Interested Parties should contact:
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Position	**Senior Director, Regulatory Affairs**
Location	**Miami, FL**
Reports to:	**VP, Quality and Regulatory Affairs**

POSITION SUMMARY:
This position will be provide regulatory leadership, oversight and strategy in support of biologic, medical device, tissue and cosmetic products in the post-approval lifecycle 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 commun**ication.
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 biologics, medical devices, tissues and cosmetics.
3. Work collaboratively with stakeholders and peers to align on priorities and support corporate strategic goals.
4. Assess CMC post-approval 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 Quality Council meetings, review boards and other relevant forums.

11. Supervise a small number of staff and provide direction for daily activities to include problem solving and mentoring; responsible for planning, organizing, communicating, and motivating employees; responsible for prioritizing workday schedules.
12. Perform the functions necessary for the effective management of the department, including provision for the selection and development of employees, budget administration, cost control, employee safety, employee counseling and motivation.
13. Serve as a subject matter expert resource on regulatory requirements for the Technical Division.
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 – Minimum 15 years' progressive Regulatory Affairs experience working in FDA regulated industry, such as biotech, pharma or equivalent; significant management experience required.
- Knowledge of biopharmaceutical industry regulatory affairs discipline throughout the product lifecycle, including Development, CMC, (including analytical characterization), Labeling, Promotion and Advertising, Commercialization, and Operations.
- Knowledge of clinical development, including responsibilities for successful management of development milestones and marketing authorization, meeting facilitation, labeling negotiations, deficiency letter and regulatory responses.
- Knowledge of domestic laws, regulations, and guidance that affect biologic prescription 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.