

JOB VACANCY

As an innovative and internationally oriented manufacturer of premium intraocular implants (IOLs and artificial iris prostheses including the CUSTOMFLEX® ARTIFICIAL/RIS), we develop, produce and distribute medical devices in order to provide the human eye the best possible vision.

In order to strengthen our team in Erlangen (Bavaria) or in Sankt Augustin (North Rhine-Westphalia), we are looking for a full-time position a

REGULATORY AFFAIRS & RISK MANAGEMENT ASSISTANT (M/F/X)

MAIN RESPONSIBILITIES

- Support the risk management (risk analysis & risk assessment) of the entire product life cycle
- Support the registration of implantable medical devices in international markets
- Preparation of documents for certification and legalization
- Transfer of existing risk analysis data into a newly introduced risk management software (BAYOOSOFT Risk Manager) according to ISO 14971
- Risk minimization and risk control of preclinical, clinical and PMS
- Scientific verification and validation (V&V) of risk control measures
- Support R&D, RA and PMS teams in design control and risk vigilance & risk management
- Implementation and assessment of the state-of-the-art in risk management

YOUR PROFILE

- Advanced degree in medical life sciences or a related discipline (optic and ophthalmology preferred)
- Knowledge in pre-clinical and clinical regulatory
- Experience in the product approval of medical devices (class IIb)
- Experience in medical device risk management process according to ISO 14971
- Experience with the usability engineering process according to IEC 62366-1
- Experience with risk minimization measures, as well as their verification and validation according to the state-of-the-art (e.g. ISO standards, MDR)
- Knowhow in biocompatibility according to ISO 10993 series and ideally also ISO 11979 series, FMEA, PHA, etc.
- Fluent in English and German

- Ability to work in a team and assertiveness
- Proficient skills with MS Office
- Residence in Germany

WE OFFER

- The possibility to work remotely or to work in our offices based either in Erlangen (Bavaria) or in Sankt Augustin (North Rhine-Westphalia)
- Flexible, friendly, and dynamic working environment
- Various social benefits and 30 days of leave per year
- Christmas and holiday allowance

CONTACT

Please send your application, stating the earliest possible date of entry and your salary expectations to:

HumanOptics Holding AG | Mr. Sass, Head of Human Resources | Spardorfer Str. 150 | 91054 Erlangen

OR WITH E-MAIL TO

bewerbung@humanoptics.com