JOB DESCRIPTION

Position Title: Associate Director/Director Regulatory Affairs	**Manager:** Carole Pugh Managing Director, EUDRAC Ltd
Incumbent's name:	
Date prepared: September 2020	

APPROVAL SIGNATURES

Incumbent:		
Name:	Signature:	Date:
Manager:		
Name:	Signature:	Date:

JOB SUMMARY

- Part of UK management team leading development and growth of the company
- Provides a full range of consulting services to clients to a high quality and on time delivery.
- Leads project activities.
- Line management.
- Is a source of regulatory expertise in the development, registration and post-licensing activities of pharmaceutical products with a focus on clinical activities.
- Contributes to the effective functioning of EUDRAC.

KEY DUTIES AND RESPONSIBILITIES:

Client Activities

- Provides a full range of consulting services (strategy and writing) with an emphasis on clinical documents (overviews, briefing packages, orphan drug designations, paediatric investigation plans).
- Delivers complex projects on time and to a high quality.
- Acts as EUDRAC team-lead.
- Supervises and reviews work of personnel.
- Interacts professionally at multiple levels within a client organisation.
- Prepares and/or delivers presentations with minimal support of Management.

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).
- Manage specified client relationships.

EUDRAC Activities

- Part of management team to develop and grow the company.
- Develops and maintains personal contacts with regulatory agencies or professional associations to build confidence in and enhance the reputation of EUDRAC.
- Line management.
- Completes basic job related responsibilities e.g. maintenance of personal training record, timesheets, project archiving.

MINIMUM REQUIREMENTS

Education and Experience

- Life sciences or pharmacy graduate.
- Sound knowledge of European pharmaceutical regulations and guidelines. Conversant with the functions of product development, microbiology, toxicology, clinical research, manufacturing and quality assurance.
- Significant regulatory affairs experience including a successful track record in the development, registration and life-cycle maintenance of medicinal products within Europe, in particular a strong background in the review/generation of clinical documents (overviews, briefing packages, orphan drug designations, paediatric investigation plans).

Essential Skills and Abilities

- Excellent written and verbal communication skills.
- Established relationships and proven negotiation skills with management, colleagues and regulators.
- Computer literate.
- Good organisational skills.
- Good analytical skills.