



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 highly motivated team we, we are looking for a

CMC Manager – Regulatory & Scientific Documentation

Your Tasks & Responsibilities

- Coordination and preparation of internal and external CMC related documentation (study plans and reports related to cell line and GMP process development and process validation, development and validation of analytical methods)
- Review of CMC documentation provided from contract manufacturing organizations (CMOs) and external laboratories
- Interaction with experts from R&D development (microbiology, protein analytics, analytical development) and Quality Assurance
- Providing input for the preparation of regulatory quality documentation

Your Profile

- University or similar degree ideally in pharmacy, chemistry, biology with 3+ years of experience in the pharmaceutical industry in the area of CMC biologics
- Knowledge of pharmaceutical product development processes, especially interactions between GMP development, production, analytical laboratories and QA
- Basic knowledge of regulatory requirements regarding quality of pharmaceuticals (GMP, ICH, EU and FDA)
- Extensive experience in documentation in accordance with EMA/FDA regulations
- Focus on accuracy and precision regarding documentation and data evaluation
- High level of personal responsibility and social skills
- Good knowledge of English and German

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 are looking forward to your application at Bewerbungen@apogenix.com.

Apogenix AG • Im Neuenheimer Feld 584 • 69120 Heidelberg • apogenix.com