

Job Opening



Junior Regulatory Affairs Officer

BAAT Medical Products BV
Hengelo, The Netherlands

Jr. Regulatory Affairs Officer (0-3 years of work experience) to support the Regulatory Affairs officer.

BAAT is looking for a starter in this position. The person will be trained and guided by the Regulatory Affairs officer and the Quality and Regulatory manager. The purpose of this position is to train and grow the person into the position and responsibility of an (Sr.) Regulatory Affairs officer.

Job Description Junior Regulatory Affairs Officer

The Junior Regulatory Affairs Officer supports the Regulatory Affairs Officer in ensuring that the products placed on the market by Baat Medical comply with the relevant legislation and regulations.

Typical Tasks:

- Compile/review/update Technical Files (MDR or 510(k))
- Maintain regulatory databases (FDA, EUDAMED)
- Regulatory Reportability Review of Complaints, Changes, etc.
- Regulatory Review of Product Development Deliverables
- Review of updates and changes to standards
- Investigation and setup of regulatory pathway for new medical devices (EU MDR, USA, MDSAP countries)
- Registration of devices with authorities and notified bodies

Role profile:

- Bachelor or Master working level
- Good command of English, both spoken and written
- Profound writing skills
- Affinity with technical environment
- Attention to detail, diligent
- Analytical
- Result driven
- Team player
- Pro-active/self starter
- Interested in learning new standards, regulations, etc.

BAAT will provide an intensive training to onboard the candidate into ISO13485, QMS and DMS, A personality test may be part of the recruitment process.

For more information or applications please contact:

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