

**BIOURFACES, INC.  
QUALITY MANAGER**

Post Date: August 23, 2022

Position Requirements:

- Minimum 3 years' experience as a Quality Engineer in the medical device industry preferred
- BA/BS degree in science or another technical field preferred
- Medical Device Quality System knowledge including 21 CFR Part 820 and ISO 13485:2003/2016 preferred
- Experience participating in internal and external audits (e.g., FDA, Notified Body, Supplier) preferred
- Experience in writing Standard Operating Procedures, Test Procedures, Work Instructions and other Quality Documents preferred
- Experience with CAPA, complaint investigation and risk management preferred
- Regular, on-time attendance at work is an essential function of every job at BioSurfaces, Inc.
- Strong organizational and time management skills
- Individual must have a hands-on approach

Reports Directly To: Vice President of Manufacturing

Position Description:

The purpose of this position is to assume responsibility for the on-going improvement of the Quality Management System (QMS) at BioSurfaces, Inc. The Quality Manager will be responsible for managing customer and internal quality expectations by proactively establishing, managing and improving quality systems to ensure consistent product quality. This is a hands-on position that will require the active involvement in all aspects of the quality function, testing, investigating, handling of product and auditing functions.

Duties And Responsibilities:

- Must work closely with all Functional Departments to build quality into the product/process and continue to build a culture of quality at BioSurfaces, Inc.
- Manage and direct all activities of the QMS including on-going improvement, training and audits
- Determine training needs and daily schedule required for Quality Department
- Assume the role of Quality Management Representative for ISO 13485 and other future certifications
- Develop metrics to monitor process performance and proactively monitor existing processes and drive continuous improvements using a disciplined approach
- Determine customer quality requirements and drive processes and systems to meet the requirements
- Be the champion and driving force in obtaining and maintaining ISO certifications



Salary and Benefits:

- Salary will be commensurate with experience.
- Company pays 100% of benefits (HMO Blue Medical, Dental and Vision).
- Employee will receive three weeks of Earned Time Off (Flex Time) as well as 10 paid holidays and 2 floating holidays
- Company offers competitive 401K plan (after 6 months employment)
- Company offers phantom stock plan
- Company supports professional development of its employees through attending scientific conferences, meeting with key opinion leaders in various fields and assessment of devices in the preclinical setting to better understand both the doctor and patient needs.

About BioSurfaces:

The BioSurfaces mission is to improve lives throughout the world by applying our unique Bio-Spun™ nanofiber materials and our decades of expertise to develop and provide a range of products that are superior to those available today, including medical devices, research and diagnostic tools, and even personal care products. We achieve this mission through fair, profitable and satisfying collaborations with our customers and strategic partners. We know that we will continue to grow and prosper by making sure the members of our diverse and expanding team are happy to work with us and have our support in both their professional and personal lives. Finally, we also know that we will accomplish our mission only if we give back to the community around us, locally, nationally and around the world.

To Apply:

Please send your resume and cover letter to: [info@biosurfaces.us](mailto:info@biosurfaces.us)

