Diamond BioPharm Limited

Job Specification

Regulatory Affairs Biologics [Exact title dependent on experience]

Reports to: Technical Director
Based at: No 4 East Wing, Gemini House, Flex Meadow, Harlow, Essex, CM19 5TJ, UK or Cambridge Science Park, Milton Road, Cambridge, CB4 0FN or London Stratford, E15 2ST

Job description: Diamond BioPharm Limited is a Regulatory consultancy company dedicated to providing high quality and competitively priced services to the biotech and pharmaceutical industries. This role is to support the Development team in providing clients with a strong Regulatory professional with experience of working on Biologics/ATMPs.

General Responsibilities and duties of organisation:

- To write, review & submit clinical trial applications and associated documentation (incl. IMPDs, IBs)
- Strategy & Development of products, from early stage to Post-marketing
- Write and compile MAAs – Modules 1-5 (as applicable)
- To write or review all types of simple & complex variations
- Write and review SOPs/processes
- Write and/or review sections of dossiers for Centralised/Decentralised procedures
- Project Management of all regulatory requirements

Key Responsibilities and duties of role:

- To be a client lead
- Expert regulatory documentation author (IMPDs/INDs)
- Provide leadership in scientific advice meetings at national agencies and EMA
- Lead EMA procedures including orphan applications, PIPs and MAAs
- Point of contact for agency interaction
- Provide EU regulatory strategy
- Project management/lead responsibilities
- Client facing with strong communication skills, willing to travel

Professional Experience
Essentials:

- 2:1 (or above) graduate in relevant scientific discipline
- 5+ years broad & deep European regulatory affairs experience with Biologics/ATMPs
- Biologics/ATMP regulatory expert with demonstrable experience in liaising and negotiating with regulatory authorities
- Strong understanding of the regulatory environment including guidelines
- Ability to lead team members in a matrix management environment
- Ability to work under pressure and achieve timely submission and regulatory approvals
- Excellent computer skills

Personality attributes - Regulatory Affairs

- Confident/Enthusiastic/Outgoing
- Ability to work on their own and to be an influential leader of a team
- Self-motivated with excellent communication skills
- Well organized and good planning abilities
- Good eye for detail
- Multi-tasking