





## LOS ESTAMOS BUSCANDO.

career-cr@admedes.com





## **QUALITY ENGINEER**

## **RESPONSIBILITIES**

- Support process validation studies, including IQ/OQ/ PQ, equipment, and software validation
- Interface to manufacturing engineers during review of process outputs and propose improvement activities
- Support in internal/external audits (by customer and/or notified body)
- Support in supplier evaluation, qualification, maintenance of supplier files
- Provide quality control support for incoming inspection, in-process, and final inspection
- Assist quality management (Admedes GmbH) in implementing, maintaining, and aligning quality systems that are compliant with ISO 13485 and FDA QSR requirements
- Training management
- Perform final quality release of products and documents.
- Document translations and transfers from English into Spanish
- Creation of production lot documentation
- Performs other related duties and responsibilities as assigned by Quality Manager

## **REQUIREMENTS**

- Graduate degree or equivalent
- Experience in an ISO 13485/FDA regulated environment
- Knowledge of applying statistical analysis for testing, process control, and design of experiments
- Knowledge in the areas of GMP, qualification, validation & verification, risk management or incoming inspection
- Strong verbal and written communication skills in English and Spanish
- Advanced knowledge in MS Office
- Ability to work under pressure, flexibility, and independence
- Organized, detail-oriented team player capable of working in a deadline dedicated environment
- Valid passport for an on-site training in the German headquarter for approximately 1-3 months