification, and validation. This position reports to the Sr. Quality Engineer.

Job Duties and Accountabilities:

- Provide Quality Engineering analysis and assessments for impact to product quality/validation to support changes, investigations, CAPA, nonconformances, and manufacturing processes.
- Review technical documents as quality approver.
- Quality contact for validation of manufacturing process, facility, and equipment.
- Supports and may own elements of the validation program including procedures, validation master plan, product qualification, and related training.
- Manage or support periodic validation and testing for product, equipment, and facility. Including studies for process monitoring, radiation sterilization, shipping/transport, packaging, and shelf-life.
- Organize and manage product test samples and lab results for testing of bioburden, particulates, endotoxin, biocompatibility, and extractables.
- Will be assigned additional tasks and projects as needed to meet business objectives.

Required Education and Experience:

- A bachelor's degree in a science field is acceptable with ≥ 3 years of relevant industry experience.
- Minimum 2 years in a Quality Engineering or Validation role, or 3 years in a related role such as Product Development Engineering, Manufacturing Engineering, or Industrial Engineering.

- Minimum 2 years of experience working with products regulated by GMP/biopharma (21 CFR 210/211, ICH Q7/10), medical products field, or other regulated industry (aerospace/AS9100).
- Advanced skills with MS Office applications Word, Excel, as well as Adobe Acrobat.

Preferred Education and Experience:

- Bachelor's degree or higher in an Engineering field.
- Experience with design control in medical device (21 CFR 820, ISO 13485/14971) or medical products (ISO 9001, ISO 13485).
- Experience with polymer processing – injection molding, machining, and extrusion.
- Experience with software, computerized systems, and/or control system validation.
- Experience using one or more engineering tools and methods such as CAD, statistical analysis (Minitab, JMP, SigmaXL, SAS, R, Matlab, Dataplot, or equivalent), statistical sampling/acceptance methods (ANSI, MIL-STD, AQL), design of experiments, design control, DFM, etc.

Compensation

- Compensation and job level will be commensurate with the skills and experience of the individual candidate.
- PBS provides equal employment opportunity to all applicants and employees.
- Work location is in Camarillo, California. Candidates must be authorized to work in the U.S.
- This position may be a combination of on-site and remote work in alignment with company flexible work environment policies.