Venn Life Sciences:

Process Optimisation & Formulation Development with Commercialisation in Mind

Designing drugs for the real world: A look beyond the clinical trial

What does a "successful" study drug truly mean? In the pharmaceutical world, a study drug may be clinically effective, yet if too expensive to manufacture, it risks being deemed non-viable. Often, drug development moves from one phase to the next without considering the long-term feasibility, including cost-effectiveness, scalability, and market access. Building future-proof strategies from the outset is key to ensuring sustainable success. Erik Gout, Director of Chemistry, Manufacturing, and Controls (CMC) and Azra Gholami, CMC Consultant at Venn Life Sciences ("Venn") share their expertise in process optimisation and formulation development, with a focus on thinking beyond the development phase to ensure long-term success.

Venn's consultancy has expertise in biologics and small molecules, each of which requires a distinct optimisation approach. For biologics, development is divided into upstream and downstream processes. The upstream process defines the cell line – typically prior to Phase 1 – which is rarely changed, as modifications may require a complete redesign of the downstream purification. In this article, we will focus on small molecules.

Optimisation and formulation development to ensure scalability

Phase 1 clinical development primarily focusses on evaluating the drug safety, using a basic or no formulation. The formulation of small molecules is typically not optimised and the synthesis route for the drug substance may still be under development. When moving from Phase 1 to Phase 2, the feasibility of the drug substance process and formulation will be assessed for use in future Phase 3 and commercial production. This stage focuses on optimising both the drug substance and drug product, keeping the final formulation and process in mind.

Erik highlights the importance of aligning development with long-term goals, advising clients to consider cost of goods and scalability early on in development. "It's not just about reaching the next phase," he explains, "Early decisions should assess whether the formulation can scale effectively." Key considerations include cost-efficient excipients, adaptable production processes that allow for Contract Development and Manufacturing Organisations (CDMOs) changes, and standardised methods to support a smooth transfer to commercial manufacturing."

"For (bio)pharmaceutical clients using separate CDMOs for drug substance and drug product, Venn can manage both to ensure alignment", says Erik, "We offer consultancy on decision-making, testing, process control, risk management, and logistics. While CDMOs have scientific expertise, Venn bridges knowledge gaps – like stability differences– by facilitating information exchange. We guide stability testing to ensure shelf life and help define critical manufacturing parameters through scalable process controls and risk management."

Mitigating risks

"Our most important key services include process troubleshooting and risk management", says Azra, "From the outset, we proactively identify and mitigate risks associated with the manufacturing process. Mitigating risks of unstable products can be achieved through process control and selecting the right packaging material. The choice of packaging – whether opting for cost-effective or more specialised materials – can significantly impact cost of goods during commercial production. Similarly, transport conditions, like storage at 5°C or lower versus room temperature, play a critical role. Storage at room temperature will generally be more cost-effective in the long run. Ultimately, the goal is to minimise unnecessary complexities while optimising for cost efficiency and quality."

Perfect versus the real world

There is often a gap between what is technically possible and what is commercially viable. Long-term success depends on finding the right balance between innovation and feasibility. (Bio) pharmaceutical companies should take a strategic view from the start, focusing not just on short-term goals but on commercial outcomes. Early informed decisions aligned with long-term objectives greatly improve the chances of sustainable success.

Venn provides expert guidance on process optimisation and formulation development, identifying potential obstacles in upcoming development phases. This includes evaluating transport, storage conditions, and associated costs – all with a clear focus on the commercial goal.

About Erik Gout and Azra Gholami

Erik Gout, Director of CMC at Venn, has 40 years of experience in the pharmaceutical industry. Erik worked as an analytical and pharmaceutical development scientist, CMC lead, and QA engineer. His CMC expertise spans drug development, technology transfers, GMP audits, and regulatory, making him a trusted and expert partner in due diligence and compliance. With a deep understanding of industry standards and best practices, Erik plays a crucial role at Venn to ensure the successful development and regulatory approval of pharmaceutical products.

Azra Gholami, CMC Consultant at Venn, has over 11 years of experience in the pharmaceutical industry. With a PhD in Molecular Biology from Ghent University and a background as a pharmacist, she specialises in Quality-by-Design-based analytical method development and validation for both small and large molecules. Since joining Venn in 2022, she has focused on using her experience in process optimisation, technology transfers, and CMC documentation to ensure compliance and efficiency in drug development.

Erik Gout

Azra Gholami