

Verification & Compliance Specialist

m/f/d, Zug

In this role, you will be responsible for the independent regulatory verification and evaluation of third-party products in relation to the applicable European (EU-MDR / EU- IVDR) and Swiss regulations (MedDO / IvDV).

Location: Rotkreuz

Duration: 6 months

Tasks & Responsibilities:

- * Regulatory verification: Independent review and evaluation of technical documentation, declarations of conformity (DoC), CE certificates and markings of 3rd party medical devices and in vitro diagnostics, verification of the correct labeling with regard to CH-REP (Swiss Authorized Representative) and importer obligations according to MedDO/IvDO.
- * Vendor & Partner Management: Communication with suppliers and partners to demand, review and clarify missing regulatory evidence and quality agreements.
- * PRRC Support: Creation of recommendations for the release or blocking of third-party products for the Swiss market.
- * Operational support in the area of regulatory as required: e.g. supplier enquiries, document review (non-exhaustive list)

Requirements:

- * Successfully completed studies in the field of medical technology, natural sciences, industrial engineering or a comparable qualification
- * Regulatory expertise: Demonstrable, several years (3+ years) of professional experience in Regulatory Affairs / Quality Management in the medtech or IVD sector
- * In-depth knowledge of EU MDR (2017/745) and EU IVDR (2017/746), Swiss Medical Devices Ordinance (MedDO) and In Vitro Diagnostic Medical Devices Ordinance (IvDV)

Job profile

 Life Sciences - Quality Management

 Zug

 Contracting

 Full Time



As soon as possible - 6 month after start date



MDR, IVD, Quality Assurance, Regulatory Affairs



Sounds interesting?

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- * Experience with 3rd party processes: Hands-on experience in auditing, approving or verifying supplier and third-party documentation
- * **Fluent in German and English, both written and spoken**

Sounds like a great job?

Then we look forward to receiving your complete application documents through our online application form.

When applying by email, the sender agrees that his or her data will be used in accordance with our data privacy policy.

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