



CMC Project Director, Asian Activities

To take responsibility for the Ascendis CMC activities in Asia

As **CMC Project Director, Asian Activities** at Ascendis Pharma the primary tasks are to coordinate the input to the filings and lead the CMC discussion with the partners in Asia. This will be in a very close collaboration with the CMC team as well as the regulatory, clinical and project management teams. The position reports to the SVP of Product Development.

We are seeking a highly motivated CMC project leader who has strong experience in the CMC aspects of regulatory filings in China, Japan and/or other Asian countries.

The main responsibilities are:

- Coordinate all CMC activities for clinical as well as marketing regulatory filings in Asia, which include direct interaction with our Asian partners:
 - Prepare CMC project plans and align internally and with our Asian partners
 - Implement and monitor progress against project plans
 - Develop the strategy for the CMC content of Asian filings together with the Regulatory team
 - Manage partner collaborations while having resource constraints
 - Prioritizing activities and problemsolving to meet milestones and timelines
 - Update timelines, resources, and budget as timelines and/or strategic priorities shift, and/or issues arise; communicate to all relevant stakeholders (including Senior Management) accordingly
 - Lead preparation of materials for internal updates, including Monthly Project Reports, Project Reviews etc.
 - Lead/contribute to operational initiatives as needed
 - Review and contribute to key project documents (e.g., regulatory documents, scientific publications, investor updates) and ensure cross-functional collaboration and alignment when regulatory documents are being prepared
 - Prepare and communicate CMC Asia project budget, facilitate resource/capacity planning, and follow up on accruals
- Contribute to the Ascendis Asia strategy
- Foster excellent cross-functional collaborative spirit and approach

You hold a relevant university degree – preferably a Masters of Sciences in Engineering, Pharmacy, or the like and with +10 years of experience in the biotechnology or pharma industry.

The successful applicant will already have a proven record of accomplishment in working with Asian countries primarily China and/or Japan. The following qualifications are appreciated:

- Experience with CMC regulatory filings in Asia
- 5+ years of strong and effective CMC project management experience including preparation of CMC project plans and problem solving
- A proven track record of working cross-functionally
- Demonstrate an excellent understanding of the entire value chain of drug development



You are proficient in English at a professional level, both written and spoken, and you master MS Office.

You have an interdisciplinary and intercultural mindset. You are an energetic and resourceful self-starter with high integrity and a can-do attitude. You are a team-player and comfortable in fast-moving, dynamic environments. You are adaptable and resilient with a problem-solving attitude who has a personal commitment to delivering results. You are pragmatic with an open and communicative approach and with the ability to develop effective working relationships with employees at all levels. Further, you can handle and deliver on routine jobs when necessary, while at the same time having the ability to move projects forward.

Ascendis Pharma offers you an exciting and challenging position in an entrepreneurial and international company with a short line of command. You will be involved in activities that are central to Ascendis Pharma's strategy and work together with highly skilled and experienced colleagues to advance our exciting product pipeline.

Travelling: 20 – 40 days per year.

Place of work: Ascendis Pharma resides in a wonderful office facility in Tuborg Havn in Hellerup with a view to the harbour, the canals and the sea.

For more details about the job or the company, please contact Partner Jørn Duhn, Unique Human Capital on M: +45 21 75 19 25. All applications must be submitted in English and are treated confidentially.

Click here to [APPLY](#).

Ascendis Pharma A/S is an international company with offices in Copenhagen, Germany and the US. Ascendis Pharma is building an integrated biopharmaceutical company to advance its [pipeline of long-acting prodrug therapies](#). They employ their proprietary TransCon technology platform to generate therapeutics with best-in-class profiles that address large markets with significant unmet medical needs. Ascendis Pharma has a diversified and balanced high-value [product pipeline](#), including internal programs and partnerships with market leaders.

Read more at www.ascendispharma.com