Venn Life Sciences
Think Research

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Chemistry, Manufacturing & Control

Realising the performance of your candidate medicinal products

The dynamic process of drug development based on patients needs, rapid evolving knowledge, methodology and technology and changing regulatory landscape drives the demand for independent, up-to-date and hands-on CMC consultancy.

Venn Life Sciences CMC department provides advice on CMC development strategies striking the balance between the technical and regulatory demands of each drug development program and the goals of the sponsor; resulting in solutions which are fit for purpose.

Why partner with Venn's CMC team?

- Broad and in-depth CMC development expertise in small molecules and biologics including peptides, therapeutic proteins, vaccines, antibodies and advanced therapy medicinal products (ATMPs) e.g. gene therapies and cell therapies
- Knowledgeable of cutting-edge methodology and technology
- Experience gained in industry and with regulatory authorities
- Committed to sponsor's projects and timelines
- Independent and objective advice
- Effective project management
- Flexible approach
- Soft skills: proactive and direct communication
- Detailed experience of quality systems (GxP)

Our CMC Consultancy Services

- CMC Consultancy focusing on addressing the strategic and technical aspects of pharmaceutical development
- Management of pharmaceutical development programs for small molecules and biologicals from chemical or cell line development up to submission of marketing authorization application (MAA, NDA/BLA)
- Design of integrated pharmaceutical development plans
- Provide independent advice e.g. due diligence, gap analysis, define (or review) the CMC development strategy
- Participation in multidisciplinary compound development teams and/or assist sponsors by managing in-house CMC development activities with onsite support
- Interim management services are provided e.g. CMC Manager, Head of CTM Manufacturing, Head of Analytical Development, Head of Formulation Development, Head of Chemical Development and Qualified Person (QP)
- Selection of contract manufacturing organizations (CMOs) and contract research organisations (CROs)
- Managing and supporting of CMC activities at contracted CMOs and CROs
- Trouble-shooting of technical challenges
- Timely delivery of non-clinical and clinical trial materials

'Keeping CMC development off the critical path'

Acceleration of drug development programs

CMC Regulatory Affairs

- CMC Regulatory Affairs Consultancy focusing on strategic and regulatory aspects of pharmaceutical development
- Thorough understanding of the regulatory demands for small molecules and biologicals for EU, US, and Most of World registrations in various indications and phases of development and market approval, based on the most relevant and recent guidelines
- Provide RA-strategic advice (e.g. due diligence, gap analysis), authoring and review of drug development plans and related documents, translation and authoring of scientific/development data into regulatory language for dossier parts in compliance with applicable laws, regulations and guidelines
- Experienced with the differing focus and interpretation of guidelines by national authorities often contributing significantly to the success of regulatory submissions
- Employment of "insider" knowledge to determine the relevant CMC regulatory strategy
- Assurance of the quality, consistency and technical validity of regulatory documentation
- Constructing of a documentation hierarchy which supports the relevant quality sections of regulatory submissions e.g. IMPD, IND, DMF, NDA, BLA, MAA, ANDA and CTD Module 3 (Quality), and scientific advice briefing packages

'Solving CMC challenges shifts the risk profile favourably'

For more visit www.vennlifesciences.com or email us at getintouch@vennlife.com