

We are hiring at Innitius: QA/RA Manager

Innitius is developing novel patented medical devices based on torsional wave technology for the diagnosis of conditions or syndromes based on the consistency of the tissue being tested. The company's initial focus is on improving the outcomes and reducing the costs associated with preterm labor (PTL).

As part of the development plan, Innitius is hiring a QA/RA manager to join the company as soon as possible. Please, feel free to share this article or the attached documents to anybody that fits with the description:

Duties and responsibilities

- **Create a regulatory strategy & work-plan.** (supported by Regulatory affairs outsourced assessment)
- **Regulatory pre-submissions to EMA & FDA.** (supported by Regulatory affairs outsourced assessment)
- **Establish a design history file.**
- **Establish a risk management file.**
- **Build relationships with suppliers – manufacturers.**
- **Establish document controls.** *As Innitius is creating its own product, it'll generate plenty of records, and it's important to have a system for organizing and maintaining them – they'll later be reviewed by the FDA, ISO, and possibly others to establish Innitius' compliance with medical device regulations.*
- **Technical File & FDA documentation drafting** (supported by Regulatory affairs outsourced assessment)

A. Establish, manage and maintain compliance with FDA QSR, including establishment registration, new product submissions, CAPA System.

B. Establish, manage and maintain compliance with MDD 93/42/EEC directive, including CE Mark applications via Technical Files.

- **Implement Manage and maintain compliance to ISO13485 requirements.**
- **Create a QA strategy**
- **Perform Risk Assessment and Audit Planing**
- **Perform QA audits**
- **Vendor management, oversight and/or auditing**
- **Mobility**

Experience required

1. 3+ years' experience in Quality Assurance **within the medical devices** field of use
2. Understanding of European & American Health Authority regulations, guidelines, policies.
3. Ability to maintain a high level of accuracy and attention to detail.
4. Effective project management skills.
5. Excellent planning, organization, interpersonal, time and change management skills.

Working in Innitius

1. **Salary:** competitive salary and equity plan associated.
2. Any other work environment propositions could be studied.