

Regulatory Affairs CMC Manager (f/m/d)

Professional Skills

- Natural science/scientific background (HTL, FH, university) and several years of professional experience in below fields
- Profound knowledge of GMP and CMC regulations/guidelines
- Experience in writing / reviewing IMPDs and CTDs (Module 3)
- Knowledge of RA procedures and submissions
- Practical experience in CMC development of small molecules, oral solid dosage forms or parenteral products (injectables, lyo) – synthesis, formulation, manufacturing, analytics
- Strong communication and presentation skills in English and German
- IT skills (MS Office, Adobe Acrobat, alternatively MS-Project)

As part of our Pharmaceutical Development team you will play a key role in bridging CMC-related development and RA submission activities from pharmaceutical development to life cycle.

Ready for an ambitious job?

- You are responsible for creating processes for RA-CMC intelligence as an interface between the CMC development and RA submission department.
- You are aware of Module 3.2.S/P CMC-related guidelines.
- You define the strategy for CTD Module 3 content for new and already existing drug products.
- You write sound scientifically and regulatory justifications for changes to existing dossiers.
- You assess CMC-related documentation and translate it into a CTD, suitable for a smooth authority submission and assessment process.
- You interpret authority feedback in a way to identify potential missing data, define strategy for and author responses during a deficiency process or life cycle/variation process.

Able to align?

- You work and collaborate with our CMC Leads in a dynamic team.
- You ensure effective communication between CMC Leads and RA-department as well as Quality

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.

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

Your contact

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Management.

- You are strongly able to align CMC strategies for our products with the RA department.

