We evolve beyond the obvious
and make a positive impact on people's lives

Regulatory Affairs CMC Specialist

(Ref: RACMC_0424)

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 talented **Regulatory Affairs CMC Specialist** to play a crucial role in ensuring compliance and facilitating the regulatory approval process for our pharmaceutical products.

The role main accountabilities will be the following:

- Compiling and authoring of module 2-5 and of Quality Overall Summary of the dossiers intended for registration at global scale.
- Compiling and authoring of responses and scientific documentation at correspondences with authorities or clients related to variations, renewals, new registrations, upgrades and new developments.
- CMC regulatory directions provision at the various company departments, external parties and suppliers for the projects which have been assigned
- Continuous follow up of the regulatory affairs activities of all projects that have been assigned
- Update of the regulatory database in collaboration with the regulatory partners.
- Understand and use the International Regulatory guidelines.

Experience & Qualification Standards:

- BSc in chemistry, pharmaceutical science, chemical engineering, or other relevant disciplines. A postgraduate degree will be considered a plus.
- At least 1-2 years of CMC regulatory experience in similar position or in Formulation within pharmaceutical sector
- Comprehension and knowledge of basic guidelines related to the CMC regulatory compliance
- Ability to handle with strict timelines of projects and set priorities.
- Proven ability in resolving of complex issues related to the department and the competent authorities.
- Excellent knowledge of English, both written and oral.
- Highly detail-oriented and organized, able to work both independently and as a team player with a positive attitude.

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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.