Bio Varam

We are HIRING to drive

Regulatory Affairs
Quality Control and
Quality Assurance

Send your resumes to

careers@uratpx.com

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

Regulatory / QA / QC Specialist – Medical Devices & Advanced Therapies:

Number of Positions: 1

Qualifications: 5 to 7 year's experience

Role Overview

We are seeking a **Regulatory / QA / QC Specialist** with at least 5 years of proven experience in **medical devices, biologics, or advanced therapy medicinal products (ATMPs)**. The role will be responsible for **regulatory strategy, compliance, and quality systems management** to ensure our innovative products meet **Indian (CDSCO, ICMR, BIS)** and **global regulatory standards (US FDA, EMA, ISO, ICH, WHO, GMP, GLP, GCP, ISO 13485, ISO 14971)**.

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

Key Responsibilities

Regulatory Affairs (RA):

- Develop and execute regulatory strategies for **medical devices, ATMPs, and combination products**.
- Prepare and submit regulatory dossiers (IND, IDE, BLA, CE Marking, CDSCO submissions).
- Liaise with **regulators (CDSCO, FDA, EMA, WHO, DCGI)** and support clinical trial authorizations.
- Monitor and interpret evolving regulatory guidelines for **cell & gene therapies, exosome products, collagen-based devices, and diagnostic kits**.

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

Quality Assurance (QA):

- Establish, maintain, and continually improve **QMS** (ISO 13485, GMP, GLP, GDP, GCP compliant).
- Conduct internal audits, supplier audits, and ensure regulatory audit readiness.
- Oversee **SOP development, CAPA, deviation management, and risk assessments**.
- Ensure compliance with **biological safety, sterility assurance, and device validation protocols**.

Quality Control (QC):

- Design and implement QC systems for **biomaterials, peptides, collagen scaffolds, exosome-based kits, and medical devices**.
- Oversee analytical testing, stability studies, and release criteria for R&D and GMP batches.
- Develop assay validation protocols in line with **ICH Q2(R2)** and **ISO standards**.
- Collaborate with R&D to scale QC methods for preclinical and clinical products.

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

Qualifications & Experience

- Master's degree or higher in **Biotechnology, Biomedical Engineering, Regulatory Science, Life Sciences, or related field**.
- Minimum **5 years of experience** in Regulatory Affairs / QA / QC in **medical devices, biologics, or advanced therapies**.
- In-depth knowledge of **ISO 13485, ISO 14971, GMP, GLP, GCP, FDA 21 CFR Part 11, ICH Q series, EU MDR, ATMP regulations**.
- Experience in **clinical trial regulatory submissions** and interactions with authorities (CDSCO, FDA, EMA).
- Strong background in **documentation, compliance audits, and QMS implementation**.
- Familiarity with **exosome products, collagen scaffolds, bioprinting,**

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

stem cell or peptide therapeutics is a strong plus.

Skills & Attributes

- Excellent knowledge of **global and Indian regulatory frameworks**.
- Strong leadership and ability to train teams on **compliance and quality standards**.
- Detail-oriented, process-driven, and skilled in regulatory writing.
- Ability to work in a **fast-paced, innovation-driven environment**.
- Strong communication and liaison skills with regulators, auditors, and cross-functional teams.

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine

What We Offer

- Opportunity to be part of a **pioneering biotech ecosystem** working on world-class innovations.
- Exposure to **international collaborations**

UR ADVANCED THERAPEUTICS
Engineering Personalized Medicine