

Regulatory Affairs Project Director

Summary and Reporting

The position requires person with genuine executive authority over the Regulatory Affairs projects in EU, CIS and other geographical region of interest. RA Project Director is responsible for deliverance of projects goals and success in covered geographical region.

RA Project Director will report directly to RA Director.

LRO/RA specialists will report functionally (in line with assigned projects) to RA Project Director.

Main Job Tasks and Responsibilities

Core responsibilities:

1. Manage assigned RA projects, timelines, budget and resources (both internal and external).
2. Manage and facilitate all marketing authorization / registration related activities in the applicable countries Development and implementation department strategy and tactics in business development and geographical expansion.
3. Fully responsible for obtaining and providing consistent, value-added, and timely information on project planning, review and project management for minimizing impact/risks on project objectives and deliverables.

Other responsibilities and competencies:

1. Maintain contact with regulatory authorities' client/sponsor representative.
2. Provide the Regulatory team with regulatory input in order to obtain timely regulatory approvals for the products.
3. Implement and develop RA high-level project management for multiple medium to large projects.
4. Direct, supervise and manage the scope of work, objectives, timelines, quality of deliverables, and all other project management activities.
5. Direct, supervise and manage project plans development for all regulatory phases of the project lifecycle.
6. Continually communicate with Client to meet project deliverables and milestones.
7. Manage and oversight LRO, RA Projects Manager, RA Specialist to ensure appropriate communication channels are maintained and reporting schedules adhered to.
8. Conduct monthly LRO team meetings (phone, skype) to discuss project related activities, workload, issues, change, communications, and updates.
9. Produces weekly status reports that address outstanding work, issues and risks.

Requirements and expectations

- More than 5 years experience in Regulatory Affairs field.
- Team / project management experience.
- Fluent English.
- Russian would be an advantage.
- communication
- Strategic thinking, innovative and creative approach.
- Excellent planning and decision making skills.
- Ability to travel.

If you have any questions or would like to find out more about the position, please, contact us by e-mail personalas@biomapas.eu or call directly to HR and Training Manager Raimonda Klimiene +370 698 15736.