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

Senior Preclinical Project Manager (m/f/d) Department: Pharmacology and Toxicology

EG 10

You are an innovative person with a passion for details and team spirit? We are looking for graduates for the scientific and pharmaceutical sector. We can offer you new challenges, regular continuing education courses, internal mobility and attractive benefits in a company that thinks of the future and acts accordingly. With passion, team spirit and appreciation for one another.

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

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

drug applications, paediatric investigational plans, CTD modules 2.4, 2.6 and 4

- 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
- Team spirit, dedication and sense of responsibility as well as an independent and reliable way of working

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About medac

medac is a prestigious Hamburg pharmaceutical company specialising in the new and further development of therapeutic and diagnostic agents for oncological, urological and autoimmune conditions. Although we can already look back on over 50 years of successful company history and solid values, we are not bound by the past. Over 1,800 dedicated employees ensure the reliable provision of innovative and safe pharmaceuticals and medical devices. In the process, we run our business in a forward-looking, personal manner, with a focus on the individual quality of life of the patients.

If you are looking for a new career challenge and a future-oriented role, then we are looking forward to receiving your application including your earliest possible starting date and salary expectations. For your convenience, please feel free to use our online application form on medac.de.

Apply now

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Dagmar Reitze

Working together for sharper focus on patients.