



## PR/086876 | German-speaking Regulatory Affairs Officer (m / f / d)

Job Information Recruiter JAC Recruitment Germany Job ID 1517621 Industry Pharmaceutical Job Type Permanent Full-time Location Germany Salary Negotiable, based on experience Refreshed February 25th, 2025 08:01 **General Requirements Minimum Experience Level** Over 3 years **Career Level** Mid Career **Minimum English Level Business Level** Minimum Japanese Level **Business Level Minimum Education Level** Associate Degree/Diploma Visa Status No permission to work in Japan required

Job Description

## **Company Overview**

The company is committed to researching and developing treatments for rare diseases. It strives to deliver high-quality medications that enhance the health and well-being of patients. As a prominent player in the orphan drug sector, the company collaborates with various partners, including its headquarters in Japan, to expand its business.

## Job Responsibilities

- Coordinate, prepare, and review regulatory submissions.
- Manage type IA, IB, and II variations, including preparing documentation for variation packages.
- Communicate with regulatory agencies about submission strategies and follow-up on submissions under review.
- Maintain current knowledge of existing and emerging regulations, standards, and guidance documents.

• Participate in internal or external audits.

## **Job Requirements**

- Scientific degree (preferably in Pharmaceutical Chemistry and Technologies).
- 3-5 years of experience in the Regulatory Affairs department.
- Full knowledge of local and EU rules/regulations.
- Recent experience in the biotechnology industry is strongly preferred.

Apply online or feel free to contact me directly for more information about this opportunity. Due to the high volume of applicants, we regret to inform that only shortlisted candidates will be notified. Thank you for your understanding.

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**Company Description**