

VOISIN CONSULTING LIFE SCIENCES CAREERS

Voisin Consulting Life Sciences assists biotechnology, pharmaceutical and medical technology companies in the design and implementation of innovative and global regulatory strategies to expedite product development. Products include drugs, biologics, medical devices, in vitro diagnostics, combination products, cell, gene and tissue therapies and borderline products including nutraceuticals and cosmeceuticals. We collaborate with start-ups and mid-size companies to bring products to the market in the most efficient and cost-effective manner, within evolving regulatory frameworks.

VCLS offers various career opportunities to life science professionals in Europe, the USA, Switzerland, UK, India, and Singapore.

OPEN POSITION: Senior CMC Regulatory Scientist

Locations:

VCLS-Lausanne, Switzerland Office

VCLS- Rennes, France Office

VCLS-Cambridge, MA, US Office

Responsibilities:

- Assist with the preparation, reviewing and submission of the CMC sections supporting US and EU regulatory submissions. (IND, IMPD, BLA, MAA). This will include gap analysis of existing documentation, risk assessments, identification of potential challenges and propose solutions in the design of CMC strategies.
- Evaluate CMC changes during clinical development and assess impact on CMC regulatory strategy while providing guidance to the clinic.
- Contribute to the development of comparability, validation and stability programs, participate in defining drug substance and drug product specifications while maintaining up to date knowledge of the EU and US regulations and guidelines related to CMC.
- Link CMC to potential issues related to observations made during the non-clinical and clinical development of drugs and biologics.
- Participate in the preparation of Scientific Advices with Competent Authorities as it relates to CMC strategy (preparation of Briefing Packages, identification of key questions, elaboration of company positions, rehearsal, attendance of agency meetings, etc.)

Requirements:

- Good knowledge of the evolving regulatory environment in terms of CMC, quality, and science-based development strategies (quality by design is a plus)
- Knowledge on biologics with cell-gene therapies as a plus
- Good writing skills – experience in writing Module 3, Module 2.3, and Quality sections of IMPD
- Experience with Life Cycle Management as it relates to the management of CMC modifications (process changes, scale up, manufacturing site technology transfer, etc.) and the associated dossier amendments and variations
- Prior project management experience, with direct supervision responsibilities is a plus
- Client and business development oriented with excellent communication skills; able to manage time spent on projects; negotiation skills
- Knowledge of regulatory requirements in other regulatory regions is a plus (e.g. Asia)
- Proactive, highly motivated, flexible person, enthusiastic approach to team work and able to work in a multicultural environment
- Fluency in English with strong communication skills (oral and written).
- Knowledge of MS Office, specifically Word essential

Please email your CV and cover letter at hr@voisinconsulting.com