Venn Life Sciences

part of Open Orphan plc

CMC team capabilities New Chemical Entities

For 20+ years, members of the CMC (Chemistry Manufacturing and Control) team have supported and are supporting numerous pharmaceutical companies to ensure the timely development and manufacture of high-quality drug substances and drug products for non-clinical- and clinical studies. The support includes:

- CMC management and strategy development
  Including CMC development strategy, project management, due diligence and gap analysis, CDMO (Contract Development and Manufacturing Organization) selection and management, QbD (Quality by Design) support,
- Drug Substance process development
  Including process development and scale-up, tech transfer, and design of stability studies
- Drug Product formulation & process development
  Including early phase "fit for purpose" formulations, late phase formulations, process design and validation, tech transfer, and design of stability studies,
- Analytical Development
  Including selection of methods (for in process controls, characterization, release and stability), method development and validation, method transfer, drug substance and drug product specifications setting,
- Preparation and review of development protocols and reports, and regulatory documents,
- GMP Audits.

Through this support we enhance asset value and company profile through robust concept definition, development planning and technical strategy.

Expertise provided throughout the Drug Development lifecycle

Pre-clinical	Phase I	Phase II	Phase III	Post-approval
Strategy definition, preparation of a Drug Development Plan				
CMC project management				
Writing and reviewing of documentation				
IMPD/IND (module 3) preparation				MAA (module 3) preparation
CMC due diligence and gap analysis				
CDMO selection and management for development and manufacturing of DS and DP				
Drug Substance process development				
Drug product formulation & process development				
Analytical Development				
	GMP Audits			
	Quality Target Product Profile (QTPP)	Quality by Design (QbD) support and Design-of-Experience (DoE) study design		
			Inspection readiness assessment and support	

CMC team capabilities New Chemical Entities

Over the past 5 years, the team supported more than 30 companies with all aspects of the CMC development:

- Developed early strategies and drug development plans for 10+ discovery and preclinical stage programs leading to several clinical candidates progressing into the clinic,
- Participated as a CMC project manager in 5+ multidisciplinary early clinical phase projects as part of an internal Venn Life Sciences team or as part of a multidisciplinary team in collaboration with the Sponsor,
- Prepared high-quality CMC-related documents for multiple product types to support global registration of clinical trials in several therapeutic areas. This included 25+ IMPDs/INDs for early stage (Phase 1 and 2) and late stage (Phase 3) clinical trial applications,
- Performed 10+ audits and inspections, QA support and tech transfers.

Therapeutic areas supported

- oncology
- neurology
- infectious diseases
- inflammatory diseases
- others

Drug type

- oral solid dosage forms (tablets, capsules, powders)
  - immediate release
  - delayed release
  - extended release
- parenterals
  - solutions
  - emulsions
  - suspensions, including extended release formulations
  - freeze dried formulations
- creams
- nasal sprays

Case study

Development from discovery till Phase 1 clinical trials

A small-size discovery company had developed a new chemical entity (NCE) at laboratory scale. They contacted Venn Life Science (VLS) for further support to develop their NCE entering Phase 1 clinical trials.

A Venn multidisciplinary team prepared a drug development plan (DDP) to support the early phase development of their compound until phase 1. After drafting the drug development plan the VLS team started with the necessary activities.

Before starting the clinical phase 1 study the safety of the NCE needs to be confirmed by non-clinical toxicology studies. The CMC consultant started selecting the CDMO for the development and synthesis of the (non GMP) drug substance necessary for these toxicology studies, led by VLS non-clinical expert, and the phase 1 clinical study that would follow the toxicology studies. In parallel a CDMO for the development of a phase 1 “fit for use” formulation for the drug product was selected. The CDMO selected for this work was also able to perform the GMP manufacture of the clinical phase 1 investigational medicinal product (IMP).

The analytical methods, necessary to characterize and release the drug substance and the IMP, were developed and stability data were generated to ensure the stability of the medication during the toxicology and clinical study. Furthermore, our consultant advised on critical quality requirements for their IMP in this stage of development, e.g. drug substance and drug product specifications and justification of specifications.

For the preparation of the Clinical Trial Application (CTA) for the phase 1 study, that was performed in The Netherlands, the CMC consultant authored the IMPD and prepared the label text for the IMP.

The IMPD was approved by the Competent Authorities without questions. After that, the IMP could be shipped to the Phase 1 clinical site, ensuring a timely start of the clinical study.

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