POLY-MED, INC.

Corporate Office:
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www.poly-med.com

Part A - General Position Information

Job Title:	Department Name:	Reports to:	FLSA Status:
Quality Specialist I	**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: Possesses in-depth knowledge of all document control and Quality Assurance requirements. Has broad knowledge of commonly used concepts, practices, and procedures within Quality Assurance and Quality Control fields. Works independently on tasks and projects. Relies on experience and judgment to plan and accomplish goals.

Scope: This role is an Independent Contributor. There are no direct reports for this position, however this person may mentor or direct the activities of Quality Specialist I and Quality Specialist II as needed. Interaction is with all levels of the organization. This position reports to a Quality Engineer or Quality Manager.

Responsibilities:

QC Reviewer.

1. *Sample tracking* - Work with manufacturing and QC to ensure samples are properly received, logged in, and tracked.
2. *Review* - Receive completed QC sheets, review and help analyze data.
3. *IP* - Do incoming inspections as required, scheduling and/or performing. Review IP/PS documents as required.

Manage PMI calibration program and coordinate or complete in-house calibrations.

4. *In house calibrations* - plan and perform certain equipment calibration
5. *Out of house calibrations* - Quote, schedule and manage onsite calibrations and ship items to calibration firms as required. Ensure all OOTs are recorded, investigated and closed properly. Ensure there are Calibration SOPs for each type of equipment and they are up to date. If not, work with the appropriate engineers to get them updated.

6. *Calibration records* - Keep paper files of all calibration records and certificates, and update the calibration database as required. Run reports to plan monthly calibrations.
7. *Calibration control* - Secure the calibration equipment cabinet. Keep stock of routinely calibrated and replaced items.

General

8. Environmental Monitoring (temperature, humidity, bioburden and non-viable particulate) throughout buildings and in Cleanroom as requested.
9. Seek resolution to issues encountered during the course of routine quality duties.
10. Support projects by participating in Validation Studies and various other activities as required.
11. Additional duties may be assigned by management.

Education/Experience Requirements:
Required- Associate's Degree with 1-2 years' professional work experience
Preferred- Previous experience working in document control

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.