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:
Validation Engineer I/II	**Quality**	**Quality Supervisor**	**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 self-directed and is responsible for performing product, process and equipment validations/qualification 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:

- Primarily responsible to develop, perform, review and approve process, test method and equipment validation/qualifications.
- Perform product and process evaluations to identify areas for improvement. Recommend solutions to identified problems. Implement approved changes using sound quality engineering principles and fully document requirements.
- Review product and process changes for effect on existing validations, recommend and perform revalidations as required.
- Investigate product quality problems and determine root cause, gather and analyze data, and implement corrective actions to reduce or eliminate cause.
- Support the audit process including types of audits, planning, preparation, execution, reporting, and follow-up
- Assist in defining, developing, maintaining, and supporting various quality programs along with their performance measurements and reporting requirements
- Basic knowledge of risk-management and risk analysis activities
- Represent Quality on multifunctional design teams and Project/Program Core Teams
- Work closely with Manufacturing to identify and resolve production and quality system deficiencies

Required Knowledge, Skills and Abilities

- 2+ years hands on equipment qualification and test method validation experience in GMP regulated environment (preferably pharmaceutical)
- Skilled with Microsoft Office Software (Microsoft Word, Excel, et. al.)
- Good knowledge of statistics and Mini-tab software
- Good work organizational skills
- Ability to manage time and prioritize

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- Excellent communication and interpersonal skills
- Ability to assertively interact with people at all levels of the organization
- 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 Chemistry, Polymer Science or Mechanical Engineering) and 2+ years of Pharmaceutical industry experience

Preferred – Experience validating the following test methods: GPC, HPLC, GC, Mechanical testing (tensile, burst, arial density, etc), DSC, IR, NMR, SEM

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.