



## DIRECTOR, QUALITY COMPLIANCE

### Client Information

Our client is a NASDAQ-listed, multinational science-based pharmaceutical company, dedicated to the discovery, development, manufacture and marketing of proprietary pharmaceuticals, as well as an array of over-the-counter (OTC) health care and generic products. With vertically integrated operations in Israel, the United Kingdom, Canada and the United States, this client manufactures in excess of 100 products.

This position is located in attractive, quality-of-life Westchester County, NY location. This position will provide a highly competitive salary package of base/incentive compensation, along with an outstanding benefits program. The position will report to the General Counsel. A full relocation package is available for the successful candidate.

### Position & Responsibilities

- Consultant and trainer for all quality matters and product compliance matters
- Ensuring compliance with pharmaceutical laws and regulations, International cGMPs and the GMPs of both the country of manufacture and the country of export (Israel, Canada, Ireland)
- Ensuring compliance of all goods with marketing application in both the country of manufacture and where it is being exported (NDAs, ANDA, ANDS, etc.)
- Ensure that all individuals have adequate training for their position
- Ensure that appropriate actions are taken so that all vendors and contract manufacturers have adequate GMPs and are appropriately audited
- Working with senior management provides guidance in determination of extraordinary matters (recalls, withdrawals, regulatory matters, compliance issues, etc.)
- Conducts (or causes to be conducted) regular audits (scheduled and unscheduled) of the QA/QC departments as well as manufacturing at all manufacturing sites (or cause such audits to occur) and makes either on site recommendations and improvements or obtains a timetable and commitment
- Conducts or reviews audit reports of outside vendors (raw material and contract manufacturers and testing sites including clinical testing sites) to confirm that products or appropriate testing or studies are produced or performed under appropriate GMPs.
- Participates either in person, via video or by telephone in all regularly scheduled GMP compliance meetings

- Is a consultant, advisor and trainer to senior management, operating personnel, R&D and QA/QC on all matters relating to quality compliance issues and regulatory matters relating to operational compliance
- Thoroughly reviews all guidances (ICH, FDA, MOH, TPP, etc.) relating to quality matters and reports on same to appropriate personnel. Keeps abreast through reading, contacts and attendance at workshops the latest GMP, other compliance trends and enforcement priorities
- Attends as a spokesperson for the parent, all regulatory inspections that are appropriate

## **OTHER ATTRIBUTES**

- Ability to balance and easily alternate between tactical and strategic requirements
- An executive with a quality vision and desire and passion to execute it. Leadership/presence – highly disciplined and able to anticipate and get things done. “Hands on”
- A diplomat, persuasive style, and exceptional behavioral skills with the ability to establish trust and rapport in all parts of the organization
- Apolitical
- A strong and effective communicator. Recognized as knowledge source
- A manager knowledgeable in cGMP and regulatory trends as it applies to laboratory techniques and manufacturing processes
- Ideal candidate will foster team development and be results oriented with a high energy level and superior communications skills

## **Education/Experience**

### Mandatory

- BS in science
- 8-10 years experience in pharmaceutical operations, including at least 3 years in overseeing QA/QC compliance
- Appropriate training and experience in FDA Law and regulations and cGMPs (including but not limited to validation, cleaning, process and computer) auditing of pharmaceutical operations and auditing of QA/QC laboratories and procedures
- Ability to interact with all levels of personnel and to communicate effectively both orally and in writing

### Preferred

- Three years direct industry experience in one or all of QA/QC, manufacturing, or consulting to industry
- Exposure to international GMP compliance and international regulations
- FDA headquarters experience and/or five years as FDA Inspector at pharmaceutical organizations
- Five years experience as an FDA inspector for pharmaceutical operations
- Advanced degree in a science (MS or PhD)