Venn Life Sciences

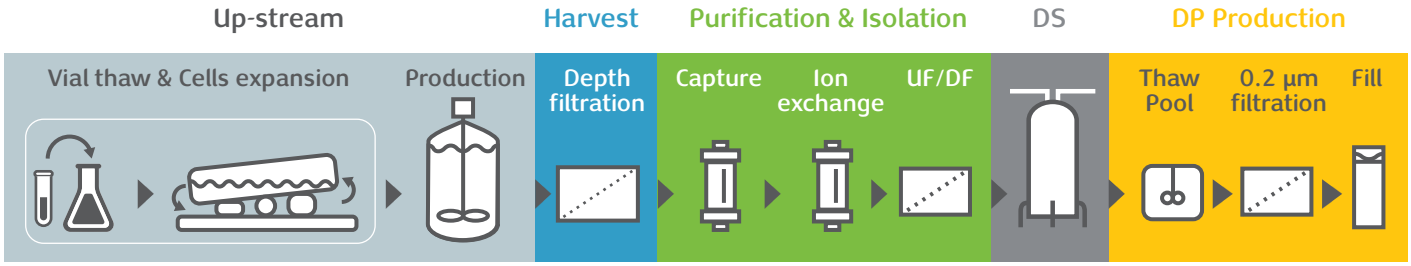
part of hVIVO

CMC team capabilities for biologics

For 20+ years, members of the CMC (Chemistry, Manufacturing and Controls) team supported numerous (bio)pharmaceutical and biotechnological companies to ensure the development and manufacture of high-quality drug substances and drug products for

- CMC management and strategy development
  Including CMC development strategies from early phase (concept) through marketing authorization, project management, due diligence and gap analysis, CDMO (Contract Development and Manufacturing Organization) selection and management, QbD (Quality by Design) support including risk assessments and Design-of-Experiments (DoE) study design, and GMP audits.
- Drug Substance process development
  Including cell line development (CLD), cell culture, harvest, and isolation/purification process development and scale-up (from 75L to up to 7,500L scale), formulation development, tech transfer, non-GMP/cGMP manufacturing (up to 75,000L scale), and design of forced degradation and stability studies. Main expertise with Upstream part of the production (USP) and various fermentation processes, such as Solid state, Batch, Fed-batch and Perfusion system; Experience with harvest Downstream processing (DSP); with a focus on microbial and mammalian systems plus virus production and isolation.
- Drug Product formulation & process development
  Including early phase “fit for purpose” formulations, late phase formulations, process design and validation, support for sterile Fill & Finish, tech transfer and design of stability studies, and clinical in-use compatibility studies with selected medical devices.
- 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, and design of comparability studies.
- Preparation and review of development protocols and reports, and regulatory documents.

Example of simple GMP DS/DP production for monoclonal antibody (mAB)



CMC team capabilities for biologics

Over the past 5 years, the CMC team supported more than 20 companies in developing and productions of biologicals:

- 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 several 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,
- Participated as a CMC consultant within the internal CMC team for early phase and late phase development projects,
- CMC support for Technical due diligence.

Therapeutic areas supported	Drug type
» oncology	» recombinant proteins
» immunology	» monoclonal antibodies
» infectious diseases	» vaccines (recombinant viral vectored vaccines, live-attenuated vaccine, bacterial protein vaccine, plasmid DNA vaccine)
» haematology	» antibody drug conjugates (ADCs)
» others	» non-investigational medicinal products (NIMPs)
	» blood products

Case study

Drug Development from discovery till Phase I/II clinical trials

A small-size discovery company had developed a new complex recombinant protein at laboratory scale. They needed further support to develop a cGMP-grade process and product for entering Phase I and II clinical trials. A Venn multidisciplinary team has developed the Phase I/II Drug development plan including selection of outsource partners (CDMO/CROs) to support and execute the full early phase development of their compound.

Our CMC experts worked in conjunction with the client to draft a Drug Development Plan, based on which the company secured seed funding. In close collaboration with the company, Venn CMC team drafted plans and selected outsource partners for the various development activities. In addition, Venn CMC team was responsible for outsource management, such as: Cell line development (leading to the creation of a cell line expressing the complex biologic product and enabling further development), Production of research-grade product and testing this materials in non-human primates (based on the results, the company secured Series A funding), and Process Development, Analytical Development and Formulation Development (all activities at a top-ranking CDMO which leaded to batch production for formal GLP toxicology studies and FIH clinical trials).

In close collaboration with the company, Venn CMC team developed the regulatory strategy, and was guiding the execution. Venn CMC team authored the briefing books and leaded the combined company / Venn team in regulatory meetings with the US (FDA), as well as with European authorities (Dutch; CBG, and German; PEI).

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