

Team Lead Regulatory CMC Drug Product (gn)



Formycon is an international leading, independent developer of high-quality biopharmaceutical medicines, especially biosimilars. With an experienced team comprised of around 200 highly skilled professionals, the company is able to span the entire value chain of biosimilar drug development, from market analysis and target definition by protein analytics, to the development of production processes, to clinical trials and the regulatory approval process.

Our focus is on treatments in ophthalmology and immunology as well as for other key chronic diseases. Formycon is making a major contribution towards providing as many patients as possible with access to vital and affordable medicines.

To support our team in Martinsried near Munich, we are looking for suitable candidates for this full-time and permanent position, to begin work as soon as possible.

Your responsibilities

As Head of Regulatory CMC Drug Product you will be responsible for aligning and implementing regulatory strategies for Formycon's product pipeline with regard to drug product development and manufacturing including design control aspects in the context of drug-device combination product development.

In this role you will lead a team of 4 RegCMC managers. You will be acting as a regulatory CMC expert coaching your team and aligning regulatory strategies with experts from various departments, external partners and CDMOs. Your main tasks include the following:

- Align RegCMC DP strategy for Formycon's development projects and approved products (focus on aseptically manufactured parenteral products in various dosage forms) with project management, DP, device & packaging development departments and other RegCMC groups (DS and Analytics)
- Review and align strategy for essential overarching concepts with focus on DP aspects (e.g. L&E studies, combination product development including design control, process characterization and validation studies including transport validation) and define presentation in regulatory dossiers
- Ensure timely preparation and appropriate review of regulatory documents for Briefing Books, IMPD/IND, BLA/MAA submissions and variation packages
- Establish and implement strategies for drug-device combination products during development and throughout lifecycle. Ensure that relevant regulatory requirements and guidelines are taken into account and implemented in the combination product development programs. Liaise with clinical department for design of human factor studies
- Oversee preparation of documentation packages and submission to Notified Bodies for receipt of Notified Body Opinions according to Article 117 and coordinate establishment and maintenance of design history files
- Guide RegCMC Drug Product team in defining the best strategy for each submission and their content
- Support defining response strategies for requests from authorities in close collaboration with involved SME departments and CDMOs



- Maintain knowledge of global competitive landscape, regulatory environment, and regulations with focus on drug product aspects including drug-device combination product development and design control
- Participate in meetings with regulatory agencies (e.g. EMA, FDA)
- Manage capacity allocation in team and coordinate regulatory CROs in charge of assigned work packages
- Compile and maintain budget and capacity plans

Your Qualifications

- Scientific background with master's degree or PhD, preferably in biology, chemistry, biochemistry, pharmacy or equivalent
- Minimum of 6 years work experience in Regulatory CMC area including experience with parenteral products and drug-device combination products
- Thorough knowledge of the drug development process with demonstrated experience in multiple development phases up to submission
- Excellent staff leadership and communication skills
- Fluency in written and spoken English
- Very good team player, result oriented, persistent, well organized, proactive, problem solver and able to work independently
- German work permit is mandatory

What we offer

- Hybrid working model and flexible work arrangements
- 30 days of vacation plus additional days off on Christmas Eve and New Year's Eve
- Formycon Mastercard and employer-supported pension scheme
- Comprehensive health & wellbeing offering, including occupational health services, fitness discounts, group accident insurance and mental health support
- Individual development and career paths, internal trainings and participation in conferences and scientific events
- A collaborative, inclusive culture with a strong focus on diversity, equal opportunity and respect in a modern working environment

More details on our culture and benefits can be found on our [career page](#).

Bring us your skills and energy and shape your own career in a stimulating and open work environment. We are looking for highly motivated individuals who are ready to take on new challenges with enthusiasm and personal commitment. Working at Formycon means being part of a smart, innovative team with minimal hierarchy and opportunity to share your own ideas. Interested? Then we look forward to receiving your application through our online application portal: [Apply here!](#)

Please note that we do not accept applications or candidate profiles from recruitment agencies or headhunters for this position.

We welcome applications from all people – regardless of gender, gender identity, sexual orientation, origin, religion/belief, disability, age or lifestyle. Applicants with severe disabilities will be given preferential consideration in cases of equal suitability. Please note that our building is currently not fully wheelchair accessible. However, we warmly encourage you to contact us so that we can discuss and explore suitable solutions together to accommodate individual needs. If you have any questions, please email us at recruiting@formycon.com.