

## Job description

Position: QA/RA Specialist

Work place: KME German Branch Eschborn

Territory (sales only): n.a.

Item	Demands/Requirements
<b>Report into</b>	Senior Manager QMR and Regulatory Affairs
<b>Qualification</b>	<p>Qualified in regard to EN ISO 13485:2016 (especially complaint handling, supplier control, change control, nonconforming products, audits, CAPA, document control, record control)</p> <p>Qualified in regard to the Medical Device Regulation (2017/745 EU)</p> <p>Completed study in science or engineering</p> <p>Must be interested in regulatory requirements for medical devices</p> <p>Good written and oral communication skills</p> <p>Medical Device Consultant according German Law on Medical Devices</p> <p>Experienced in conducting audits</p>
<b>Skills</b>	<p>Versed in sampling, evaluating and interpreting data</p> <p>Fluent in English, German</p> <p>Communicative and reliable internal and external communication partner</p> <p>Analytical, structured and detailed working style</p> <p>Very well versed in using Microsoft office (Word, Excel, PowerPoint, Visio), SAP experience welcome</p> <p>Persistent in implementing legal and standard requirements</p> <p>Flexibility in adapting implementation of legal and standard requirements to KME processes</p> <p>Capability to detect, understand and communicate new legal or normative requirements</p>
<b>Staff responsibility</b>	none
<b>Main Tasks</b>	<ul style="list-style-type: none"> <li>- Designated complaint Coordinator</li> <li>- Handling requirements of WEEE (Portal EAR)</li> <li>- Handling and documenting changes</li> <li>- Conduct QA tasks such as controlling SOP "verification of purchased product", usage-decision for returned product, incoming inspection</li> <li>- Maintain registration data base</li> </ul>

**Responsibilities**

Processes:

- complaint handling
- change control
- verification of purchased and non-conforming products
- waste management
- medical device registration monitoring

Signature :

Signature employee:



Date: 2024-02-01

Date: