



CMC Stability Manager

Position Code: 230563 18B

Summary Description

This position is responsible for management of drug substance and drug product stability programs for Gossamer Bio drug candidates and managing the reference standard program.

Key Responsibilities

- Manage stability program for development stage pharmaceutical products including supportive and formal stability studies.
- Support selection of the analytical labs/vendors to conduct the stability programs.
- Review and approve stability protocols.
- Track stability test schedules at the contract test labs.
- Review, analyze, summarize and trend stability data.
- Determine expiry and retest periods.
- Generate stability reports (including regulatory submission ready reports) and presentations.
- Author and review appropriate sections of CMC regulatory submissions.
- Review and approve specifications, change controls, out-of-specification (OOS) and out-of-trend (OOT) reports.
- Review and approve stability vendor invoices against contract and identify out-of-scope activities.
- Manage reference standard program including:
 - Manage inventory, resupply and retest schedules of reference standards
 - Manage shipment of reference standards to the test sites

Experience & Education

- Bachelor's Degree in health or life sciences or equivalent with 5+ years' experience in the pharmaceutical/ biotechnology industry.
- Thorough knowledge of Good Manufacturing Practices (GMP), International Conference on Harmonization (ICH) Guidelines.
- Proficiency in Microsoft applications (Word, Excel, PowerPoint, Outlook, etc.), and Collaborative platforms (e.g., SharePoint).
- Ability to establish and meet multiple concurrent priorities, deadlines, strategic department goals and objectives.
- Ability to establish and maintain cooperative and effective working relationships with co-workers, managers and clients.
- Willingness and ability to travel domestically and internationally as needed
- Demonstrated leadership capabilities, effective organizational skills, and excellent verbal and written communication; ability to present in large and group settings.
- The successful candidate will be a team player with integrity, a commitment to quality, and the ability to think critically and creatively in a fast-paced, changing environment.

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