Industrialization Engineer

Contract: Permanent (CDI)

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

We are actively looking to recruit an **Industrialization Engineer** to be part of Gecko's Development Team. This person will lead and execute the company's equipment installation and qualification along with process validation and improvement activities.

- **Duties & Responsibilities**
  - ✓ Under the leadership of the Site Director, manage and support the company's production efforts including equipment qualification, process validation, process improvement, and scale-ups either internally or in collaboration with the company's suppliers;
  - ✓ Define, implement, and manage all aspects relating to the installation and qualification of new equipment and improvement and requalification of existing equipment within the manufacturing site;
  - ✓ Define, implement, and manage all aspects relating to the validation of manufacturing processes used for the production of Gecko Biomedical products either internally or in collaboration with the company's suppliers;
  - ✓ In collaboration with the product development team, define, manage, and interact with various suppliers for the procurement of raw materials and semi-finished products used for the production of Gecko Biomedical products;
  - ✓ Support the development and implementation of the company's manufacturing strategy and related processes;
  - ✓ Proactively advise and support the product development team at all stages of the product development cycle to yield highly manufacturable products and minimize manufacturability, sourcing, and scalability risks;
  - ✓ Participate in suppliers' audits.

- **Job Environment/Interactions**
  - ✓ Assist in the preparation of the Design Dossier documentation by working closely with the company's product development team;
  - ✓ Assist in the preparation of the company's various audits to ensure compliance with ISO 13485, the US FDA, and other foreign authorities;
  - ✓ Support the QA department in the conduction and management of the company's CAPA activities.

- **Qualifications & Skills**
  - ✓ Engineering degree or equivalent;
  - ✓ 3 to 5 of experience in manufacturing of medical products (pharma or medical devices);
  - ✓ Strong know-how in equipment validation and process validation;
  - ✓ Excellent understanding of quality requirements for the production of medical devices and specifically the requirements of ISO 13485;
  - ✓ Excellent grasp of quality requirements including document change controls; investigations and CAPA related activities; and management of suppliers;
  - ✓ Excellent communication skills (written and verbal) in English.

- **Other Skills**
  - ✓ Understands the importance of quality and patient safety in a medical device manufacturing environment;
  - ✓ Autonomy and great organization skills;
  - ✓ Strong planning, problem solving, and negotiation skills;
  - ✓ Strong ability in driving third parties to adhere to timelines and budgets;
  - ✓ Excellent team work abilities;
  - ✓ Ability to understand complicated processes and associated suppliers' interactions;
  - ✓ Creativity in approaching and solving technical challenges.

The Industrialization Engineer will report to the Site Director. The position is based in Roncq (59), France. To apply for this position please email your CV to *jobs@geckobiomedical.com*