

Our client is a NASDAQ listed biotechnology company with the global Headquarter in Germany. The companies focus is the research and development of new medicines for the treatment of inflammatory diseases within a global development approach. Our client stands out for an excellent team of highly motivated and skilled individuals who put strong emphasis on a team effort

To support their expanding Regulatory Affairs Team we are looking for a:

# Head of Global Regulatory Affairs (m/f/d) RX Pharmaceuticals

Standort: München  
Kennziffer: 26573

## Ihre Aufgaben

- Lead the development and execution of all clinical, non-clinical, and commercial regulatory strategies for the new product and new assets to maximize global regulatory success
- Provide regulatory guidance and strategy and assessing regulatory risk for the company.
- Understand standard and alternative approaches to registration for antibodies and small molecules in the area of Infectious Diseases/COVID, Immuno-Dermatology, Dermato-Oncology and Autoimmune Diseases.
- Ensure project team colleagues, line management, and key stakeholders are apprised of developments that may impact regulatory success, exercising sound judgement and communicating in a professional and timely manner
- Lead interactions with EMA and FDA, including planning, executing, and leading the coordination and preparation of teams for health authority meetings.
- Develop regulatory project plans and timelines, manage execution and ensure all projects are appropriately prioritized and key goals are met on time.
- Establish an internal Regulatory Affairs Team and provide leadership and development for direct reports
- Provide leadership and direction to staff, consultants, and vendors supporting regulatory affairs.
- Leading Regulatory Affairs Operations, i.e., leading the development of regulatory operations including the prioritization of internal or external resources to best support the several clinical programs from early phases to filing and registration.
- Oversee compilation, electronic processing, and publishing of US and global submissions (INDs, CTAs, NDAs, etc.) in time and compliant with regulatory authority requirements, including authorship of critical documents as needed
- Oversee the creation and maintenance of relevant SOPs, Work Instructions, and other necessary guidance.
- Budget responsibility for the assigned department
- Participate in strategic and regulatory evaluations of in-licensing matters

## Ihre Qualifikation

- MD or PhD or similar advanced degree in relevant scientific field (e.g. pharmacology, immunology, molecular biology).
- Minimum of 10-15 years' professional experience in the biotechnology/pharmaceutical environment in the development of NBE's and NCE's.
- Strong knowledge of the Regulatory environment in US and EU at minimum.
- Ten or more years of experience in global Regulatory Affairs for pharmaceutical drugs and/or biologics. Senior-level experience interacting with competent authorities, in particular, the FDA and EMA.
- Successful track record of filing Marketing Applications (NDA, MAA, BLA, etc) along with briefing packages, orphan drug applications, and various other regulatory documents.
- Extensive leadership, management and project management experience in the multiple facets of drug regulatory affairs and drug development.
- Ability to both think strategically and, in the meantime, be hands-on, pay attention to details and be involved in the everyday aspects for all regulatory activities.
- Ability to drive decision-making within a cross-functional, cross-divisional and cross-cultural, global team structure and requires global mindset and cultural awareness in working with senior leadership in other regions and in managing cross-regional projects
- Proven ability to manage complex projects, with the flexibility and adaptability to re-prioritize workload to meet changing timelines.
- Strong written and verbal Communication Skills: ability to express oneself clearly and concisely to external partners, vendors or with others within the team; ability to message key issues appropriately and document issues and/or concerns concisely and comprehensively; ability to adjust language and/or terminology appropriate for the audience; demonstrated ability to clearly and concisely communicate / present key information to senior management
- Strong team-player with collaborative, respectful and flexible attitude and high engagement
- Highly self-motivated and able to drive activities, solution-oriented personality
- Entrepreneurial spirit, agile and flexible in a rapidly changing environment.
- Experience with Immuno-Dermatology or Autoimmune programs.
- Must be comfortable working for a small organization, and able to handle ambiguity.

Seit 2003 vermittelt Optares Medical erfolgreich Fach- und Führungskräfte an Unternehmen der pharmazeutischen, biotechnologischen und medizintechnischen Industrie. Dabei profitieren Sie als Kandidat (m/w/d) durch unsere langjährige Branchenexpertise und unser weit reichendes Netzwerk zu den jeweiligen Entscheidungsträgern. Wir ermöglichen Ihnen somit den Zugang zu passgenauen Positionen inklusive echten Herausforderungen und entsprechenden Weiterentwicklungsmöglichkeiten.

Die professionelle, diskrete und transparente Betreuung unserer Kandidaten (m/w/d) während des gesamten Bewerbungsprozesses steht dabei für uns im Mittelpunkt.

## Ihre Ansprechpartnerin

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Folgen Sie uns auf

