

Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120



Position Director/Senior Director, Regulatory Affairs
Location Cambridge, MA
Reports to: Chief Technology Officer

POSITION SUMMARY:

This position will be provide regulatory leadership, oversight and strategy in support of AAV gene therapy products based on sound regulatory insight and a balanced approach to risk in a changing regulatory environment; provide guidance to senior leadership in the development of initiatives and strategies to solve complex problems and mitigate potential regulatory challenges; serve as a key member, contributing scientific, regulatory and business knowledge to the team developing effective CMC strategies for the submission of INDs and BLAs that meet requirements for the relevant markets.

DUTIES AND RESPONSIBILITIES:

1. Drive the application of regulatory strategies and concepts across multiple disciplines via timely and thoughtful communication.
2. Work with multidisciplinary team members to ensure the quality, content, timeliness and format of regulatory submissions and amendments comply with all applicable regulations and guidelines governing the development, licensure, marketing and distribution of AAV gene therapy products.
3. Work collaboratively with stakeholders and peers to align on priorities and support corporate strategic goals.
4. Assess CMC changes to define regulatory strategies and develop effective and efficient CMC regulatory strategies based on insight, risk management and changes in emerging regulatory climate.
5. Direct, create and complete regulatory documents such as marketing applications, clinical trial applications, amendments, variations, renewals and other relevant filings, including forms, cover letters or other administrative components for regulatory submissions.
6. Provide guidance to all appropriate departments to assure compliance with applicable regulations, remain knowledgeable of current regulations and guidance, provide thoughtful interpretation of same and notify appropriate personnel.
7. Develop risk assessment scenarios and options for review with multidisciplinary team.
8. Develop, review and maintain Regulatory and other applicable SOPs and policies.
9. Serve as a liaison with FDA and international Health Authorities, directly or in coordination with local country representation, fostering and managing the relationships; provide leadership and guidance for agency meeting preparation and attend key agency meetings to ensure full discussion of issues and opportunities, tracking critical outcomes and commitments.
10. Participate in departmental review boards and other relevant forums.
11. Perform the entirety of the functions necessary for the effective management of the department, including budget administration, cost control, etc.

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12. Draft and submit applications for designations for expedited programs (eg, Breakthrough Therapy, RMAT) or special status (eg, Orphan Drug) and portions of other submissions
13. Serve as a subject matter expert resource on regulatory requirements.
14. Other duties and projects as assigned.

POSITION EXPERTISE/QUALIFICATIONS:

- Education – Bachelor’s degree in Science or health related field (advanced degree, such as PharmD, PhD, MS or equivalent preferred)
- Experience – 6-8 years’ progressive AAV gene therapy Regulatory Affairs experience; significant consulting or management experience required.
- Knowledge of biopharmaceutical industry regulatory affairs discipline throughout the product lifecycle, including Development, CMC / analytical characterization.
- Knowledge of clinical development, including responsibilities for successful management of development milestones, meeting facilitation and appropriate regulatory responses.
- Knowledge of domestic laws, regulations, and guidance that affect biologic products.
- Demonstrated experience leading, managing and preparing regulatory submissions with a track record of successful approvals.
- Strong business acumen and ability to see business drivers outside of Regulatory Affairs
- Strong interpersonal skills with the ability to negotiate and influence others in a positive and effective manner, with or without direct authority.
- Capacity to react quickly and decisively in unexpected and dynamic situations.
- Skills – ability to lead, provide direction and guidance, make decisions, think critically, solve problems and respond proactively; must have excellent communication skills (both written and oral); strong project management skills required.
- Fluent (oral/written) English.
- Computer Proficiency – Word, Excel and Access.