Senior Regulatory and Audit Compliance Specialist

Job Location: New York, New York

Full Time/Days

OVERVIEW

At **New York Blood Center Enterprises (NYBCe)**, one of the most comprehensive blood centers in the world, our focus is on cultivating excellence by merging cutting-edge innovation with diligent customer service, groundbreaking research, and comprehensive program and service development. Join us as we work towards meeting and exceeding the growing needs of our diverse communities, further our lifesaving strategic goals in a rapidly changing environment, and expand our impact on the local, national, and global communities we serve.

RESPONSIBILITIES

The Senior Regulatory and Audit Compliance Specialist (Specialist) is responsible for regulatory and accreditation activities related to cGxP manufacturing at New York Blood Center Enterprises (NYBCe). These include, but are not limited to, the FDA (Food and Drug Administration), state departments of health, state laboratories, blood and tissue regulators, Foundation for the Accreditation of Cellular Therapy (FACT) and CMS (Center for Medicare and Medicaid Services) / CLIA (Clinical Laboratory Improvement Act). This position may be required to support similar accreditation activities for non-US regulatory bodies, such as, but not limited to, EMA, PMDA, MFDS, and ANVISA.

This position is also responsible to author, assess, and/or maintain regulatory filings, including, but not limited to the Chemistry, Manufacturing, and Controls (CMC) section of Investigational New Drugs Applications (IND) and Biologics License Applications (BLA) and/or international equivalents for NYBCe.

They represent the department as a direct liaison to regulators, managing communications, licensing submissions, and ongoing compliance matters, including coordination of the filing of Biological Product Deviation Reports (BPDRs).

The incumbent serves as subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation.

Additionally, this role will support the divisional audit programs. They will coordinate and manage regulatory inspections and client audits throughout NYBCe sites. They will also conduct internal and external audits as needed in accordance with a risk-based quality auditing program for the NYBCe division. They will monitor and evaluate divisional compliance with regulatory requirements, professional accreditation standards and internal policies and procedures to ensure the ongoing quality and safety of NYBCe products and services. The auditor also plans and executes audits of key suppliers and external service providers. The auditor makes recommendations on areas of improvement based on audit observations and findings.

- Protects the safety of patients and blood or HCT/P donors by notifying management and taking immediate action when a critical quality issue is identified that may warrant a stop to production and/or delivery of products and services.
- Coordinate external inspections/audits by regulators, accrediting bodies, and customers. Provide guidance on regulatory issues to quality during the inspections, as needed. Collate and review responses to inspection findings and prepare final response report.
- Stay current on pertinent laws, regulations, rulings, interpretations, and decisions as they relate to NYBCe operations, and communicate to appropriate audience.
- Develops and conducts organizational training in regulatory and accreditation requirements and inspection readiness, as assigned.

- Prepare and submit regulatory registrations, license and permit renewals submissions, and amendments to support operations.
- Maintain records of regulatory communications and filings.
- Verify that operational SOPs comply with applicable regulations, accreditation standards, and current NYBCe policy.
- Support business clients with regulatory filings and strategies as outlined in Statements of Work (SOWs).
- Schedule, host, and/or support regulatory and client audits.
- Conduct and/or support internal audits.
- Conduct and/or support supplier audits for the NYBCe division for critical materials and outsource testing vendors.
- Contributes to process improvement efforts and leads team projects as needed.
    - Identifies opportunities for improvement and makes recommendations based on monitoring and assessment activities.
    - Assesses effectiveness of corrective action and preventive action plans.
    - Leads or participates in formal process improvement team projects as assigned.
- Actively participates in regularly scheduled quality management system review meetings with operational staff and managers.
- Authors Standard Operating Procedures, work instructions, forms, templates and other documents associated with the audit process as needed and for periodic review.
- Track, trend, analyze and report on regulatory and performance data.
- Participates in Quality Improvement activities as assigned.

QUALIFICATIONS

- Bachelor's degree in life sciences, pharmaceutical, biotech or biologics manufacturing, engineering, or quality management. Bachelor's degree in another field of study may be considered with strong, relevant work experience.
- American Society for Quality (ASQ) Certified Quality Auditor (CQA) or ISO Lead Auditor certification.
- Experience as an ISO-9000, FACT, CAP or AABB Assessor is a plus.
- Understanding of the manufacture and testing of biologics and/or cellular and gene therapies is desirable.
- A minimum of 8 years of experience implementing, interpreting, and providing guidance on health authority regulations and regulatory applications for biologics is required.
- Experience performing and/or hosting quality audits and inspections in a related, highly regulated environment, preferably in the blood, biologics or pharmaceutical industries.
- Position requires the ability to travel domestically up to 25% of time.

PREFERRED QUALIFICATIONS

- American Society for Quality (ASQ) Certified Quality Auditor (CQA) or ISO Lead Auditor certification.
- Experience as an ISO-9000, FACT, CAP or AABB Assessor is a plus.
- Understanding of the manufacture and testing of biologics and/or cellular and gene therapies is desirable.

FOR MORE INFORMATION/TO APPLY

https://careers-nybloodcenter.icims.com/jobs/5777/senior-regulatory-and-audit-compliance-specialist/job?mobile=false&width=1594&height=500&bga=true&needsRedirect=false&jan1offset=-300&jun1offset=-240