Job Description
CMC Manager

Title:	CMC Manager	**Department:**	CMC
Reports to:	Line Manager	**Date Prepared:**	August 2021

Broad Function

The duties as CMC Manager will be varied however the key duties and responsibilities are as follows.

Principal Responsibilities:

- Responsible for day-to-day management of external Contract Manufacturing Organization(s) (CMO) specialising in sterile fill /finish operations to deliver robust, scalable and cost-effective drug product (DP) that meets or exceeds the target clinical profile.
- Act as point of contact for contract research organizations (CROs) performing GMP drug product release and stability testing.
- Work with the CMC lead to identify and select Contract Manufacturing Organizations (CMOs) as required for process optimization, cGMP manufacture and supply of DP in support of ongoing pre-clinical and early phase clinical programs.
- Responsible for the transfer of DP processes from laboratory to clinical scale.
- Establish and review process documentation including; batch manufacturing records, agreements CoAs, deviations, change controls etc
- Work with CMC lead to project API and DP needs for preclinical and clinical programs (with clinical team), and associated budgets (with finance team).
- Work with CMC lead to manage supply chain and logistics in support of clinical studies..
- Liaise with subject matter experts in establishing release and shelf-life specifications for Arecor franchise products.
- Manage and oversee ICH stability studies for Arecor franchise products.
- Follow current and emerging regulatory requirements and guidelines in the CMC field in order to advise other functions within Arecor on possible implications.
- Liaise with key stake holders for scientific writing where needed and perform critical reviews of pre-INDs, INDs, IMPDs, to ensure a high-quality regulatory submission. Represent the company in regulatory authority communications or meetings as required.
- Assist in encouraging continuous improvement across the functions
- 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.

Job Description
CMC 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.

Education & Experience

- A BSc, MSc or PhD in Life Sciences or equivalent
- Proven industry experience of cGMPs (MHRA, US, EU,) for biologics or pharmaceuticals, and knowledge of sterile fill finish operation, and different modes of sterilization process 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.