
Regulatory Affairs & Quality Assurance – Manager

- JOB DESCRIPTION -

Department: RA & QA Department (Medical Devices, In-Vitro Diagnostics, Cosmetics & Others)

Directly Reports to: C.C.O

Company Profile: Obelis s.a is a quality driven, service oriented company, with over 28 years of experience in EU Regulations. Providing consultancies on medical devices, cosmetics and other consumer goods - we believe in making manufacturers better through compliance and making safe products available on the market.

Objective: To contribute to the smooth operation of the Regulatory Affairs & Quality Assurance Department as well as support the department's and team's performance, KPIs and daily activity.

Main Duties:

- Provide professional, high level and smooth client service;
- Perform various work associated with the RA/QA department at the highest level; (Product Classification, Pre-Market Notification, National Registration, Free Sales Certificate Application, GMDN Code Verification, Communications with EU Authorities, etc) at the highest level;
- Should follow-up on the tasks assigned to him as well as coordinate the tasks assigned to a medium team (more than 15);
- Ensure the research on requirements (whether it is regulatory, admin, marketing, etc);
- Initiate the development and design of at least 2 new methods, systems and resources;
- Ensure preparations for Management & Board Meetings;
- Assistance to Unit Directors and C-Level Executives;
- Present at Management & Board Meetings;
- Provide internal & external trainings on department related matters;
- Represent Obelis and its interests at external events;
- Contribute to online and offline publications;
- Ensure the implementation of ISO 9001:2008 and ISO 13485:2003;
- Participate to Obelis events;
- Coach & Mentor;

Requirements :

Education

- MA Degree in Economy, European law, Pharmacy, Chemistry or Quality Management Systems (or similar)

Experience

- Minimum of 6 years' high level experience in project management and Quality Management systems (QA/RA);
- Minimum of 6 years' high level Experience managing a team;
- Professional experience in EU Administration is considered an asset
- Scientific background is considered an asset;
- Familiarity with Cosmetics and or Medical Devices is considered an asset

Language(s)

- Fluency in English (written & oral) ;
- Any other languages are always a plus;

Computer Skills

- Proficiency at Microsoft Word, Excel, PowerPoint, Outlook;

Desired skills & Competencies:

- Strong management experience at the highest level
- Strong knowledge of Quality Management systems;
- Exceptional ability to manage the execution of multiple projects without error, and with high attention to detail;
- Customer and Solution oriented;
- Strong analytical abilities ;
- Ability to prioritize, coordinate and manage tasks;
- Excellent time-management skills;
- High adaptability, flexibility, dedication supported by a positive 'can-do' attitude;
- Strong oral and writing skills to be able to communicate effectively internally and externally;
- Ability to assume responsibilities;
- Ability to structure workflow within a team;
- Ability to take own initiatives;
- Ability to motivate team members;
- Be able to and willing to travel in / out of the European Union

How To Apply:

Please send your CV **in English**, accompanied by a short motivational cover letter outlining your suitability for this position, to the following e-mail address: career@obelis.net

Early application is recommended.

Every CV will be carefully reviewed, however due to volume of applications only successful candidates will be contacted.

Obelis is an equal opportunities employer and supports workforce diversity.