

Astellas Pharma is one of the world's top 20 pharmaceutical companies, established through the merger of two global Japanese companies, Yamanouchi and Fujisawa, in 2005. A young and forward-thinking company, with a rich pipeline of innovative medicines, Astellas Pharma is dedicated to improving the lives of people around the world through providing innovative and reliable pharmaceutical products. In 2011, Astellas Pharma established its European 21st affiliate, headquartered in Ljubljana, covering Romania, Bulgaria, the countries of former Yugoslavia, and Albania. Through some of its products distributed by partners, Astellas Pharma is already present in Serbia, and now we want to expand our business by creating a representative office.

We are looking for an excellent candidate for the following position:



Regulatory Affairs Manager

Core Responsibilities

- Initiation of processes for obtaining Marketing Authorisations in Serbia
- Maintenance of Marketing Authorisations by submission of appropriate variations and approvals
- Ensuring Product Information is up to date
- Regular contacts with regulatory authorities and follow up of all regulatory requirements
- Support for the preparation and submission of reimbursement application
- Acting as back up Drug Safety Officer

Required qualifications and skills

- University degree in Pharmacy or Medicine
- Minimum of 5 years' working experience in a similar position
- The drive to achieve success
- Precision, thoroughness and dedication
- Adaptability and creativity
- Ability to work in a team
- Strong English language skills
- Comfort working in a multinational, commercial corporate environment
- IT literacy
- Driving licence

We offer:

- The opportunity to join a young, growing company with clear goals and an exciting pipeline
- Employment contract for an indefinite period in a very dynamic team of professionals
- Regular training and role-related education
- Competitive salary and benefits package
- Company car

Please send a CV and introductory letter in English, explaining your interest in the position, to recruitment.si@astellas.com. We will respond to all applications, except those that do not meet the minimum educational requirements and are therefore not eligible for the position.

