

## **CMC Expert (20% - 40%) in innovative Healthcare Company**

Opterion Health, a Swiss-based life sciences company, is currently looking for a CMC Expert. The ideal person for the job will be providing scientific guidance, project management support and regulatory writing in the field of Chemistry, Manufacturing and Controls of drug substances and products. She/he will be acting as CMC Expert to define, drive and monitor CMC activities aiming at manufacturing for pre-clinical and clinical studies (Phase I). The position (20% - 40%) is based in Muttenz, Switzerland, and we offer flexible working options.

### **Responsibilities & Operational Tasks include**

- Managing of CMC operational activities
- Assessing of critical quality attributes, critical process parameters, in-process controls, reference standards, stability studies, etc.
- Transferring knowledge, material and documentation from different laboratories
- Coordinating development tasks towards collection of required information and contribution to respective documents (risk analysis, briefing book, IND, IMPD, study plans and reports) in close collaboration with CMOs and Opterion Health Management team
- Supervising CMOs in charge of manufacturing tox and clinical supplies of Drug Substance and Drug Product to ensure smooth execution of the CMC part of the project plan
- Communicating with CMOs and analytical laboratories for GMP manufacturing and quality control for supply of pre-clinical and clinical studies
- Supporting in-licensing/out-licensing process by shaping technical development strategy for post-due diligence projects under negotiation

### **Skills and Qualifications**

- An Advanced Degree (MS/PhD) in Chemistry, Chemical Engineering, Biochemistry, Biopharmaceuticals, Biology or Pharmacy with several years professional experience in an international, pharmaceutical environment
- Sound knowledge of working in different scientific/technical CMC development functions (process development, regulatory, pharmaceutical and/or analytical development, manufacturing, knowledge of GLP and GMP).
- 5+ years of industry experience and, scientific and technical knowledge
- Excellent communication skills and ability to communicate complex technical matters clearly and concisely to senior management

**What we offer**

- Permanent contract starting as soon as possible
- Competitive salary
- Flexible working arrangements

**Please send your CV to**

[info@opterion.com](mailto:info@opterion.com)