TISSIUM

# Head of Site Quality

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 **Head of Site Quality** to be part of Tissium's Development Factory. This person will manage and improve all of the production site quality related system and activities to ensure that:

- ✓ The QMS is in compliance with all applicable standards and regulations;
- ✓ All production activities are in compliance with the company's QMS;
- ✓ The Quality Control (QC) strategy and laboratory are in compliance with applicable standards and regulations;
- ✓ Provides Quality Assurance (QA) leadership;
- ✓ Batch release is performed according to company's policies and procedures.

## Duties & Responsibilities

- ✓ Manages continuity and compliance of the QMS to applicable standards and regulations.
- ✓ Ensures application of the QMS for all activities on Tissium's production site.
- ✓ Provides Quality Assurance (QA) leadership;
- ✓ Establishes, in collaboration with the production department, and supports the execution of the production site's quality control strategy.
- ✓ Ensures compliance with the QMS for all production activities by:
    - Ensuring that all site batch records and anomalies are identified and investigated and that only conforming products are released;
    - Ensuring that site incoming inspections are undertaken appropriately;
    - Ensuring that the system and organization in place is designed to efficiently manage inventory, including adequate identification and traceability;
    - Ensuring that production documentation is adequate.
- ✓ Establishes and manages the production site's metrology strategy.
- ✓ Provides guidance on process quality requirements and risk management to the teams on the production site and any other involved parties (i.e. subcontractors).
- ✓ Acts as the medical device vigilance correspondent back-up.

## Qualifications & Skills

- ✓ Engineering Degree or equivalent;
- ✓ A proven experience in aseptic production processes is a must;
- ✓ Ten years minimum of experience in Quality in a medical device or a life science company and in a production environment;
- ✓ Experience in management of a multi-disciplinary team;
- ✓ Working knowledge of EU medical device directive 93/42, ISO 13485, and FDA (FDA 21 CFR part 820) regulations;
- ✓ Auditing experience;
- ✓ Excellent communication skills (both oral and written) in English;
- ✓ Competent in interactions with executive management, regulators and suppliers;
- ✓ Proficiency in analytical methods a plus.

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**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 Head of Site Quality will report to the Chief Development Officer. The position is based in Roncq, France.
To apply to this position please email your CV to *jobs@tissium.com*



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