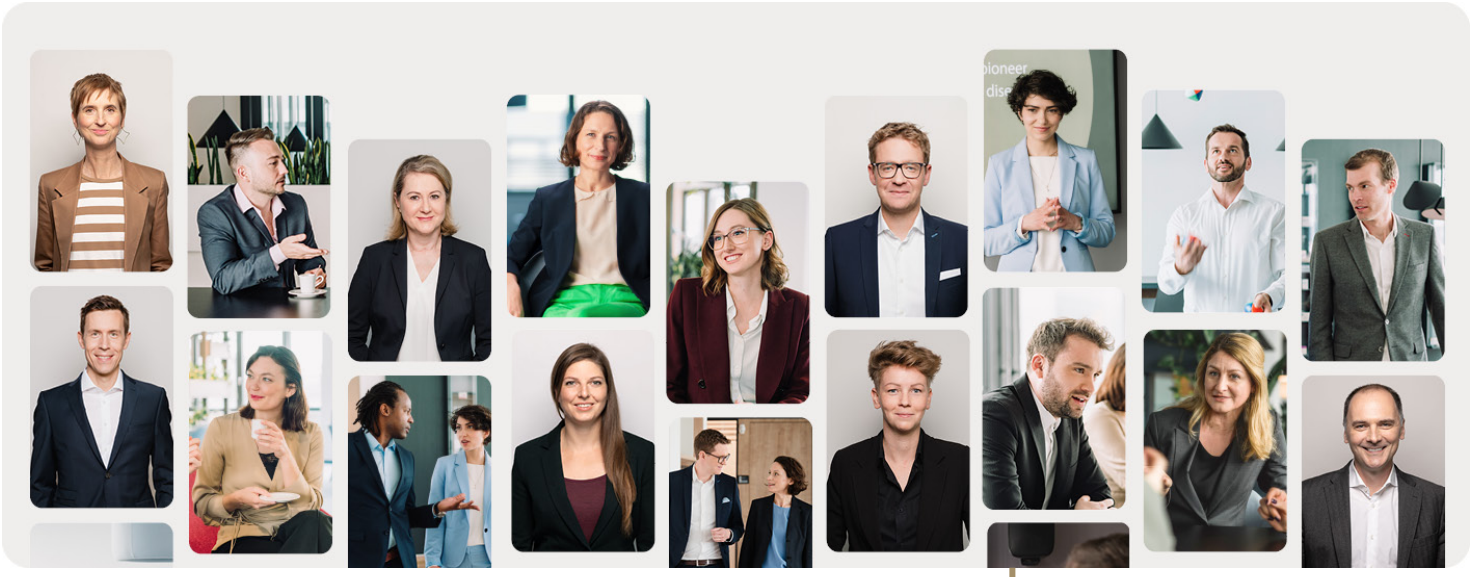
OrphaCare is a member of the AOP Health Group. To enhance our team in Vienna we are looking for a:

Biocompatibility Specialist - OrphaCare (m/f/d)

1190 Wien | Vollzeit | Start: as of now |



The Biological Evaluation Specialist acts as the internal expert for biological safety and risk-based material evaluation of high-risk (implantable) class medical devices, e.g. catheters and disposable materials for device maintenance. This role is responsible for planning, conducting, coordinating and documenting the biological safety assessment of medical devices in compliance with ISO 10993 series, ISO 14971, and EU MDR 2017/745 and to support other pre-clinical work packages.

Work in partnership with an external biocompatibility partner (cooperation already initiated) to align strategy and exchange complete inputs and data packages. This collaboration is already initiated and may remain external or transition/dual□source over time.

Your tasks

Biological Evaluation

- Develop and maintain BEPs in accordance with ISO 10993-1.
- Define test strategies based on device type, intended use, body contact, and exposure duration.
- Identify relevant endpoints and ensure appropriate justification for testing or test waivers.

Material and Process Assessment

- Collect and evaluate detailed information on raw materials, additives, and manufacturing processes.
- Assess potential biological hazards associated with chemical, physical, or processing residues.
- Work closely with R&D, manufacturing, procurement and external

Main Benefits

- Bonus
- Homeoffice
- Employee mobile phone
- Flexible working hours
- Laptop
- Initial and continuing education
- Canteen
- Good transport connection
- Employee events
- Meal allowance
- Company doctor
- Healthmeasures
- Employee discount

suppliers to ensure material traceability and documentation completeness.

Coordination of external service providers

- Select and manage external accredited laboratories (GLP-compliant) for biocompatibility testing.
- Prepare test orders, review study protocols and reports, and ensure alignment with ISO 10993 series requirements.
- Evaluate and interpret test results; assess their adequacy for risk management and regulatory submissions.

Documentation and Reporting

- Prepare BER and integrate results into Technical Documentation.
- Maintain traceability between biological testing, risk analysis, and clinical evaluation.
- Ensure compliance with internal quality procedures and ISO 13485 documentation standards.

Cross-Functional Collaboration

- Collaborate with Regulatory Affairs, Quality Assurance, R&D, and Clinical Affairs.
- Participate in Design Reviews and contribute to overall product safety and risk-benefit assessment.
- Provide biological safety input during material selection and change control processes.

Your profile

- Master’s degree or Ph.D. in Biology, Toxicology, Biomedical Engineering, or related field.
- Minimum 3 years of experience in biological evaluation of medical devices (or pharmaceuticals).
- In-depth knowledge of ISO 10993 series, ISO 14971, and MDR requirements.
- Experience with GLP studies and coordination of external testing laboratories.
- Strong understanding of biocompatibility principles, toxicological data interpretation, and chemical characterization.
- Excellent technical writing and documentation skills.
- Ability to analyze complex data and translate findings into clear regulatory conclusions.
- Strong communication and cross-functional teamwork abilities.

Our offer

- An open corporate culture with the opportunity to contribute your own ideas
- Working independently in a collegial and committed team
- Modern working environment with good public transport connections (U4 - Heiligenstadt)
- Flexible working hours (flexitime/time-out days), bonus scheme, additional benefits and employee events
- Structured onboarding and support through a buddy system
- Due to legal requirements, we are obliged to disclose the collective agreement minimum salary, which is EUR 59 794,- gross per year, based on full-time employment. However, our actual remuneration packages are

Your Contact

Kenny Trappl
Talent Acquisition Manager

Further information on our website:
aop-health.com

market-oriented and aligned with your qualifications and professional experience.
- Willingness to pay more if you have the appropriate qualifications and experience

If you would like to work as a team player in an international environment and can identify with our values "Agile, Ambitious, Aligned, Accountable and Appreciative", then: Take this CHANCE and