

QUALITY ASSURANCE ENGINEER

BACKGROUND: Global Interconnect Inc., an established company with a highly entrepreneurial culture located on Cape Cod, is looking to find a standout Quality Assurance Engineer to join our dynamic and growing team. If you are looking for a change and want an opportunity where you can truly make an impact and take your career to a rewarding level, we want to talk with you!

WHY IS GLOBAL INTERCONNECT, INC. (GII) INTERESTED IN HIRING A QUALITY ASSURANCE ENGINEER?

GII has ambitious growth goals and is committed to doubling the size of the organization in the next 5 years. The opportunity is extremely ripe for the right candidate to be a key contributor to this growth.

ABOUT GII Global Interconnect, Inc. is a design, engineering, and manufacturing firm with headquarters in the US and offices in Hong Kong and China. Our niche and primary focus is providing custom cable, wire and harness assemblies of unparalleled quality for medical device and high-end industrial OEM's. These end devices and instruments are used around the world impacting, improving and in many cases saving lives each and every day.

JOB SUMMARY:

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KEY RESPONSIBILITIES

INCLUDE, BUT ARE NOT LIMITED TO:

- Manage risk analysis documentation, including Process Failure Mode and Effects Analysis (PFMEA), with support from engineering and manufacturing.
- Manage control plan documentation, with support from engineering and manufacturing.
- Participate in project risk assessments as a consultant for quality.
- Participate in process flow chart development as a consultant for quality.
- Develops, finalizes, and approves Device Master Record (DMR)/Medical Device File (MDF) throughout the lifecycle of the project.
- Provides quality and regulatory support, as needed as a member of the project team.
- Reviews/approves all test plans and test reports to ensure procedures and adequate testing is being completed as part of the project.
- Reviews/approves all IQ/OQ/PQ protocols and reports associated with the project to ensure compliance as part of the project.
- Act as customer liaison in support of compliance and quality during the lifecycle of the project.
- Ensures project documentation required is complete, accurate and maintained as part of the project file, prior to transfer to manufacturing.
- Assist with any nonconformities, out of specification result, and investigations/RCA during the lifecycle of the project.
- Support sustaining Quality Assurance Team investigations for postproduction activities such as customer complaints, risk updates, revalidations, nonconformities, process changes, engineering change requests/orders, and audit nonconformities.
- Support regulatory and customer audits as the quality assurance engineer for projects.
- Collaboration with cross functional team and drive quality standards and influence team members as it relates to quality.
- Ability to foster a deep rooted quality culture throughout the project team.
- Act as a quality leader and develop team members in compliance, quality and regulatory requirements.
- Responsible for FDA listings and use of FDA portal to update Global Interconnect's listings for finished medical devices, per customer requirements, as required.
- Act as subject matter expert in sterile barrier systems, packaging validations, equipment validations, cleanroom, sterilization, statistical sampling rationales, change control, deviation management (for projects and support of sustaining quality assurance).



**GLOBAL
INTERCONNECT**

Global Interconnect, Inc. USA

11 Jonathan Bourne Drive
Pocasset, Massachusetts, USA 02559

Telephone: 1-508-563-6306

WHAT WE OFFER

- Competitive salary and performance-based bonus
- Comprehensive benefits package (health, 401(k) with match)
- Opportunities for professional development in a growing medtech organization
- Collaborative environment focused on quality, innovation, and patient safety

www.globalinterconnect.com

REQUIREMENTS & SKILLS:

- 3 to 5 years of experience in quality engineering, design assurance, or new product development in a regulated industry (such as medical devices)
- Bachelors degree in technical field (engineering, quality engineering)
- Ability to apply logical, scientific or analytical thinking to a wide range of intellectual and practical problems
- Regulatory Knowledge in the following:
 - ISO 13485
 - FDA 21 CFR 820, QMSR
 - ISO 14971
 - ISO 14644
 - ISO 11135
 - ISO 11607
 - Lead Auditor Training certificate, a bonus
- Strong working knowledge of Validation (IQ/OQ, PQ), sterile barrier systems, sterilization, biocompatibility, cleanroom,
- Able to establish and maintain good customer relationships
- Embrace process and easily adjust to change
- Outstanding communication skills (verbal & written)
- Able to meet deadlines and work well under pressure in a fast-paced office environment
- Self-motivated with excellent time management and organizational skills
- Proficient with platforms such as Outlook, Excel, QMS software (i.e. QCBD) and MRP systems
- Available to meet with customers via video call and in person (some travel required)
- Knowledge of sterilization and sterile barrier packaging
- Knowledge of REACH, RoHS, conflict minerals
- Ability to proficiently read specifications, drawings and schematics
- General knowledge of cable assemblies, connectors, electrical testing, material biocompatibility.
- Experience in generating PFMEA's, DMR's, Control Plans

Position is based in Pocasset, MA. Workdays, M-F. In office M-Th, WFH Friday. If interested in exploring this exciting opportunity, we are eager to speak with you!

Please direct cover letter and copy of your resume to

**davellar@globalinterconnect.com and
jbates@globalinterconnect.com**



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