Diamond Compliance & Quality Limited
PHARMACEUTICAL QUALITY CONSULTANTS

Job Specification

Job Title: Senior Manager Compliance
Reports to: The Directors, Diamond Compliance & Quality Limited
Based at: No 4 East Wing, Gemini House, Flex Meadow, Harlow, Essex CM19 5TJ

Job purpose: Diamond Compliance & Quality Limited is a consultancy company dedicated to providing high quality and competitively priced services in the area of manufacturing and compliance to the biotech and pharmaceutical industries. The role will be to run the day-to-day activities associated with all GxP consulting tasks required by pharmaceutical clients and to ensure Diamond Compliance & Quality has the necessary quality systems and processes in place in order to meet all Quality and Regulatory GMP standards.

Key responsibilities and accountabilities:

- To set up and maintain a quality management system in compliance with current GMP requirements.
- To provide clients with support for all aspects of GxP compliance for example auditing, validation, training.
- Advising clients on all aspects of GxP.
- Manufacturing site audits – both API and finished dose form.
- Provide training/education as necessary to both in-house and client staff on aspects associated with GxP.
- To provide support for clients undergoing Regulatory Inspections.
- To ensure Diamond Compliance & Quality Limited obtains and maintains the necessary manufacturing licences to support its and its clients business needs.
- To maintain an awareness of current legislation associated with GxP.
- To ensure Diamond Compliance & Quality Limited is available for clients Regulatory Inspection(s).
- General advice on development aspects.
- Regular interaction with the various EU Regulatory Agencies ensuring that the person is conversant with their current expectations with regards to GMP compliance.

If the candidate is a QP:

- Responsible for carrying out Batch Certification where named as a Qualified Person responsible for batch release (as described in EU Directive 2001/83/EC as amended), on a Marketing Authorisation held by the client.
- To participate in conjunction with the Marketing Authorisation Holder with any batch recall where Diamond Compliance & Quality Limited have been responsible for Batch Certification.
- To ensure that the necessary Agreements are in place to define the responsibilities of both parties in relation to Batch Certification.

The role will involve considerable travel worldwide.

Person profile

The following attributes and skills are a guide:

- A life science background, with a degree
- Experience of working in the pharmaceutical industry or regulatory authority inspections division
- Around 5-10 years' experience
- May already be an independent consultant
- Capable of actively seeking and bringing in new business
- May have worked in all facets of the industry ranging from R&D; Production; Quality Control; Regulatory and Quality Assurance.
- Must have the experience to work across a range of dose forms (oral, topical, inhaled, injectable); biological experience would be an advantage
- Experience in auditing manufacturing sites a must
- Good computer skills

If possible:

- A registered Qualified Person for the release of Finished Goods and Investigational Medicinal Products.
- Act as a Responsible Person for companies relating to their Wholesale Dealers Licence(s).

Personality attributes

- Confident
- Ability to work on their own or as part of a team
- Lively
- Self-motivated
- Enthusiastic
- Excellent communication skills
- Well organized and good planning abilities
- Team-based work ethic
- Good eye for detail
- Multi-tasking