JOB TITLE: Technical Engineer 3-Device Regulatory focus

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JOB SUMMARY

Work requires originality and judgment in the independent evaluation, selection, and substantial adaptation and modification of standard techniques, procedures, and criteria. Performs work which requires a broad knowledge of precedents in the specialty area and a good knowledge of principles and practices of related specialties. Duties are assigned to provide experience and familiarization with engineering methods, independent thinking, and company practices and policies. Strong experience in device regulatory certifications (eg. CSA, UL, TUV, IEC, MDD. Also, experience in EMC/EMI medical device testing and materials standards compliance (RoHS, REACH, etc.).

ESSENTIAL DUTIES

- Perform independent evaluation, selection, and application in making adaptations and modifications to projects.
- Receives assigned total project leadership responsibilities on a portion of major significant projects and will be given total management responsibility for smaller projects.
- Manages and provides leadership for the functional group's development, direction, and effectiveness, adhering to organizational policies and processes and supporting overall business and corporate objectives.
- Implements and understands FDA or regulatory requirements as necessary.
- Medical and laboratory device regulatory certifications (e.g. CSA, UL, TUV, IEC, MDD, MDR)
- Applies technology principles to multiple tasks. Working knowledge of cross-functional and related technical areas.
- Highlights risks and understands how to approach and complete tasks, avoiding serious delays and considerable expenditure of time and resources.
- Advises team members pro-actively on technical ideas and promotes skill development of team work.
- Interacts with peers across projects to secure resources and commitments.
- Handles frequent inter-organizational and outside customer contacts. Represents the organization in providing solutions to difficult technical issues associated with specific projects.
- Follows technical specification requirements and provides feedback on various technical processes and procedures.
- Presents effectively complex technical information/analysis and responds to questions from technical staff members and management.
- Works cooperatively and effectively within a team environment to achieve common goals and results, often influencing the outcome of the team(s).

OTHER DUTIES AND RESPONSIBILITIES

- Work direction responsibility may include technicians and junior engineers.
- May work with manufacturing and other functional groups on manufacturing and regulatory compliance issues.

MINIMUM QUALIFICATION REQUIREMENTS

Education

- Bachelor's degree or equivalent of education and experience sufficient to successfully perform the essential functions of the job may be considered.
- Bachelor of Science Degree in Engineering, preferred.

Experience

- Minimum 4 years' experience.
- Two years of GMP manufacturing experience required.

Skills

- Requires demonstrated skills in technical innovation, technical leadership, mechanical and or chemical engineering, fluids engineering, and cellular biology.
- Strong interactive skills in general communication, cross-functional participation and influence, mentoring and acceptance of guidance, technical leadership, project management, coordination with cross-functional team member, team behavior, and support for subordinates, junior engineers, technicians, and management.
- Strong technical problem-solving skills.
- Mechanical and electronic ability aptitude to assist with equipment trouble-shooting.
- Understanding of and adherence to GMP practices and FDA regulations.
- Knowledge and ability to implement FDA or regulatory requirements as necessary.
- Demonstrated skill in direct communication and negotiation with certification agencies, including on-site agency audits and inspections.
- Demonstrated ability to communicate effectively both verbally and in writing.
- Knowledge and use of relevant PC software applications and skills to use them effectively.

-Or-

An equivalent competency level acquired through a variation of these qualifications may be considered.

PHYSICAL REQUIREMENTS

General Labor Environment requirements include: use of personal protective equipment, reading, speaking, hearing, walking, bending, standing, stretching/reaching, hand/finger dexterity, and occasional lifting up to 50 pounds, or transporting up to 500 pounds via carts or mechanized equipment.

The physical demands described here are representative of those that must be met by an associate to successfully perform the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

Additional Physical Requirements

Requires travel based on business needs.

We are proud to be an Equal Opportunity Affirmative Action Employer. All applicants will be afforded equal opportunity without discrimination because of race, color, religion, sex, sexual orientation, marital status, order of protection status, national origin or ancestry, citizenship status, age, physical or mental disability unrelated to ability, military status or an unfavorable discharge from military service.

We maintain a drug-free workplace and perform pre-employment substance abuse testing and background verification checks. As of January 1, 2017, the Terumo BCT Lakewood, Colorado location will be a tobacco-free workplace. For more information about Terumo BCT, visit our website www.terumobct.com/careers.

Join Terumo BCT as we unlock the potential of blood. We are a global leader in blood component and cellular technologies, and the only company with the unique combination of apheresis collections, manual and automated whole blood processing, and pathogen reduction coupled with leading technologies in therapeutic apheresis and cell processing. We believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.

As the largest medical device manufacturing company headquartered in Colorado, we are home to more than 2,300 associates and our products are in use in more than 125 countries and territories. Our Global footprint includes more than 5,500 associates and partners with regional headquarters in Brussels, Buenos Aires, Singapore and Tokyo.

Our company has almost $1B in annual revenues and has been voted and recognized as:

- Largest corporate sponsor in Rocky Mountain Region for Leukemia and Lymphoma Society (LLS)
- Winner of the Association for Talent Development (ATD) BEST Award for providing exceptional employee learning and talent development (2011 & 2012)
- One of Colorado's Healthiest Employers by *Denver Business Journal* (2014 & 2015)
- Recipient of the *Way to Go* Employer award through the Denver Regional Council of Governments (DRCOG) 2015

Our award-winning culture embraces:

- Leading technology through innovation and R&D
- Wellness programs
- Commitment to quality
- An environment that values, respects and rewards your individual contributions
- A philosophy of intentional growth and responsiveness to world health issues

Click Here to see what our associates have to say about our culture.

Each associate has a positive impact on our future by:

- Connecting to the lives of the patients we ultimately serve
- Growing through professional and leadership development activities
- Sharing company success through incentive plans

If you are the best at what you do and want to do work that is changing the delivery of healthcare globally, we invite you to work with us now to see how we can unlock your potential.