Quality and Regulatory Manager

NuShores' mission is to improve the quality of life for people globally while competing successfully by applying its licensed and internally developed advanced materials portfolio to the Biomaterials industry. NuShores has exclusive global license to patented bone and tissue regeneration technologies developed at University of Arkansas – Little Rock from over $15M in research, and nearly $11M in NuShores funding.

We seek a seasoned Quality and Regulatory Manager to join our growing team. Are you career-driven, have strong mentoring skills, and have a depth of experience in leading biomedical product quality and regulatory efforts and teams? Come help us launch our NuCress™ scaffold product family, our award-winning bone void filler line of medical device products. If working with a smart and creative team that designs and builds products that improve quality of life interests you, then consider a career with us.

NuShores' Quality and Regulatory Manager will work closely with C-level management, research scientists, manufacturing, and our Quality and Regulatory services providers to move NuShores' product development efforts from our pipeline of licenses and internally developed innovations and inventions to achieve strategic and tactical business goals. The Quality and Regulatory Manager owns, audits, and drives improvements within the NuShores (CMP) Quality Management System (QMS). He / She also manages NuShores' registrations, applications, readiness to enter new markets (domestic and international), and NuShores' compliance with standards and requirements in all of the markets where NuShores engages in.

Main Job Tasks and Responsibilities

Quality:

- Manage all certifications and registrations including, but not limited to, ISO 13485:2016, MDSAP, 510K, and CE Mark.
- Manage all Quality Procedures and supporting documentation.
- Own the Document Management System (DMS) and provide recommendations for continuous improvement of document change control and document retention.
- Manage all and audit all Quality Procedures and supporting documentation and establish audit schedules to ensure all policies and procedures are followed. Audit all departments to ensure the QMS is being implemented appropriately.
- Manage and Own the Corrective & Preventative Action (CAPA) System.
- Support Management for successful implementation and adherence to departmental procedures, and to make recommendations for continuous improvement.
- Oversee all IQ, OQ, & PQ.
- Support Process Improvement within the organization.
- Support future ERP/MRP/QMS software implementation.

Regulatory:

- Manage Regulatory Submissions, Regulatory Updates, Renewals, Registrations, 510K's or other as required.
- Manage medical device reporting to regulatory bodies.
- Maintain / update PDAC System.
- Manage device labeling requirements or policies.
- Responsible for submission of all paperwork and/or documentation to government bodies or appropriate entities (domestic or foreign) that regulate medical devices and / or the different companies that NuShores will engage with, in the sale and / or distribution of its products or labeled products.

Education & Experience:

- Bachelor's Degree or higher (preferred).
- ISO 13485: 1 year (preferred).
- Quality audits: 1 year (preferred).
- Degree or Certification in Quality Systems or industry relevant experience.

- Knowledge and experience in technical writing and government submissions.
- Management experience preferred.
- Knowledge of computer systems, Document Management Software or Similar.
- Team player. Personal effectiveness in a team setting.
- Time management; goal oriented and metric driven.
- Self-driven with excellent follow through. Ability to prioritize activities to accomplish stated project/product objectives.
- Analytical; excellent attention to detail.
- Effective communicator - strong oral and written communications skills.
- Ethics – respects others, inspires trust, integrity in his/her work, upholds organizational values and culture.
- Ability to work well with a diverse team of science, engineering, and business members.
- Ability to work with and manage a team.
- Previous work at a startup is a plus.

Physical Demands: Employees may be regularly required to use hands to handle or feel, reach with hands and arms, and talk or hear. Employees may be frequently required to sit or stand for periods of time. He/she may be required to push, pull, or lift objects up to 50 lbs. He/she may be required to use a ladder. Specific vision abilities required for this job include close vision, distance vision, color vision, peripheral vision, depth perception and ability to adjust and focus. These physical demands and work environment are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform these functions.

Working Conditions: offices, manufacturing areas, engineering lab, clean room, warehouse environment.

Job Type: Full-time.

Pay: $61,227.00 - $124,130.00 per year.

Schedule: Monday to Friday.

Ability to commute/relocate: Little Rock, Arkansas 72211; reliably commute or plan to relocate before starting work (preferred).

Work Authorization: proof of legal right to work in the US will be required of all candidates.

Job Type: Full-time professional employee.

Reporting: Chief Executive Officer (CEO).

Salary: Competitive, with benefits.

Location. NuShores Biosciences is located in Little Rock, Arkansas, a city of momentum and energy with strong institutions like Fortune 500 companies, urban universities and technical colleges, hospitals, arts, historic museums and civil rights organizations. At the heart of the Natural State, Little Rock offers all the perks of an urban mid-size city with easy escapes to the bountiful surrounding nature (and its many biking and hiking trails, water sports, and outdoor adventures). Due to our solid economy, low cost of living and general quality of life, Little Rock is constantly featured in many quality-of-life lists from reputable magazines and blogs. We love it here, and we know you will too. Find out more at littlerock.com

To apply, submit resume at www.nushores.com or email at info@nushores.com.