TISSIUM

Qualification & Validation Manager

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 **Qualification & Validation Manager** to lead and manage all aspects relating to the site equipment's qualification and process validation.

Duties & Responsibilities

- ✓ Defines, writes and follows the applicable validation strategies for any new equipment or process introduces on the production site, according to the applicable standards;
- ✓ Defines, writes and follows the strategy and frequency of the equipment and process requalification;
- ✓ Defines, writes and follows all the documentation necessary for the conduct of qualification / validation activities on the production site;
- ✓ Defines, writes and follows all the documentation necessary for any change control that may have an impact on the qualification / validation status;
- ✓ Support the design department for any new process transfer to the production site;
- ✓ Ensure a permanent regulatory watch on the evolution of standards and technologies related to its qualification / validation activity;
- ✓ Participates as an expert for the investigation of potential non conformities occurred on the production site, but also on supplier's site;
- ✓ Participates as an expert to the regulatory audits or inspections and writes the qualification part of the regulatory documentation.

Qualifications & Skills

- ✓ Engineering degree, pharmacist or equivalent;
- ✓ A minimum of 5 to 10 years of experience in manufacturing of medical products (pharmaceuticals or medical devices);
- ✓ Strong experience in aseptic production and associated processes;
- ✓ Strong experience in qualification / validation's activities management;
- ✓ Excellent understanding of quality requirements for the production of medical devices or pharmaceutical products and specifically the requirements of ISO 13485, ISO 13408 and GMP standards and practices;
- ✓ Strong know-how in manufacturing process design, technology transfer, scale-up operations, analytical development and process validation
- ✓ Good communication skills (written and verbal) in English;

Job Competencies & Personal Attributes

- ✓ Strong leadership skills and attention to details;
- ✓ Strong planning, problem solving and negotiation skills;
- ✓ Excellent team work abilities;
- ✓ Capacity to understand complicated processes;
- ✓ Autonomy and good organization skills.

The Qualification & Validation Manager will report to the Site Director. The position is based in Roncq (near Lille, France). To apply to this position please email your CV to jobs@tissium.com ; Ref: 202001-001

+33 1 76 21 72 28
74 Rue du Faubourg Saint-Antoine
75012 Paris, France