



Director, CMC Regulatory Affairs

Remote

Summary

Reporting to the Vice President, Global Regulatory Affairs and Quality, the Senior Director, CMC Regulatory Affairs will assist in development planning and interactions with Regulatory Agencies as necessary to support CMC activities.

Responsibilities

- Provide leadership in establishing product specific strategies to ensure successful development of CMC packages to support early development, registration and life cycle management.
- Partner with other development functions to ensure alignment of strategy.
- Participate on due diligence teams as necessary.
- Coordinate and draft CMC regulatory sections for submission to Health Authorities.
- Participate and/or lead various multi-disciplinary teams or taskforces related to CMC.
- Participate in meetings (including meeting package preparation) for global Regulatory Agencies as they pertain to CMC.
- Liaise with all relevant groups to ensure high quality CMC documentation is developed.
- Lead development of all CTD submission elements relating to CMC and effectively communicate comments/recommendations and proactively engage teams to establish solutions to issues.
- Experience with all phases of drug development, Phase 1 through post-marketing.
- Occasional international travel to attend meetings is required.
- Other related duties as assigned.

Qualifications and Requirements

- Bachelor of Arts/Bachelor of Science in a related discipline with a minimum of 7-9 years of increasing documented success in biopharmaceutical field, with a minimum of 6 years in regulatory affairs CMC or the equivalent combination of education and experience.
- CTA and/or IND experience required, and NDA experience preferred.
- Must be able to travel without any legal restrictions across international borders.

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.