Venn Life Sciences

part of hVIVO

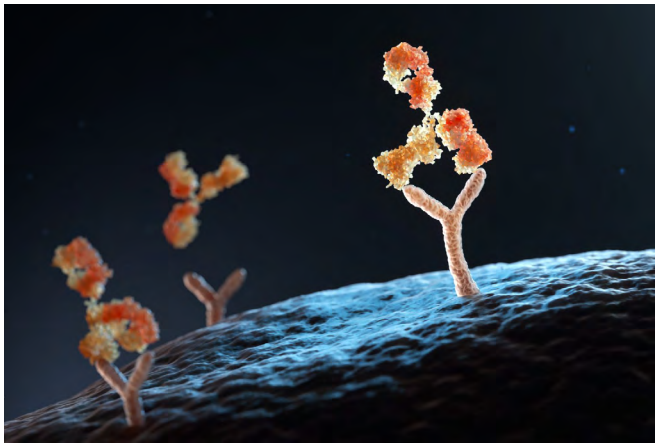
Chemistry Manufacturing and Controls (CMC) Late Phase Development

Overview

As pharmaceutical products progress through clinical trials, the Chemistry, Manufacturing, and Controls (CMC) division plays a crucial role in ensuring these products are effective, consistently safe, and of high quality. During late-stage development, the focus is on scaling, refining, understanding and validating manufacturing processes, validating analytical methods, and ensuring regulatory compliance to meet stringent market approval requirements.

With over 20 years of expertise, Venn Life Sciences' CMC department excels in the strategic and technical advancement of a wide range of new molecular entities. Our approach to pharmaceutical development, spanning from early to late-stage development, encompasses small molecules, biologics, and advanced therapy medicinal products (ATMPs), and reflects the dynamic nature of modern medicine and patient care.

Our team of experienced professionals – including project managers, subject matter experts, and quality/GMP specialists – offers comprehensive late-stage development services to ensure the successful transition of pharmaceutical products from development to market. We provide expert guidance and support throughout the late-stage pharmaceutical development process in the following key areas:



Gap Analysis: Transitioning from early to late phase development introduces additional requirements. At Venn, we perform a gap analysis of the current CMC status of your drug in development and provide actionable recommendations for late-phase implementation.

CMO Selection and Management: We specialise in scaling up manufacturing processes and managing Contract Manufacturing Organisations (CMOs). Our support ensures efficient and reliable drug production, including decision-making and strategic oversight on the scope CMO activities to align with late-stage requirements.

Scaling, Refining, and Understanding Manufacturing Processes: Our goal is to optimise production processes to ensure efficiency, cost-effectiveness, and high-quality output. We support in:

- **Process Optimisation** – enhancing existing methods to increase yield and reduce waste
- **Scale-Up:** Transitioning from small-scale production to full-scale manufacturing
- **Process Understanding:** Identifying critical process parameters and material attributes, defining their ranges, and determining a manufacturing control strategy
- **Technology Transfer** – facilitate seamless transfer of production processes from development to commercial manufacturing sites, including planning and coordination with all parties involved
- **Process Validation/Process Performance Qualification** – ensuring a smooth validation by designing and creating validation plans (including sampling plans) with input from development process engineers and commercial operators

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Analytical Method Development

Our CMC experts support the validation of phase-appropriate analytical methods to ensure quality of drug substance and product. We also help establish pharmaceutical product specifications, design stability studies, and guarantee safety and efficacy through rigorous analysis.

Quality Control and Assurance

By implementing Quality by Design (QbD) and Quality Risk Management principles, and conducting GMP audits, we ensure compliance with international standards to enhance the overall quality of our products.

Regulatory Compliance

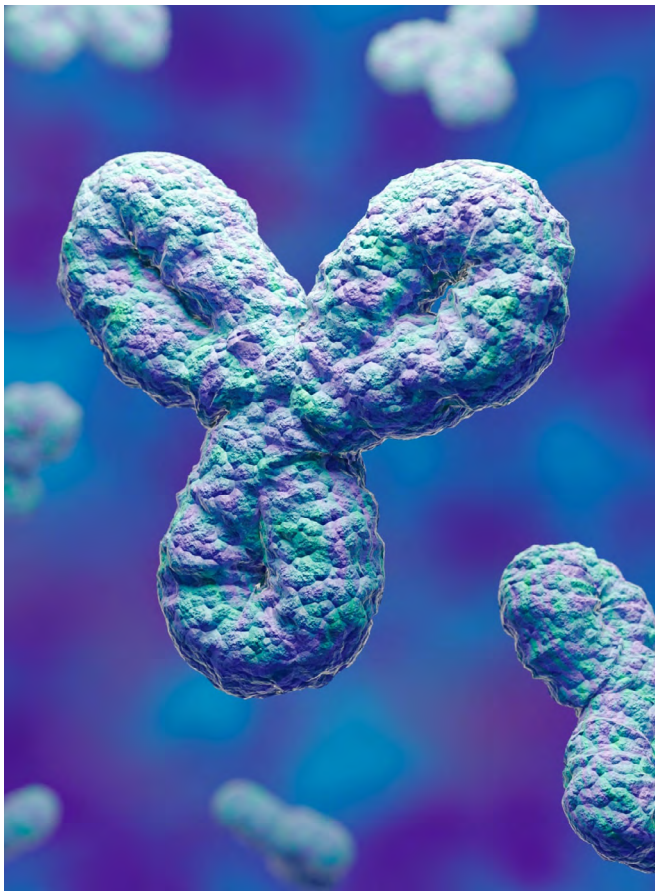
We develop comprehensive regulatory strategies tailored to the specific requirements of your product and target markets. Our services include:

- **Dossier Preparation** – authoring and/or reviewing high-quality regulatory documents, including (A)NDAs, BLAs, and MAAs
- **Regulatory Liaison** – acting as a liaison with regulatory authorities, facilitating communication, and addressing queries to ensure a smooth approval process
- **Compliance Audits** – conducting meticulous compliance audits to identify and mitigate potential regulatory risks
- **Post-Approval Support** – providing ongoing support for post-approval regulatory requirements, including variations and renewals

Continuous Improvement

We are committed to continuous improvement by regularly reviewing and updating processes, incorporating feedback, and staying abreast of the latest industry standards and regulatory guidelines.

By integrating these practices, Venn Life Sciences ensures that our CMC processes are robust, compliant, and capable of delivering high-quality pharmaceutical products to market. Our proven CMC expertise in late-stage development has enabled our partners to achieve their commercial goals while adhering to the highest standards of quality and safety.



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