



Job Description

QA Manager (part-time 30% - 50%)

Coat-X SA is an innovative company providing unique coating services and equipment solutions. The company is looking for a QA Manager whose main missions will be to maintain and improve the existing Quality Management System in compliance with ISO13485 and lead the medical customers qualification projects within the company.

Responsibilities

- Manage, review, improve and approve procedures, templates and work instructions assuring compliance to ISO13485 and ISO14971.
- Define and drive the internal audit plan.
- Lead and assist during external audits (certification bodies and customers).
- Organise and lead management reviews, act as management representative.
- Perform the standards regulatory surveillance.
- Define and execute process validations with the Engineering Manager.
- Review documentation and release of production batches, including non-conformities.
- Owns internal CAPA process and CAPA reports.
- Manage supplier classification and validation.
- Oversight and management of change requests and documents control approval flow.
- Ensures proper monitoring of equipment calibrations and clean room qualification (ISO5).
- Definition and execution of customer project process validation.
- Medical customers project lead or co-lead assuring customer requirements are met, including Quality Agreement, Process validation and Purchase Specifications.

Position requirements

- Bachelor's /master's degree in science, engineering, or equivalent degree/experience in a relevant discipline.
- Minimum 5 years Quality (QA/QS/QC/Compliance) experience with medical devices manufacturing and/or medical devices quality systems.
- Thorough understanding of ISO13485 & ISO14971.
- Excellent interpersonal, collaborative, and organizational skills.
- Ability to communicate effectively in French and English (German is a plus).

We offer a very dynamic work environment within a small and highly motivated team. Our customer base is very diverse and provides great exposure to very varied technical challenges and use cases.

Applications should be sent to the email address: hr@coat-x.com