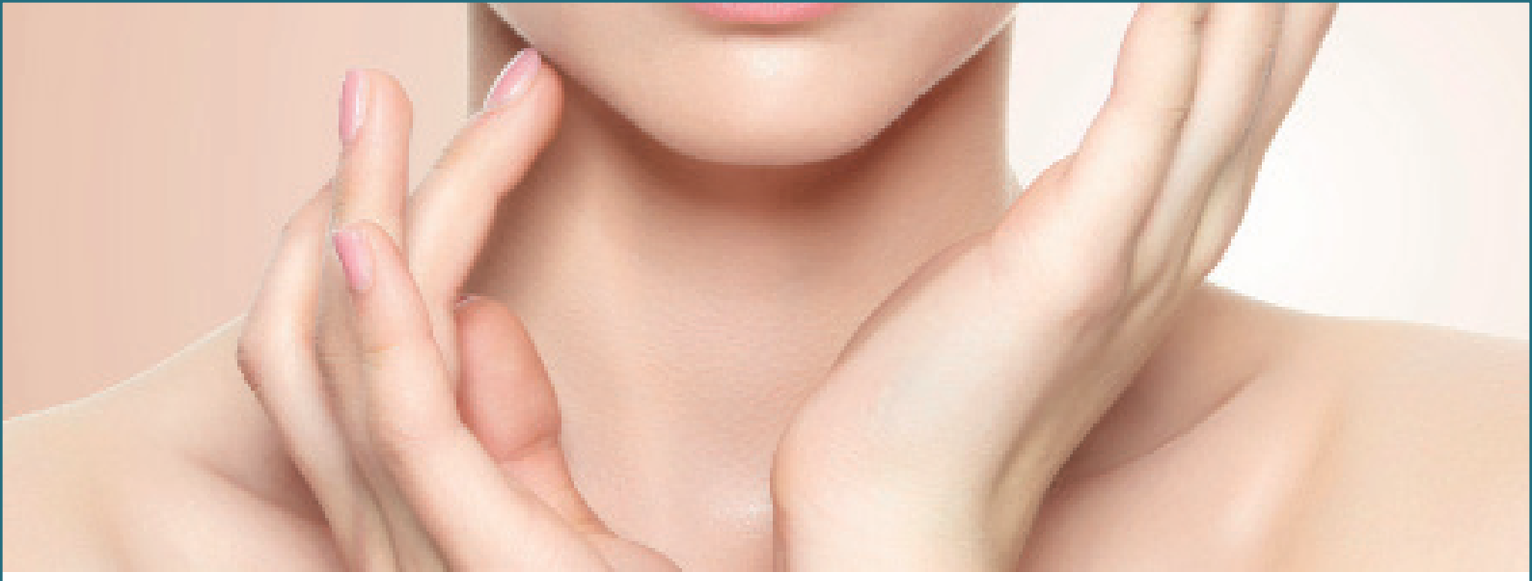

dermaliq therapeutics

Founded in 2021, Dermaliq is an US and Germany based specialty pharmaceutical company focused on dermatology. Our mission is to develop a new generation of premium topical therapies and medical skin care products with greater efficacy and fewer unwanted side effects for millions of patients. **More on www.dermaliq.com.**

For the representation in our German office in Heidelberg (20-40 % remote), we are currently looking for a

Director CMC (m/f/d)

As Director CMC you will facilitate product development, scale-up and manufacturing by leading the planning and execution of the Chemistry, Manufacturing and Controls (CMC) strategy for all our pipeline products, including API vendor selection, drug product manufacturing, drug packaging development, contribution to regulatory submissions and interactions with regulatory authorities.

Your responsibilities

- Transferring clinical stage drug candidates into final pharmaceutical drug products
- Establishing relations to and liaising with global CMOs to ensure efficient external pharmaceutical supply chains
- Interact competently with global authorities, service providers and partners
- Author, review and approve CMC related documentation, SOPs, protocols, and reports for completeness, cGMP compliance and acceptability of data as required for (investigational) drug product applications
- Define and select primary and secondary packing materials according to technical requirements and market needs
- Coordinate projects with other internal functions such as Clinical Development, Regulatory Affairs and Quality Assurance
- Design, direct and manage experiments in the laboratory in support of pre-formulation, formulation development, and manufacturing process development
- Ensure establishment of appropriate API and DP specifications, design and execute stability studies to support product development programs
- Serve as “Subject Matter Expert” for CMC related questions during discussions with regulatory agencies and inspections

Your profile

- Degree in Pharmacy or Chemistry, or related pharmaceutical sciences, preferably PhD.
- 10+ years of industry experience in pharmaceutical product development with experience in managing CMC activities, including transition of new product ideas from development through clinical programs to commercial manufacture, ideally in the field of topical dermatology
- Solid understanding of FDA, EMEA, and ICH cGMP guidelines, regulations and industry best practices
- Strong technical leadership and activity management of CDMOs to ensure external manufacture, and testing activities follow cGMP
- Project management and organizational skills, process-oriented, structured, and proactive thinking.
- Experience in authoring CMC sections for IND, IMPD, and NDA equivalents required.
- Experience with medical device and/or cosmetic product regulations would be a plus.
- Independent yet team-oriented working style with the ability to work in a fluid environment and foster a strong collaborative spirit
- Excellent communication skills in English (written and spoken); German language skills would be an advantage

What we offer

- A highly innovative and international biotech environment with a promising and growing product pipeline in dermatology
- An open, communicative atmosphere with opportunities for personal growth and development
- A competitive salary, flexible working time, partly home office based (20-40 %) and a wide range of social benefits

Apply now!

Please send your application in English (incl. CV, certificates, salary expectations, and possible start date) via email to: **jobs (at) dermaliq (.) com**. State the **reference DLQ-CMC**.

Dermaliq Therapeuti cs GmbH • Im Neuenheimer Feld 515 • D-69120 Heidelberg • www.dermaliq.com