



Regulatory Affairs Specialist (Ref: RAS_0224)

About the company

RAFARM is an innovation-driven, dynamically growing pharmaceutical company and a well-established European manufacturer with an outward-looking orientation that invests 13% of net turnover in Research and Development. We introduce high technology in our state-of-the-art sterile manufacturing plant and create new production lines with cutting-edge technology and robotic equipment. RAFARM is a place where our people evolve and are full of passion and interests. We are a dynamic team that empowers talent, embraces diversity and accelerates development.

About the role

Our **Regulatory Affairs** department is growing and we're seeking a highly motivated and detail-oriented **Regulatory Affairs Specialist** to play crucial role in ensuring compliance with regulatory requirements and supporting the timely approval of our pharmaceutical products.

The role main accountabilities will be the following:

- Review, Prepare, submit the necessary documentation/registration file for Marketing Authorisation applications, variations and renewals to the competent Health Authorities.
- Maintain the lifecycle of the Pharmaceutical products, continuous follow up with the Authorities and/or the customers related with the assigned projects and tasks.
- Direct communication and efficient collaboration with other departments of the company
- Prepare the product information (SmPC, Labelling & PIL) and review of the relevant AWs.
- Monitor EU & non-EU regulatory legislation & providing recommendations for adopting those
- Keep up to date the internal regulatory database with respect to assigned projects.
- Registration of medical devices to the National Notified Bodies.

Experience & Qualification Standards:

- BSc in Chemistry, Chemical engineer, Pharmacy, Biology or other relevant disciplines.
- 2-3 years of regulatory experience in similar position in the pharmaceutical sector
- Excellent knowledge of English, both verbal and written
- Ability to cope with strict timelines and work on tight deadlines. Planning and time management.
- Ability to work effectively in team environment, both independently and as a team player with a positive attitude.
- Highly detail-oriented and organized. A methodical mind with strong problem solving abilities.
- Communication and negotiations skills.
- Excellent knowledge of MS Office and e-CTD software.

Benefits

- Competitive Compensation
- Private Health Insurance
- Career Development Opportunities
- Work-Life Balance
- Innovative Work Environment
- Community Engagement
- Recognition and Rewards



Why Join Us

At RAFARM, you'll be part of a passionate team dedicated to making a positive impact on global health. You'll grow your career in a dynamic and innovative environment where your contributions matter.

How to Apply

If you think that the above position suits you, then we are waiting for your application!! Submit your resume to hrdep@rafarm.gr.

After the collection and evaluation of all CV's, we will contact only those candidates who meet the requirements of the position to be filled in order to set an appointment for an interview. All applications are considered strictly confidential.