

BIOSURFACES, INC.
QUALITY MANAGER

Post Date: June 22, 2020

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: Chief Operating Officer (COO)

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 and Dental).
- 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:

Our mission is to improve the quality of medical care by augmenting existing and emerging medical approaches with our cutting-edge nanotechnology. We believe that our solutions are the future of biomedical devices, and will dramatically improve patients' quality of care upon their use. The company performs research and development for various types of medical devices, with applications in areas such as cardiovascular, gastrointestinal, neurostimulation and drug delivery.

To Apply:

Please go to <http://www.indeed.com/job/quality-manager-07fb1d7cd302e0a7> to apply now!

