Job Title:	GMP Quality Assurance Consultant
Location:	Northern New Jersey
Travel Required:	No
Position Type:	Part Time, 6 month Contract (Initial)

Job Description

This position will provide strategic direction and leadership directly to the GMP Compliance organization to ensure systems are proactively established, continuously improved, and executed efficiently and effectively.

Specific Duties, Activities, and Responsibilities:

- In conjunction with Client Planning & Co-ordination for CMC/Clinical Supply, Client Clinical Supplies Management, develop and implement a remediation plan for Major and Minor Observations to an internal audit.

Principal Accountabilities are as follows:

- Responsible for all daily GMP Quality Assurance activities to ensure compliance related to manufacturing, packaging, labeling, and distribution of investigational pharmaceutical products.
- Responsible for ensuring company-wide compliance to FDA and DEA regulations relating to storage and shipment of controlled drugs.
- Responsible for oversight, management and leadership of all QA responsibilities including, internal and external auditing, Investigations, Deviations, Change Control, CAPAs, Recalls and Complaints Handling, Batch Record Approval, Product Release/Disposition, etc., as they pertain to the scope of the position.
- Ensure cGMP documentation is correct, clear and consistent with corporate and regulatory standards.
- Develop, implement and maintain QA systems & processes to ensure compliance with current Good Manufacturing Practices (cGMPs), including but not limited to:
    - cGMP Training program.
    - Self Inspection program.
    - CMO Qualification program.
- Interact professionally with company management, internal departments, and other sites to effectively implement and maintain Quality Systems.
- Write and implement changes to controlled documents (e.g., SOPs, Work Instructions, Specifications, Methods, etc.) as needed.
- Provide support for regulatory audits, as needed.

Qualifications and Experience

- Comprehensive knowledge of global cGMP requirements and expectations (FDA, EU, Japan and ICH) and the ability to assess compliance risks.
- Demonstrated knowledge and understanding of DEA Regulations and experience working with controlled/scheduled drug products.
- Demonstrated ability to handle multiple complex tasks and make timely appropriate decisions with respect to product quality, compliance and customer complaints.

- Experience with reviewing and approving batch production records, manufacturing logs, QC test results etc. in support of product release and disposition.
- Experience with working with and qualifying external vendors.
- Track record of conducting both internal and external GMP audits and managing their outcomes.
- Demonstrated experience working in a cross-functional environment and proven ability to influence and build consensus among multiple functions.
- Preferred: advanced knowledge of FDA and DEA regulations.
- Proficiency in Japanese a plus.

- BS / MS in chemistry or pharmaceutical sciences (Ph.D. Preferable) with a minimum of 5 - 7 years direct experience in CMC/Product Development in a Pharmaceutical setting.
- 10+ years in QA management experience with at least 8 years' experience managing lot release operations for both clinical and commercial product.
- Minimum 6-8 years of GMP auditing experience.