



SENIOR QA ENGINEER

Eindhoven, The Netherlands

Xeltis BV in Eindhoven is looking for a Senior QA Engineer, willing to work in a dynamic research and manufacturing environment towards the clinical realization of Xeltis' revolutionary products.

Who are we looking for?

Education

Minimum Bachelor Degree in technical area or other relevant scientific field.

Experience

- Minimum 5 years of industry experience.
- At least 2 years of experience in medical device (preferred) or in other regulated industries like pharma, automotive or aerospace.

Skills and experience

- Broad working knowledge of ISO 13485, ISO 14971, FDA QSR, EU MDD, EU MDR.
- Experience with test method validations and process validations.
- Experience in root cause analysis, corrective and preventive actions.
- Experience with risk management.
- Experience in writing and maintaining Quality Management System procedures, and providing training on them.
- Good knowledge of and experience with Quality Assurance & control methodologies.
- Experience with internal and external audits.
- Pragmatic approach to problem-solving.
- Able to work per priorities and tight deadlines in a fast paced, time sensitive environment.
- Good communication, reliable, independent, goal-oriented, pragmatic attitude.
- Strong organization skills.
- Fluent in English, reading and writing.
- Experience with statistical software, e.g. Minitab is preferred.
- General computer and software proficiency: email, Word, Excel, etc.

Activities include

Test method validations and process validations.

Release of products for clinical studies.

Review technical reports and design documentation.

Manage structural improvements in the QMS.

Introduce and implement the quality processes and tools required to ensure product quality.

Provide training for relevant QMS Management areas.

Manage and perform internal and external audits.

This is a full-time position (40 hours per week) for 1 year.

The assignment location will be Eindhoven, The Netherlands.

About Xeltis

Xeltis is a clinical-stage medical device company pioneering a restorative approach in heart valve therapy. Xeltis' technology enables natural heart valve restoration.

Xeltis is currently investigating additional applications of its innovative approach to restore other heart valves and blood vessels.

At Xeltis, we recognize that people make a difference. We are a young, dynamic, international team of 30+ professionals dedicated to improving patients' lives through innovation.

Our Company values:**We at Xeltis:**

- Innovate to improve patients' lives
- Listen and challenge with respect
- Grow through personal development
- Act like owners for a common goal
- Work with JOY!

For more information and to submit your CV and motivational letter, please contact

- Xeltis HR: recruitment@xeltis.com