



Sandoz Germany

Sandoz, a Novartis company, is a global leader in generic pharmaceuticals and biosimilars, driving sustainable access to high-quality healthcare. Sandoz supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe. The Sandoz portfolio comprises approximately 1,100 molecules, which accounted for 2015 sales of USD 9.2 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area. The company holds leading global positions in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines.

We are looking for our team in Holzkirchen a

## **Clinical Pharmacology Manager (m/f)**

### **Biopharmaceutical Clinical Development (BCD)**

(Project-No. 259430BR)

#### **Areas of Responsibility**

- Develop clinical pharmacology, PK and PD strategy for Biosimilar development programs
- Contribute to elaborating strategies that may complement or substitute for clinical outcomes to streamline Biosimilar clinical programs
- Provide expert Clinical Pharmacology counsel to the International Project and Clinical Teams, and other cross functional teams
- Ensure quality of the clinical pharmacology plans, project specifications, study protocols, reports, summaries and publications
- Responsible for designing and analyzing the PK and PD components of clinical trials in all phases of development
- Provide the PK/PD sections of clinical protocols, clinical study reports, Investigator's Brochures, Health Authority Briefing Books, CTD (Common Technical Document) summaries, and any other relevant document for Health Authority submissions
- Ensure representation as needed for all health authority interactions
- Establish efficient collaboration with key partner functions within and outside BCD

#### **Requirements**

- Advanced degree (PhD, PharmD, MD) in life sciences is required (clinical pharmacology, pharmacokinetics or related discipline)
- Minimum 5-7 year's experience in the area of preclinical and clinical pharmacology and pharmacokinetics or related field in a pharmaceutical based company
- Expert knowledge in preclinical and clinical drug development, especially for biologics
- Demonstrated proficiency using analysis tools (e.g. Phoenix, SAS, NONMEM, R)
- Contribution to successful development and registration of multiple global products
- Demonstrated leadership in a matrix organization
- Excellent English written, verbal and presentation skills, German of advantage
- Strong critical thinking and problem solving skills

Please apply via our [Online job portal](#).

We develop breakthrough treatments and find new ways to deliver them to as many people as possible to improve and extend peoples' lives. We do this, by supporting and promoting the knowledge and strengths of our employees and specifically use them to deepen our understanding of our patients and customers. Motivating conditions and an attractive salary are also part of our working environment, as well as our company culture, which is based on collaboration, curiosity, enthusiasm, courage and integrity. Novartis stands up for equal opportunities and for the integration of persons with disabilities. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability.

**SANDOZ** A Novartis  
Division