



Title: CMC Manager Department: CMC

Reports to: Line Manager **Date Prepared:** February 2021

Broad Function

To perform general duties and lead CMC related activities within the relevant section of the development department.

Principal Responsibilities:

- Day to day management of external contract development and manufacturing organisations (CDMO) associated with the manufacture, fill and finish, analysis and stability of Arecor's franchise products as required.
- Manage external contract research organisations (CRO) to develop analytical methods for process critical checks associated with the manufacture, release and stability of Arecor franchise products.
- Provide technical expertise and support as required for QA activities, such as deviations, change
 controls, out of specification etc associated with the manufacture, release and stability of Arecor
 franchise products.
- Support SMEs in setting release and shelf-life specification for Arecor franchise products.
- Manage and oversee ICH stability studies for Arecor franchise product.
- Provide expert CMC support to other areas of the business as required.
- Represent Arecor at project team meetings and provide expert technical advice to stakeholders.
- Analyse and report data to the standards expected by Arecor and associated stakeholders.
- Ensure all activities follow standard operating procedures and/or protocols as required.
- Work with other departments to resolve issues and implement corrective actions.
- Ensure all interactions and engagements are carried out with the highest ethical and professional standards and that all work is accomplished with the highest quality.
- Carry out other reasonable tasks as required by the line manager.

The above duties and responsibilities are not an exhaustive list and you may be required to undertake any other reasonable duties compatible with your experience and competencies. This description may be varied from time to time to reflect changing business requirements.

Principal Relationships

- Accountable to line manager.
- Liaise with internal personnel at all levels of the business as required.
- Liaise with external third parties as required.

Job Description CMC Manager



Education & Experience

- A BSc, MSc or PhD in Life Sciences or equivalent
- Experience of working within the pharmaceutical industry or related discipline, with in-depth drug product development and manufacturing knowledge and expertise.
- Experience of setting up, managing and analysing ICH stability studies for drug products.
- Experience in the development of drug product manufacturing processes from laboratory to clinical.
- Experience in the regulatory and quality environment and associated guidelines as required for the development and manufacture of pharmaceutical and biopharmaceutical drug substances and drug products.

Skills and Attributes

- Ability to use a wide range of communication methods to ensure information is presented appropriately.
- An influential and effective member of cross-functional teams or projects.
- Plans ahead, using established tools, techniques and methodologies, to meet objectives.
- Ability to liaise with others to ensure plans remain on schedule.
- Actively seeks change that brings about improvement, making recommendations.
- Introduces corrective actions that resolve issues or improve service.
- Looks for ways to make further improvements and introduce new innovations to foreseeable problems, opportunities, or risks.
- Commits and delivers high quality output by closely monitoring every process.
- Competent and organised self-starter with the ability to perform multiple tasks concurrently.
- Knowledge of methods and processes used to conduct a systematic and objective analysis and reporting of results.