Position: Associate Director – Quality Operations

TARIS Biomedical is a unique therapeutically-focused urology company developing drug-device combination products for the treatment of genitourinary diseases.

The individual will be responsible for the or ensuring products, processes and systems effectively meet expectations of TARIS' Quality Assurance and Overall Business from a new product development and quality compliance perspective from concept through commercialization. The successful candidate will be a seasoned professional with experience in Design assurance, Quality engineering and quality assurance in a pharmaceutical or combination product related FDA regulated industry.

This role is a part of TARIS' mission to achieve excellence in new product development and regulatory compliance through Quality Engineering, application of Quality Standards and Procedures. This role has a primary responsibility of Design Assurance and Quality Assurance. This role will provide Quality Oversight to work performed internally with Product Development group and Contracted Vendors. This position will provide QA Management the assessment of design development from QA perspective, Qualification of manufacturing and testing process development oversight internally and at Pharmaceutical Vendor(s) and serve on cross-functional project teams such as Design Control, validation and tech transfer. This position will also be responsible for Vendor Oversight, administer and maintain the Quality Management System (QMS) and other processes related to the QMS. This individual will be quality focused, responsible for ensuring product compliance and regulatory compliance to established processes in accordance with regulatory requirements, Company policies and procedures.

Principal Responsibilities:

- Represent QA function in technology assessments, device conception, design development and performance. Represent QA function in PD projects to develop DHFs, DMRs, and creating and maintaining DMFs. Work closely with PD in design control activities, including translation of user needs to design requirements, product performance specifications, design verification and validation, lead risk management activities including risk management plan, hazard analysis, and FMEAs.
- Represent QA function on product development, testing, manufacturing and others in the developmental process, vendor QA activities such as analytical methods transfer and validation, support sterilization validation, label control and qualification.
- Manage quality oversight of all vendors including Manufacturers, Packagers, Laboratories, process improvement activities and vendor control.
- Be responsible for Supplier Quality agreements, supplier control, Audits and follow-ups, QP relationship management, external product control, intermediates release and distribution oversight, vendor qualification and AVL program.
- Be responsible for activities related to specifications, changes, change logs, assist Quality management on external regulatory and compliance related matters, audits, Quality Agreements, vendor non-conformances, investigations and change controls.

Quality Assurance

- Perform product release activities and CMO management including batch record review, deviation review, MRB, risk assessment and reports.
- Support external and internal audits, follow-ups, issue tracking and closure. Compiles and maintains vendor documentation to support pivotal supplies (e.g. GLP and clinical trial supplies). Track audit observations responses and effectiveness assessments. Assist QA Management on collection of data and preparing presentations, meeting minutes and report out on the management review.
- Deviations, Investigations and CAPA – assist R&D teams in ensuring deviations, CAPAs and investigations are fully addressed and close in a timely fashion. React decisively to a wide range of non-conformance events, CAPAs, and other quality/compliance indicators.
- Improve quality management systems related to the product lifecycle from development to commercialization, overseeing activities related to R&D and technology transfer. Prepare, maintain and review internal policies, procedures, systems, and processes, to ensure compliance to federal and international regulatory requirements and guidelines.
- Maintain controlled document database for the QMS and Quality department, Change Control management, policies and procedures, manage specification changes,
- Support QA related functions as needed such as authoring and/or reviewing dossiers, Maintain controlled document database for the QMS and Quality department.
- Assists in creating management review presentations, generates trend and status reports for monthly updates for Quality function head.

Qualifications

- Bachelor's degree, minimum 8 years of experience in a quality-related or new product development role working along with QA in a pharmaceutical/biotech/medical device industry. 2 years in people management preferred.
- Experience in Quality Engineering and Quality Assurance management preferred. Demonstrated knowledge of Quality Systems and cGMP within an FDA-regulated environment, experience with electronic systems (eQMS) preferred
- Excellent organizational and time management skills with a strong attention to detail. Strong interpersonal communication skills; acts with urgency and passion. Enjoys helping others
- Ability to work both independently and with a team in a collaborative, fast-paced setting.
- Up to 15% Travel is required for this position.

To apply, please send your CV to careers@tarisbio.com