



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

### 募集職種

#### 人材紹介会社

ジェイエイシーリクルートメントドイツ

#### 求人ID

1517621

#### 業種

医薬品

#### 雇用形態

正社員

#### 勤務地

ドイツ

#### 給与

経験考慮の上、応相談

#### 更新日

2025年02月25日 08:01

### 応募必要条件

#### 職務経験

3年以上

#### キャリアレベル

中途経験者レベル

#### 英語レベル

ビジネス会話レベル

#### 日本語レベル

ビジネス会話レベル

#### 最終学歴

短大卒：準学士号

#### 現在のビザ

日本での就労許可は必要ありません

### 募集要項

#### 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.

#LI-JACDE

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会社説明