For our Marketing, Sales & Science department, we are looking for you as a

Senior Nonclinical Project Manager (m/f/d)

EG10

medac is a dynamic company that has been growing continuously for over fifty years. More than 2,000 employees work on the further development of medical products and medical devices for the diagnosis and treatment of oncological, urological and autoimmune diseases. We are one of the leading pharmaceutical companies, in particular in the field of niche products.

Your Tasks

- Conception and management of nonclinical drug development programs and life-cycle activities according to appropriate governmental and regulatory requirements (like GLP/ICH, OECD, EMA, FDA) and company's SOPs and development strategy
- Preparation of relevant nonclinical regulatory documents in the course of nonclinical and clinical development of investigational new drugs as well as in the context of generic, bibliographic or full dossier submissions for marketing authorization
- Evaluation of scientific publications and other pharmacological/toxicological reports regarding their relevance for revision/rewriting of existing nonclinical documentations such as nonclinical parts of development plans, briefing books for scientific advice, target product profiles, investigational medicinal product dossiers, investigator brochures, developmental safety update reports, periodic safety update reports, orphan drug applications, paediatric investigational plans, CTD modules 2.4, 2.6 and 4

Your background

- University degree (PhD, MD, PharmD or DVM) in biology, chemistry, medicine, pharmacy or veterinary medicine
- Appropriate training and experience in the field of pharmacology/pharmacokinetics/toxicology
- Knowledge regarding international guidelines for preclinical drug development and non-clinical dossier structure (CTD) for pharmaceuticals
- Demonstrated experience from previous work in pharmaceutical industry; communication with health authorities; understanding of regulatory submission components (including IB, IMPD, DSUR, PSUR, SA, PIP, CTA, MA)
- Fluent English (oral and written)
- Detailed knowledge of MS Word, Excel, PowerPoint, MS-Project
- Team spirit, dedication and sense of responsibility as well as an independent and reliable way of working

- Independent co-ordination and oversight of the conduct, analysis and reporting of nonclinical in vitro and in vivo studies contracted by medac to qualified research organisations/institutions
- Preparation of nonclinical parts of medac-internal due diligence reports

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Benefits

- Your work-life balance is important to us. We offer flexible working conditions with the option of working up to 60% of your hours remotely, 30 annual vacation days and an excellent cafeteria
- Attractive salaries and success-based bonuses for all medac employees
- Individual training opportunities: Our medac academy offers a wide range of programmes including leadership training, coaching essentials and language classes
- A funded pension scheme and other social benefits
- We care for our employees beyond the workplace and provide advice on caring for elderly relatives as well as offering counselling and childcare
- We promote sports and activities to improve our employees' health

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If you think you have everything we are looking for and more, we would love to hear from you. Please apply online and upload your documents (CV, letter of motivation, certificates), including your salary expectations and your earliest possible starting date. Please note that we will not be able to return postal applications.

Apply now

medac GmbH • Theaterstraße 6 • 22880 Wedel • Germany
Joanna Grabowska

Working together for sharper focus on patients.