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KEY REASONS

for Outsourcing Your Formulation Development and Manufacturing Needs

Partnering with a Contract Development and Manufacturing Organisation for your formulation development and manufacturing needs can provide a solution to help compress timelines and mitigate risk. A CDMO can provide services from early-stage clinical development through to clinical and commercial manufacturing and packaging, including full technical and analytical support, launch capabilities and final distribution. It is a compelling argument as to why engaging in this service model in the early stages of drug development can yield a positive process for all involved.

Managing development activities to compressed timelines, the identification and timely resolution of development challenges, as well as the alignment of the various components in the supply chain, has never been more important. This is leading to more companies seeking out the benefits of accessing external capacity and capabilities at CDMOs as they look to manage these pressures and access resources to progress their pipelines.

Outsourcing early development activities is something Almac is increasingly experiencing as companies look to accelerate from candidate selection to clinical trial entry, and ultimately get to proof-of-concept as quickly and efficiently as possible. Traditionally smaller pharma companies outsourced these activities, but there has been an increasing number of large-scale pharma companies utilising CDMOs for early phase development. This includes pursuing 'reserved capacity models' to guarantee access to formulation, analytical, and manufacturing capabilities and capacity so that they can move multiple assets in their portfolios forward quickly when the need arises.

Almac Pharma Services supports many key elements of the clinical and commercial supply chain. Availing of single source integration of development and commercial resources including Technical, Analytical, Quality and Project Management ensures scientific continuity and simplified effort, saving time and expense whilst reducing vendor management and mitigating risk to the overall project. This alleviates unnecessary concerns for the sponsor company, providing a cohesive and smooth transition from development to production.

Selecting a CDMO with a high level of experience is key to a successful partnership. Providing the client with a wealth of previous knowledge in early development and manufacture and being able to deliver quality data in pre-formulation and formulation of oral solid dosage forms. Collaboration through a products development and commercial lifecycle can provide the client with access to teams with specialist knowledge and experience as and when the product demands it, for example, in fields such as development and manufacture of paediatric formulations.

Engaging with a company like Almac Pharma Services not only provides a client with the benefit of knowledge and proven experience, but also access to a wide range of capabilities, technologies, and development facilities for both non-GMP and GMP product batches. This ensures not only complementary equipment trains, but also integrated technical teams to facilitate a products increasing scale demands through the development lifecycle. Dedicated pharmaceutical development teams provide analytical resources that support manufacturing activities from early phase development through registration stability, and process validation, and ultimately into commercial supply.

Partnerships with CDMOs mean that clients can expect peace of mind as development and commercial teams work together to ensure a smooth transition of their products from development into commercial manufacture.

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