

CMC Lead (f/m/d)

Professional Skills

- Natural science/scientific background (FH, university)
- Practical experience in CMC development and lifecycle of oral solid dosage forms or parenteral products (injectables, lyo) – formulation, manufacturing, analytics and their controls (cMA, cPP, cQA etc.)
- Profound operational pharmaceutical quality knowledge and reasonable implementation of GMP and CMC regulations/guidelines
- At least 5 years working experience in the pharmaceutical industry
- Strong communication and presentation skills in English and German
- Strong IT skills (MS Office, Adobe Acrobat, Minitab, MS-Project)

As part of our Pharmaceutical Development team you will play a key role in managing CMC related activities for development products.

Ready for an ambitious job?

- You plan and execute the CMC strategy for new development products and manage the practical activities at the respective contract parties (CDMOs)
- You plan and execute CMC activities for marketed products (product lifecycle-management) and manage the practical activities at the respective contract parties (CxOs)
- You create CMC relevant documents, and you draft dossier (module 3) sections and responses to authority registration processes (submission, deficiency process, lifecycle/variations)
- You plan and monitor the budgeting for your project/product

Like to take accountability?

- You evaluate new CxOs for APIs and Finished Products together with contributing departments as Business Development and SCM/QM
- You are involved in contract negotiations/quality agreements and budget monitoring of your projects
- You will be part of AOP's GMP audit team and execute QM documents (e.g. change controls, deviations)

Able to align?

- You work and collaborate with other CMC Leads in a dynamic team
- You ensure effective communication with external partners and monitor subcontracted activities
- You strongly contribute to the CMC strategy and dossier preparation with the CMC RA group
- You represent the CMC part in a global project management team and in technical product meetings

Looking for an agile environment?

- You enjoy working in a high-performing international environment
- You prefer a high degree of independence and responsibility for assigned projects
- You are keen to manage multiple projects and being able to prioritize and self-manage

The gross monthly salary provided for this function is a minimum of € 4.000.- based on full-time employment. Any potential overpayment depends on professional experience and qualifications.

- You manage the improvement of product and process knowledge and general project administration

Take this AOPPORTUNITY and [apply now.](#)



For contact

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