TISSIUM

Site Quality Assurance Engineer

Contract: CDI, permanent

TISSIUM is a fast-paced medical device company, dedicated to the development of innovative tissue reconstruction solutions. We are leveraging our technology platforms to develop novel solutions to disrupt the field of surgery and positively impact the life of patients.

We are actively looking to recruit a **Site Quality Assurance Engineer** to be part of TISSIUM's production facility based near Lille (France). This person will run, maintain and continually improve the production site Quality Management System (QMS).

Duties & Responsibilities

The Site Quality Assurance Engineer, reporting to the Head of Site Quality will ensure continuity and compliance of the QMS by:

- ✓ Developing, assisting and/or implementing procedures, as required, in accordance with the company strategy in accordance with EN ISO 13485, FDA 21 CFR part 820, CE mark regulation (MDD 93/42 CEE, MDR 2017/745) and other applicable standards and regulations;
- ✓ Ensuring an effective implementation and follow up of the continuous improvement activities: Corrective Action and Preventive Action, Non-Conformity and Change Control;
- ✓ Ensuring compliance to the QMS system of Manufacturing and supporting department on the Roncq site:
- ✓ Ensuring that production operations are in accordance with work instructions and procedures in place;
- ✓ Ensuring that identification and traceability of the products are in compliance with internal procedures;
- ✓ Ensuring that anomalies are identified and investigated in collaboration with the relevant departments;
- ✓ Participating in production documentation review;
- ✓ Performing audits.
- ✓ Performing production batch review;
- ✓ Performing the raw material/components batch release;
- ✓ Training of production site employees and new hires to Quality in general and the company's QMS in specific.

Qualifications & Skills

- ✓ Engineering Degree or equivalent;
- ✓ Three years' minimum experience in Quality in a medical device or a life science company;
- ✓ Working knowledge of EU medical device directive 93/42, EU Medical Device Regulation 2017/745, ISO 13485, and FDA (FDA 21 CFR part 820) regulations;
- ✓ Excellent communication skills (both oral and written) in English.
- ✓ Auditing experience;
- ✓ Proficiency in aseptic process a plus.

Job Competencies & Personal Attributes

- ✓ Autonomous and detailed oriented;
- ✓ Dynamic and proactive;
- ✓ Able to understand complicated processes and understand the associated documentation needs;
- ✓ Disciplined and very well organized,
- ✓ Persuasive and diplomatic.

The Site Quality Assurance Engineer will report to the Head of Site Quality. The position is based at TISSIUM's new facility in Roncq (near Lille, France). To apply for this position please email your CV to: jobs@tissium.com ; *Ref: 201912-001*

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