

JOB DESCRIPTION

Position Title:
(Senior) Regulatory Consultants
(EU, Reg Ops, CMC)

Manager: Director, Regulatory Affairs

Incumbent's name:

Date prepared: November 2021

APPROVAL SIGNATURES

Incumbent:

Name:

Signature:

Date:

Manager:

Name:

Signature:

Date:

JOB SUMMARY

- Provides a range of regulatory writing services with supervision of senior team members to a high quality and on time delivery.*
- Provides eCTD publishing services.
- Assists senior team members in their projects.
- Provides a QC function.
- Contributes to the effective functioning of EUDRAC.

* Senior Consultant expected to work independently and on more complex projects

KEY DUTIES AND RESPONSIBILITIES:

Client Activities

- Provides a range of regulatory writing services with supervision of senior team members e.g. product information, CMC variations.
- Prepares documents for eCTD publishing, publishes and submits to agencies.
- Deliver projects on time and to a high quality.
- Assists with projects with supervision of senior team member.
- Provides QC functions within the EUDRAC team (e.g. translations of product information compared to templates; clinical and nonclinical overviews compared to source data).

Knowledge Management

- Acts to develop and maintain regulatory skills and knowledge necessary to ensure effective support to clients.

Business Development

- Continues to build a network of industry colleagues.
- Assists Management in the preparation of proposals (e.g. researching new potential projects, determining activities required).

EUDRAC Activities

- Develops and maintains personal contacts with professional associations to build confidence in and enhance the reputation of EUDRAC.
- Completes basic job related responsibilities e.g. maintenance of personal training record, timesheets, project archiving.



MINIMUM REQUIREMENTS

Education and Experience

- Graduate (life science or chemistry).
- General knowledge of European pharmaceutical regulations and guidelines.

Essential Skills and Abilities

- Attention to detail.
- Computer literate i.e. good competence in MS Office programs and Adobe Acrobat.
- Positive team relationships with colleagues.
- Good communication skills.
- Good organisational skills.
- Good analytical skills.