Senior Project Toxicologist

Please apply online at www.novartis.com/careers using Job ID 220188BR

Location: Basel, Switzerland (International family relocation supported)

Our Organization

At the Novartis Institutes for BioMedical Research (NIBR), the global research organization of Novartis, we are committed to discovering innovative medicines to cure disease and improve human health. By hiring the best scientists, we have fostered an atmosphere for drug discovery where risk taking and innovation are rewarded. It is ultimately the talent of the individual that determines our success, while our state-of-the-art technologies and resources enable these ideas to be realized.

The Preclinical Safety department at NIBR is a group of more than 240 scientists supporting the safety profiling from target identification to post-marketing with the goal to develop drugs that improve the lives of patients in a broad range of disease areas.

Novartis is an Equal Opportunity Employer.

Impact of your Role

Your will represent Preclinical Safety (PCS) on the project team and assure appropriate design and execution of the nonclinical safety assessment plan to meet project team objectives.

Your responsibilities will include

1. Providing PCS support for initiation of clinical trials and registration for drug candidates.
2. Integrated, scientifically relevant and compliant nonclinical safety assessment to support development/registration of drugs of various modalities.
3. Timely communication to PCS and project teams regarding

a. theoretical or observed safety effects, their impact and proposed plans to address them.

b. resource requirements to execute nonclinical safety assessment plan.

4. Clear, concise and correct communication of nonclinical safety results and their impact to HA and investigators.
5. Successfully leading PCS subteam towards optimal design and execution of non-clinical safety profiling studies

Your Qualifications

- PhD in pharmacology, toxicology or a related biological science; MD with appropriate experience, DVM with appropriate training and experience. PharmD or equivalent with a strong biological background. Board certification (e.g., ERT; DABT; DGPT) highly desirable.
- Fluent English (oral and written).
- At least 5 years of experience in a nonclinical safety scientific discipline (eg, as study director or monitor).
- Minimum of 5 years' experience as a full-time project toxicologist (Research stage; early and late Development stage projects in Pharma organizations)
- Demonstrated experience in
  - non-clinical safety issue resolution (expected to achieve with a fair degree of independence)
  - communication and negotiation with global health authorities (ie, strong experience with IND/CTA submissions and pre-IND and EOPII meetings required; completed BLA/NDA/MAA submissions highly desirable).
- Demonstrated understanding of regulatory submission components for registration (CTD) including mastery in authoring submission components in Documentum-like system
- Demonstrated leadership in cross-industry organizations (discipline-related or related to drug development) is highly desirable (e.g., IMI; EFPIA, etc)
- Record of continuous education / publications in toxicological sciences