



**Making a difference
together.**


Head of Regulatory Operations (m/f/d) Global Regulatory Affairs

Alfred-Wegener-Straße 2, 60438 Frankfurt am Main, Deutschland
Full Time; Experienced Professional; February 2025; Hybrid

YOUR CONTRIBUTION

As **Head of Global Regulatory Operations (m/f/d)** and member of the Global Regulatory Affairs Leadership Team, you contribute to the development and success of the Merz Therapeutics organization. You lead and develop our Global Regulatory Operations team and be responsible for the management of all activities around the technical creation, filing and reporting of regulatory submissions. In this role, you act globally and work cross-functionally. Your main responsibilities include the following activities:

- **Leading the Regulatory Operations Team:** Motivating and developing team members and creating an inspiring team environment with an open communication culture.
- **Monitoring and optimizing data entry and regulatory master data management:** Managing data to ensure accurate regulatory reporting.
- **Ensuring sufficient planning and execution of electronic submissions:** Coordinating internal and external work packages and managing the budget to ensure all submissions are timely and within budget.

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- **Ensuring IDMP/SPOR requirements are met:** Ensuring compliance with all relevant guidelines.
 - **Process and quality management:** Taking responsibility for continuous process improvements and generating ideas for further digitalization project to support regulatory processes within the department while ensuring high quality within the area of responsibility.

YOUR PROFILE

- University degree in pharmacy, chemistry, biology, biochemistry or equivalent
- At least 5 years professional working experience in Regulatory Operations / Regulatory Affairs, ideally in a global environment
- Leadership experience with proven track record of successfully managing and inspiring teams
- Knowledge in contract management and validation of computerized systems
- Profound knowledge of common Regulatory Operations systems (RIMS, eDMS, eCTD Manager, eArchive), ticketing and collaboration tools
- Excellent communication skills in English
- Proven ability to coordinate multiple projects/ priorities and meeting critical milestones
- High level of leadership skills and change management competencies
- Strong and effective communicator with a team-oriented working style

YOUR BENEFITS

- Individual career development in a purposeful job: you improve the quality of life of our patients!
- Hybrid work model that allows a good work-life balance
- Attractive location with good transport links, modern workplaces and a company restaurant
- Global family business with flat hierarchies and an open, respectful corporate culture
- Attractive remuneration with extensive social benefits
- Variety of employer-subsidized benefits such as WellPass, Deutschland-Ticket, Corporate Benefits and JobBike

Find out more about our benefits [here](#).





ABOUT US

Welcome to Merz Therapeutics, a leading pharmaceutical company that helps people with movement disorders, neurological diseases, liver diseases and other health conditions regain their quality of life.

We are proud to be a family-owned and value-driven company that has been dedicated to serving the needs of our patients for 110 years and is now a global innovation leader with products in more than 90 countries.

Our goal is to use our products to improve treatment outcomes for patients around the world, thereby reducing the burden of suffering for affected people and their surroundings.

Our dedication and commitment to relentless research and development is to ensure that unmet patient needs are identified and appropriate treatments are provided.

Therefore, become part of our international and motivated Merz Therapeutics family now and help us achieve our goal: **"BETTER OUTCOMES FOR MORE PATIENTS"**

For more information, visit <https://www.merztherapeutics.com/>.

