back page

Deconstructing silos with an integrated outsourcing model

Functional outsourcing is widely used in the pharmaceutical industry to manage R&D costs and address capacity constraints. However, the rise in outsourcing over the last 10 years has fundamentally changed the industry's structure. These changes have created a siloed mentality, in which various vendors each handle an individual piece of the process—from discovery to formulation development to manufacturing. This has magnified existing time and cost inefficiencies in the drug development process and increased the time it takes for drug molecules to reach the proof-of-concept (POC) stage and beyond.

With time and money at a premium, drug companies need to bring new molecules to market as quickly as possible. One approach is to focus on smarter R&D by aligning the activities of the contract development and manufacturing organization (CDMO) and the contract research organization (CRO) into one highly integrated model. A single outsourcing partner coordinates and adapts the drug product manufacturing requirements ("make") with the specific needs of the clinical development plan ("test"). Unlike outsourcing multiple development activities to numerous firms, this integrated CDMO/CRO approach improves efficiencies to achieve milestones under a compressed timeline.

Applying an integrated CDMO/CRO model

The early stages of drug development are particularly receptive to the benefits of integrating CDMO and CRO activities. Specifically, this type of program allows the drug company to:

Accelerate molecules from first-in-human to proof-of-concept. Fit-for-phase drug product strategies are typically used in first-in-human studies to provide dose flexibility with minimal upfront investment. By using real-time adaptive manufacturing, researchers can adjust dose levels, formulations, and drug product types within a clinical protocol and make decisions based on human data. Real-time adaptive manufacturing also allows companies to maintain a continuous supply of the drug product into patient trials for establishing POC, without the need to transfer the manufacturing process to another CDMO.

Implement real-time adaptive manufacturing for patient trials. Biotech and pharma companies can conserve valuable drug substances and reduce manufacturing costs up until scale-up for late-phase trials by manufacturing only the precise amount of drug product required to meet the needs of the patient and clinical trial. Flexible, on-demand, small-batch manufacturing balances the requirements of the clinical protocol (such as subject numbers and patient recruitment) with any chemistry, manufacturing, and control challenges that present themselves (such as shelf life and drug product availability).

Develop optimized and scalable drug products. Companies can also integrate real-time adaptive manufacturing within a clinical bioavailability study, enabling researchers to rapidly screen, optimize, and select new formulations based on human data and evaluate multiple formulation technologies head-to-head in a clinical study. Researchers can also study a specific design space. For example, when developing a modified-release matrix tablet formulation, it's possible to vary the drug content and release-controlling polymer content in a two-dimensional space to optimize both the shape of the pharmacokinetic profile and its position within the therapeutic window.

Why integrate?

Integrating the early stages of drug development allows researchers to cut make-test cycles down to days rather than weeks or months. This reduces costs, streamlines processes, accelerates product development, and shortens timelines to POC.

Quotient Sciences has seen the benefits of this approach with its Translational Pharmaceutics platform, which integrates formulation development, real-time adaptive GMP manufacturing, and clinical research. The platform provides compounded timeline savings of more than six months, investment savings of more than $500,000, and drug substance conservation of up to 85 percent.

In addition to improving trial efficiency, an integrated early development program can significantly improve productivity and ease a drug company's management burden. For a drug product forecasted to generate $500 million to $1 billion in annual revenue, an integrated approach could save the company millions of dollars per day. Most importantly, however, an integrated outsourcing program enables precise dose manufacturing and allows human data to drive key decisions. *T&C*

Peter Scholes is chief scientific officer at Quotient Sciences (www.quotientsciences.com). He holds a PhD in pharmaceutical sciences from the University of Nottingham, UK, and has more than 20 years of experience in the pharmaceutical industry.