JETA Molecular B.V.

JETA Molecular is a molecular diagnostics company focused on commercialization of advanced technologies that will change the way transplantation medicine is practiced today. Early detection of transplant rejection or disease relapse is critical for the adjustment of a transplant recipient's treatment regime, graft survival and higher quality of life for patients. JETA's tests will provide best in class solutions for post-transplant monitoring of transplant rejection and disease relapse. JETA's solutions will enable new applications and will translate into better patient care and survival rates.JETA's founders have extensive expertise in the design, development and commercialization of IVD/CE-marked, ASR/GPR and RUO molecular diagnostic kits and software for transplantation and human genetic testing. JETA has support from, and collaborations with, key opinion leaders in the fields of stem cell and solid organ transplantation. It is through these relationships that clinical utility of JETA's approaches has been established.

JOB TITLE	**RA/QA Manager**		
Job Location	Utrecht	**Company Industry**	Life Sciences Transplantation Diagnostics
Divison/Department	Regulatory Quality	**Manage others**	**No**
Status	Full-time/Part-time available	**Reports to**	CEO
Contractual status	Employee	**Level**	**Level1: Junior** **Level2: Experienced** Level3: Senior/Expert Level4: Lead

JOB DESCRIPTION

The RAQS manager ensures that the products or services provided by the organisation conforms to ISO 13485 quality management system, any applicable regulatory and customer requirements. RAQS Manager establishes and documents quality management system procedures, monitors and advises on the performance of the quality management system, produces data and reports on performance, measuring against set standards.
RAQS manager act as PRRC (Person responsible for regulatory compliance) according to Article 15 of IVD-R (Regulation 2017/746).
The RAQS manager provides leadership and is responsible for overseeing day-to-day activities of the quality team, including resource scheduling, team communications and status reporting as well as promoting and overseeing use of established best practices, policies, and procedures.

PROFILE REQUIREMENTS

- Understanding of ISO 13485 standard and IVDD directive
- Must have experience with ISO 13485, CE marking, FDA approval
- Able to work fairly independently
- Experience in life sciences is an advantage
- Knowledge of biology, genetics
- Quick learner - interested in bioinformatics/biology/software testing

Fluent English

RESPONSIBILITIES

- Regulatory management
  - Act as PRRC (Person responsible for regulatory compliance) according to Article 15 of IVD-R (Regulation 2017/746)
  - Monitor applicable regulatory requirements of targeted markets
  - Define IVD regulatory pathway for targeted markets
  - Create regulatory roadmap
  - Review technical document for completeness
  - Apply for regulatory submission of IVD products
  - Apply to register a medical device at local authorities (or notify them)
  - Report incidents to authorities and notified bodies
- Quality System management
  - Monitor applicable standards and guidance documents
  - Introduce new quality processes/procedures and standards company wide
  - Lead the quality initiatives, projects for the whole company
  - Ensure that processes under QMS are documented completely
  - Establish, implement and maintain quality management system documentation for Quality management department
  - Define requirements for document control company wide, maintain Master Document list for procedures and quality documents, review procedures before approval for compliance to ISO 13485 and regulatory requirements;
  - Ensure awareness of applicable regulatory and QMS requirements company wide
  - Create yearly audit plan including internal, supplier and 3rd party (Notified body) audits
  - Manage preparation for 3rd party audits company wide
  - Perform internal and supplier audits according to yearly audit plan
  - Report to top management on the effectiveness of QMS and any need for improvement
  - Ensure quality control of supplier management by
    - establish and maintain QMS and regulatory requirements in quality annex of supplier agreements
    - define quality criteria in supplier evaluation and perform supplier evaluation with COO
    - define verification of supplied products
    - establish and maintain supplier related complaint handling process
  - Monitor execution of complaint categorization on daily basis
  - Establish and maintain CAPA procedure to drive problem solving and continual improvement processes
  - Raise CAPA and inform Compliance Committee in case of potential adverse event and regulatory issues
  - Establish process for risk management, participate in risk assessment
  - Act as Management Representative

If you are interested in applying for this position, please email your C.V. and Cover Letter to info@jetabv.com