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Regulatory Affairs & Quality Assurance – Expert Consultant

- JOB DESCRIPTION -

Department: Notification 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 Notification work associated with the RA/QA department (Product Classification, Pre-Market Notification, National Registration, Free Sales Certificate Application, GMDN Code Verification, Communications with EU Authorities, etc) at the highest level;
- Follow-up on tasks assigned to him as well as coordinate tasks assigned to a small team (more than 5);
- Ensure regulatory and scientific research on requirements;
- Support the development and design of a new method, system and resource;
- Support preparations for Management & Board Meetings;
- Assistance to Managers, Department Managers and/or Unit Directors;
- Provide internal trainings on department related matters;
- Contribute to online and offline publications;
- Contribute to the implementation of ISO 9001:2008 and ISO 13485:2003;
- Participate to Obelis events;

Requirements :

Education

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

Experience

- 3 -5 years' experience in project management and Quality Management systems (QA/RA);
- 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 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.