

We are a young and innovative medical technology company with the headquarter in Austria. With our products we have an international presence. Cooperations open up excellent prospects. Short decision paths and flat hierarchies offer much creative freedom for a committed person. Within our motivated and experienced team, we know how to use ideas and synergies for mutual success. For further information to our company and our products please visit our website www.interventional-systems.com



To support our team, we are currently looking for a

Regulatory Affairs Jr. Manager / Regulatory Affairs Trainee

Your main task:

- Supporting an innovative team to enter new products into national and international market
- Assistance with the composition of registration documents for our medical products
- Monitoring and executing regulatory requirements of medical products
- Responsibility for compliance with legal requirements (qualified person)
- Qualified contact person for regulatory issues, standards and guidelines towards specialist departments, manufacturers and authorities
- Support in communication with designated authorities
- Verification and approval of development and accompanying documents from the view of regulatory Affairs-department
- Execution and participation during internal audits
- Execution of internal training about relevant laws and standards

Your profile:

- Completed scientific or technical studies or an equivalent education
- Initial experience in the regulatory, ideally medical technology field
- Experience in quality management (ideally EN ISO 13485)
- Good knowledge of applicable european and national regulations in the medical technology field (MDD, MDR, MPG, EN ISO 13485, EN ISO 14971, 510(k)) desirable and interest to implement this
- Very good german and english skills
- High capacity of team, organization and communication
- Well structured, reliable and independent way of working

We offer to you:

- An attractive working place and flat hierarchies with direct contact
- Exciting tasks in medical technology with the aim of better patient care
- Perspectives in a growing, interdisciplinary and international company
- Pleasant working atmosphere in a young, creative and dynamic team
- A corporate culture that promotes and rewarded development, commitment and enthusiasm
- A high recreational value (mountains) in summer and in winter in Wattens and Kitzbühel

Your working place is in Ulrichstr. 40, 86836 Untermeitingen (DE), with good traffic connection (Bahn, B17) in the direction Augsburg and Munich.

Please send us a meaningful application with your references to bewerbung@interventional-systems.com. Please give your earliest starting date and your salary requirement.

iSYS Medizintechnik GmbH, Bergwerksweg 21, 6370 Kitzbühel / Austria

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