



Job Title: Director, Analytical Development & Quality Control **Department:** CMC

Reporting to: Executive Director, CMC

Location: Boston, MA

Rhythm seeks an experienced and highly motivated individual to join its team in Boston, Massachusetts. The Director will lead technical interface with API, Drug Product suppliers and contract laboratories, for analytical and testing activities for all stages of development and commercial supply.

Ensures technical capability of methods, procedures for testing of API, Drug Product, Delivery Devices and any materials required are fit for purpose, based on robust, developed and validated procedures which are suitable for the required phase of development or commercial supply.

Ensures development and validation of all test methods meets regulatory requirements including FDA, EU, ICH requirements as required.

Ensures contract laboratories/manufacturers laboratories comply with appropriate procedures testing including any investigations and changes required via Change Controls.

Provides technical leadership, planning and oversees implementation of plans for developing, validating and if required transferring test methods, or improvements required with/between Rhythm contract laboratories.

Principal Responsibilities

- Lead analytical/routine testing interaction with API, drug product and device suppliers to develop/implement plans to test/analyse/release required products, provide required regulatory documents and gain regulatory approvals and inspections.
- Ensure procedures and processes are followed in test laboratories to current.
- IND/IMP/ND/MAA and if required Design History Files for Combination products, with changes/data generated from ongoing testing to secure regulatory authority approvals/updates for any change controls.
- Lead analytical/testing assessment and work required, in the assessment of changes or modifications for any company, supplier or regulatory authority requested change.
- If required, lead technical assessment/testing of patient complaints and defects for root cause and lead required testing programs across all company/subcontractor programs to review and resolve in a compliant and timely fashion.

Qualifications Required

- Degree in relevant scientific area, or engineering/technology.
- Proven experience in managing outsourced GMP works is essential.
- Lean 6 sigma training, to at least Green Belt is preferred.

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Experience Required

- Able to demonstrate substantial experience in directly managing analytical development and testing of sterile drug products and ideally medical devices which are outsourced. Experience in development and manufacture for US and EU markets.
- Able to demonstrate substantial experience in directly managing analytical development and testing of drug substance manufacture and ideally peptide based active ingredients which are outsourced. Experience in development and manufacture for US and EU markets.
- Strong data manipulation, trend analysis and root cause analysis experience and personal involvement in problem solving activities in externalized testing.
- Interpersonal skills and experience of negotiating and managing quality and technical programs with suppliers.
- Experience in managing regulatory inspections of laboratories/suppliers.
- Major manufacturing partners based in France so ability to read and work in French is preferred.

Other Attributes Required for the Position

- Position has a key interface role within Rhythm and key suppliers at senior management levels including Heads of Development/QC/Quality in suppliers as well as day to day operational staff in suppliers and managing by influence is key.
- Position would also be managing diverse range of activities mostly external to Rhythm and managing via contractors rather than direct line management is required.