Job Opening

Quality Engineer R&D

BAAT Medical Products BV
Hengelo. The Netherlands

To further strengthen the Quality and Regulatory Affairs department, BAAT Medical is looking for a Quality Engineer for the R&D.
BAAT is a dynamic and growing medium sized (~35 employees) company which provides development, operations and contract legal manufacturing services to large multinationals and startups within Orthopedics, Trauma and Spine worldwide.

As Quality Engineer you will focus on guiding R&D teams to meet all quality requirements as efficient as possible. Reviewing deliverables from a QA perspective and ensuring we are compliant with geographical demands.

You will also be responsible for Auditing and Qualifying new suppliers and ensuring that the production files meets all requirements at the point of design transfer.

You will be working within a small QA/RA team and report directly to the Quality and Regulatory Affairs Manager.

Typical Tasks:

- Review and approve project documentation to ensure it is in line with the QMS and Quality standards
- Facilitate stage gates reviews and release of DMR's
- Support and monitor ECO's to address design and scope changes in R&D
- Audit and qualify new suppliers
- Setup and review supplier, distributor and customer quality agreements
- Lead CAPA's related to the R&D department
- Training colleagues to processes and procedures

Do you have:

- Bachelor's or master's degree in Mechanical Engineer, Industrial Engineering & Management (Technische bedrijfskunde) or similar.
- Minimum of 3 years of experience as quality engineer in the Medical Devices sector.
- Knowledge of ISO13485 and preferably also FDA 21CFR820 Quality System Regulation.

BAAT will provide additional intensive training to onboard the candidate into ISO13485 and FDA 21CFR820.
A personality test may be part of the recruitment process.

The position is for 32 to 40 hours (depending on candidate's preferences)
Salary is market conform

For more information or applications please contact:
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