



Health care. Human care.

Regulatory Affairs CMC Specialist

(Ref: RACMC052023)

Rafarm, achieving dynamic growth since its foundation (1974), is a Greek interest pharmaceutical industry of multinational orientation -with innovative medicines, branded generics and total quality services – recognizable by all stakeholders in the field of Health Care. At the forefront of Greek pharmaceutical companies continues to strengthen and build on its already important role as a serious and recognized player in the international market.

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 3 years of CMC regulatory experience in similar position in the 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.

The Company offers: Competitive remuneration package along with challenging career development opportunities within an innovation orientated organization

The candidates with the above qualifications can send their CVs to: hrdep@rafarm.gr