POLY-MED, INC.

Corporate Office:
51 Technology Drive
Anderson, SC 29625
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www.poly-med.com

Part A - General Position Information

Job Title:	Department Name:	Reports to:	FLSA Status:
Safety and Quality Engineer	**Quality**	**Quality Manager**	

Part B – Company Information

About Us:

Poly-Med is the leading developer of bioresorbable polymers and fibers. We help innovative medical device companies focused on improving patient outcomes. Poly-Med designs, develops and manufactures superior materials to get customer products to market in the most efficient manner with the greatest improvement to quality of life. Located in Anderson, South Carolina, Poly-Med, Inc. has been recognized as a leader in the industry for over 20 years. Poly-Med continues to grow in a multitude of medical device modalities. Our novel materials are key in actively enabling products ranging from vascular stents, hernia meshes, dental delivery systems, dental hygiene, and a variety of wound closure applications in the worldwide medical device market.

For additional information, visit our website at www.Poly-Med.com.

Our Team:

We employ a widely diverse team comprised of experts from material science, chemical engineering, mechanical engineering, bioengineering, biology, business marketing, and project management to create a work environment focused on solving tough medically related problems. Our team is energetic, resourceful, and, above all, collaborative. We are searching for like-minded talent to build on our success and continue our quest to improve patient outcomes through novel polymeric and drug delivery systems.

Part C - Position Information

Description:

This full-time position is self-directed and is responsible for performing product, process and equipment validations/qualification, medical device design and development document writing and review, and other quality related activities with minimal guidance and supervision. Has broad knowledge of commonly used concepts, practices, and procedures within validation and quality assurance field. Relies on personal experience and judgment to perform primary job responsibilities.

Responsibilities:

- Safety officer for ~ 80 people providing IH support, OSHA compliance, job evaluations, LOTO support, DOT and RCRA compliant waste handling
- Design, manage and improve quality systems including document control, CAPA, NCR, Complaint, and internal audit programs
- Supervise, train and coach a team of junior quality personnel
- Investigate product quality problems and determine root cause, gather and analyze data, and implement corrective actions to reduce or eliminate cause and work closely with Manufacturing to identify and resolve production and quality system deficiencies.
- Support the customer and regulatory audit process including types of audits, planning, preparation, execution, reporting, and follow-up
- Support risk-management and risk analysis activities

Required/Preferable Knowledge, Skills and Abilities

- 3+ years working in safety and compliance preferably in GMP Medical Device industry, ISO 13485 and 21CFR820
- Skilled with Microsoft Office Software (Microsoft Word, Excel, et. al.)
- Good knowledge of statistics and Mini-tab software, DOE, SPC
- Good work organizational skills
- Ability to manage time and prioritize
- Excellent communication and interpersonal skills
- Ability to assertively interact with people at all levels of the organization
- Train, supervise, coach employees
- Good technical writing skills, grammar
- Ability to handle highly confidential business information
- Strong attention to detail
- Ability to think proactively, troubleshoot, investigate and improve systems
- Highly responsible for actions of self and possibly others on the team*

Education/Experience Requirements:

Required: Bachelor's Degree (in Engineering, Chemistry, Industrial Safety) and 3+ years of medical device or pharmaceutical industry experience.

Preferred: Supervisory experience, quality systems design and development experience, OSHA, RCRA, DOT compliance.

Environmental Requirements:

Must be able to adapt to multiple indoor work environments (shared office space, shared lab space and production areas).

Physical Requirements:

- ☒ Sitting
- ☒ Standing
- ☒ Walking
- ☒ Climbing/Balancing
- ☒ Reaching – with Arms and Hands
- ☒ Stooping/Kneeling/Crouching/Crawling
- ☒ Talking
- ☒ Hearing
- ☒ Feeling/Touching
- ☒ Vision – Close, Peripheral, Depth, Ability to Adjust Focus
- ☐ Other:

If you are interested in working with us, please email your resume; tell us a little about who you are and what makes you want to join our team to recruiting@poly-med.com.