



Apogenix develops innovative immunotherapeutics for the treatment of cancer and viral infections, such as COVID-19. We have built a promising pipeline of drug candidates that target different TNFSF-dependent signaling pathways, thereby restoring the anti-tumor immune response in cancer patients and reducing lymphopenia and inflammatory cell death in patients with viral infections.

To expand our management team, we are looking for a

## VP Clinical Development

### Your Tasks & Responsibilities

- Responsible for the initiation and execution of our clinical studies
- Develop and maintain the clinical development budget plan and review and negotiate corresponding offers and contracts with external partners
- Develop and review clinical documents and Developmental Safety Update Reports
- Prepare requests for approval and coordinate contracts for clinical trials with external service providers/CROs
- Select, manage, and coordinate CROs and other contractors
- Create risk management plans
- Coordinate activities for the preparation of regulatory documents at regulatory authorities, IND, and orphan drug designations
- Serve as primary contact for physicians, ethics committees, and regulatory authorities
- Organize and document named patient use
- Create and update clinical SOPs
- Develop strategic development options together with management board, business development, and project teams
- Implement the adopted clinical development strategy

### Your Profile

- Natural science or pharmaceutical, preferably medical university education (MD) with a minimum of 10 years of experience in a pharmaceutical biotech company or a pharmaceutical company
- Development experience in various indications (particularly in oncology) from phase I to III
- Excellent knowledge of the relevant approval guidelines for EU (EMA) and US (FDA); hands-on experience in interactions with EMA and FDA
- Knowledge of relevant GxP and ICH guidelines and in-depth knowledge of Good Clinical Practice
- Strategic/entrepreneurial and interdisciplinary thinking
- Demonstrated success in leading teams, team player
- Outstanding communication skills with ability to influence others
- High level of social competence (ability to handle criticism and conflict, ability to engage in dialog)
- Fluency in English due to the international nature of the business

### Why Apogenix?

We offer a state-of-the-art, science-driven work environment in a biotech company with a strong focus on research. We are looking for people with ambition who are aware of the importance of their tasks.

Sounds interesting? It definitely is. We look forward to your application at [Bewerbungen@apogenix.com](mailto:Bewerbungen@apogenix.com).