



At STADA we pursue our purpose “Caring for people’s health as a trusted partner” worldwide. Originally founded by pharmacists, we are a leading manufacturer of high-quality pharmaceuticals. More than 12,300 employees around the globe live our values Integrity, Entrepreneurship, Agility and One STADA to achieve ambitious goals and shape the successful future of STADA.

Our global headquarters, STADA Arzneimittel AG, is located in Bad Vilbel near Frankfurt am Main. For our department Biotechnology we are looking for a

## **(Senior) Manager (f/m/d) Regulatory Affairs Biotechnology/Biosimilars**

Bad Vilbel | Germany (DE) | Full-time | Permanent

### **Your responsibilities:**

- Responsibility for international marketing authorisation applications of biosimilars
- Preparation and submission of regulatory procedures (scientific advices, clinical study applications and new MA applications)
- Responsibility for maintenance applications: variations, renewals, PSUR submissions
- Creation and review of regulatory documents (in particular CTD modules 1 and 3, IMPD) and assurance of regulatory compliance
- Evaluation of GMP compliant manufacturing documentation
- Regulatory evaluation of external project developments (due diligence) and regulatory support for new product launches in Europe and other countries
- Cooperation in inter-team and inter-company project groups

### **Your qualification:**

- University degree in life sciences (pharmacy, chemistry, biology, biotechnology or related discipline)
- Experience with European drug regulatory affairs and the centralised procedure (EMA)
- Experience with FDA and regulatory affairs in other non-EU countries is a plus
- Experience with medical devices and the EU Regulation is preferable
- Experience with regulatory intelligence software, publishing tools and document management software is preferable
- Organisational talent, team spirit and communication skills, willingness to travel
- Excellent knowledge of English is required, German is an advantage

We are looking for talents with expert knowledge and an entrepreneurial spirit that enjoy working collaboratively in a global team. We are pleased to get to know you better. Please use our online portal to submit your application: [jobs.stada.com](https://jobs.stada.com)