



## **Regulatory Affairs Manager**

**RAM-1218**

We are looking for an experienced Regulatory Affairs Manager with an excellent knowledge of EU regulatory legislation to join team yellow in the heart of Prague. Legislative knowledge from the rest of the world is a plus.

### **Responsibilities**

- Manage designated regulatory affairs projects
- Cooperate and communicate with assigned clients and vendors
- Liaise with international regulatory agencies as appropriate
- Develop and execute regulatory strategy and accurate submission planning for designated projects
- Compile/create registration dossiers in CTD, eCTD or other formats according to current country legislative requirements for all types of processes - new registration, renewal, variations, etc. as per client need and request
- Review of all documentation prior to submission or transfer to authorities/clients
- Overseas labelling updates, as per client need and requests
- Manage product life-cycle, as per client needs and requests
- Report submission development, submission and approval status, according with project governance settings
- Ensure proper archival of all documentation submitted to authorities and/or sent to clients
- Regular and accurate updating of internal or external reporting documentation
- Active participation in the assessment of impacts and risks resulting from changes in legislation
- Maintain and improve regulatory system and procedures

### **Accountabilities**

- Excellence in all assigned RA projects
- Effectively manage and build working relationships with all stakeholders, based on transparency, trust and clear communication



## Requirements

- Bachelor's degree in Pharmaceutical, Biological or Chemical Science or A related field
- Minimum of 5 years regulatory experience from Pharma/Consultancy
- Excellent knowledge of regulatory legislation - EU mandatory, RoW a plus
- Able to assess regulatory issues, request and collect relevant information, analyze data, establish facts and draw valid conclusions
- Able to create feasible regulatory strategy, for all types of registrations
- Change management experience
- Excellent written and spoken English language skills

## The ideal candidate has/is

- Great project management skills; excellent communication skill both oral and written, analytical skills; strong attention to details, strategic planning skills; capable of managing multiple projects and complex timelines; able to work in a multi-cultural environment; customer focused; innovative solution finding skills; able to inspire and set an example to junior members of the team
- Detail-oriented, proactive, a problem-solver, results-driven, good time management, a positive can do - will do attitude