POLY-MED, INC.

Corporate Office:
51 Technology Drive
Anderson, SC 29625
Phone: 864.328.0008
www.poly-med.com

Part A - General Position Information

Job Title:	Department Name:	Reports to:	FLSA Status:
Quality Engineer	**Quality**	**Quality Engineer**	**Exempt**

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 position is responsible for performing Quality Assurance tasks and activities with guidance and supervision. Has knowledge of commonly used concepts, practices, and procedures within quality assurance field. Relies on personal experience and judgment to perform primary job responsibilities. This role is an Independent Contributor with no direct reports. Interaction is potentially with all levels of the organization. Progression path would be to a senior level Quality Engineer based on performance, development, and experience. This position reports to a more senior Quality Engineer, Assistant Manager or Quality Manager.

Responsibilities:

- Participates in design and development project meetings as the Quality representative supporting compliance and PMI Quality position in product design and documentation.
- Supports compliance to Good Documentation Practices during assigned document reviews.
- Responsible for at least one set of document management and program maintenance functions such as batch cards, MIs, DHR, DMR, DMF,CAPA, ECO, Validations, IP/PS, customer complaints, FMEA, Customer Proposals, Drawings, Design Control, SDS', Calibrations, NCR, Product shipping and Label Control.
- Participate in customer and regulatory audits as well as internal audits. When trained may be internal or external auditor. For this some travel may be required.
- Responsible for the ISO 13485 and cGMP compliance of the assigned PMI programs.
- Meet annual Quality Objectives as set with manager as well as assigned Quality metrics.
- Recommends and implements Quality process improvements with the approval of Quality Manager
- Perform validations or participate in validation teams or work on analytical equipment as requested.

Required Knowledge, Skills and Abilities

- Fluency with Microsoft Office Software (Microsoft Word, Excel, et. al.)
- Excellent technical writing skills, grammar, proof reading skills
- Excellent organizational skills, attention to detail, ability to manage time and prioritize
- Ability to think proactively, troubleshoot, investigate and improve systems
- Excellent communication and interpersonal skills, able to assertively interact with people at all levels of the organization
- Ability to lead projects and train others as required

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- Ability to handle confidential business information

Education/Experience Requirements:
Required - Bachelor's Degree in chemical, plastics or polymer engineering.

Preferred – At least 1 year experience in medical device, pharmaceutical or similarly cGMP/ISO regulated industry

Environmental Requirements:

- Shared Office space

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, Color
☐	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.