We are a full-service consulting firm in the sectors of Engineering Services, Quality Assurance & Regulatory Affairs and Operational Excellence.
Our services are tailored to the specific needs of our clients.
We provide the necessary solution that help our clients to achieve their objectives, to improve their efficiency and to resolve problems.

We are looking for a

QA/RA SPECIALIST

Responsibilities

Key responsibilities include, but are not limited to:

- Establish and maintain appropriate documents and records with applicable standards and regulations,
- Ensure special process validation,
- Ensure quality engineering activities such as:
  - Special process validation (IQ, OQ, PQ methodology),
  - Design control (list of applicable standards, quality criteria definition, sampling plan, risk management, V&V activities, labelling, technical file...)
  - Quality operation (Quality control plan, Change management, NC and CAPA management, supplier management)
  - Quality system (SOP improvement, internal audit, certification audit…)
- Execute internal audit for our customers and assessment of technical documentation,
- Ensure Standards and Regulations surveillance (Assess the potential impact of new or revised standards and regulations),
- Participate to Notified Bodies audits and FDA inspections with our customers,
- Propose, develop, support customer regulatory affairs strategies,
- Lead, support CE mark submission and ensure documentation requirements related to design, risk analysis, verification & validation, testing and traceability,
- Prepare, support the country specific RA registration files for medical devices of our customers,

Profile

We are looking for a new team member with the following profile:

- Technical or scientific degree in engineering, biomedical or similar,
- 2-3 years of experience in QA/RA department in the medical devices industry,
- Knowledge/Experience in validation of special manufacturing processes (IQ/OQ/PQ),
- Knowledge/Experience in applicable standards and regulations of the medical devices industry (ISO13485, ISO14971, IEC60601-1-X, IEC62366-1, 21CFR820 QSR, MDD, MDR, MDSAP, MedDO),
- Experience in product development and risk management processes,
- Experience in validation of sterilization process is a plus.

Soft Skills

- Passionate about life sciences, technologies, and innovation,
- Quality and customer-service oriented,
- Strong communication in English & French both verbal and written, German is a plus,
- Ability to follow several projects in parallel and to quickly jump from one task to another,
- Good writing abilities,
- Flexible & open-minded,
- Entrepreneurial spirit,
- Autonomous.

Entry date

- 1st February or to be agreed

If you are interested send us your application at info@gmb-services.com

Or call us at 021 841 13 57 / 079 906 70 31