CMC MANAGER

Nanologica is a Swedish nanotechnology company developing nanoporous silica particles for applications within life science. Nanologica is world-leading in controlling the shape, size and type of porosity of silica particles. This knowledge is applied within two business areas: drug delivery and chromatography. The company's mission is to contribute to better and cheaper treatments for patients worldwide through the technology platform NLAB Silica™.

As Nanologica's inhouse study of the drug candidate NIC-001 for the treatment of gastroparesis is advancing towards clinical trials, we are now looking for a CMC Manager. The role will encompass CMC-related activities, including development and manufacturing of Investigational Medicinal Products (IMP), to support preclinical development through supplies for clinical phases. At the site in Södertälje, we offer a multi-cultural, fast-paced working environment and the opportunities within the company are vast, as we are continuously growing and developing.

Welcome to join our enthusiastic team!

Responsibilities and Duties

Contract Manufacturing Organizations	Identify, select and manage CMOs for process optimization, cGMP manufacture and supply of IMP in support of ongoing non-clinical and clinical programs.
Manufacturing	Deliver robust, scalable and cost-effective manufacturing routes for manufacturing.
Formulation development	Design and develop formulations that meet target product profile for the clinic.
Analytical methods and protocols	Implement stage appropriate analytical methods and protocols and ensure that all CROs and CMOs are using systems and processes in compliance with all relevant regulatory standards.
cGMP	Prepare, review or edit cGMP batch records, CMC regulatory and Quality documents. Execute plans for the validation and registration of IMP as required by cGMP, ICH and FDA regulations. Writing and reviewing documents for INDs/regulatory section submissions.
Supply chain and logistics	Anticipate and project IMP needs for preclinical and clinical programs and associated budgets, in collaboration with Nanologica's Management Team; manage supply chain and logistics in support of clinical studies and other manufacturing.

Qualifications

PhD or MS in Pharmaceutical Chemistry, Organic Chemistry, Analytical Chemistry, Pharmaceutics, Pharmaceutical Science, or related scientific discipline.
5+ years of experience in a pharmaceutical or biotechnology CMC/cGMP environment.
Experience in managing international CRO/CMOs for the manufacture of cGMP IMP.
Experience with IND, CTA and NDA filings; thorough knowledge of relevant FDA and EMEA regulations.
Proactive, forward-thinking team player with leadership skills to achieve successful outcomes in collaboration with internal team and external collaborators, within budget and in a timely manner.

Other Information

This is a part time position, 50% (20 hours per week).
The position is office based at our facilities in Snäckviken, Södertälje.
Only applications from persons with relevant background and Swedish working permit will be considered.
To submit your application and CV, or if you have any questions, please contact Kia Bengtsson, Director Drug Development:
kia.bengtsson@nanologica.com