Unlocking Formulation Expertise

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Partnering with an experienced service provider can help companies unlock the commercial potential of new therapeutic approaches.

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As the industry enters a phase where the patents of many major drugs will expire and the use of more novel therapeutic modalities is increasing, the desire to partner up with a company that can offer significant expertise is also rising. According to market research, the global formulation development outsourcing market is predicted to grow at a compound annual rate of 8.19% between 2020 and 2028 (1).

“Outsourcing formulation activities provides sponsor companies with the opportunity to unlock the entire commercial potential of new therapeutic approaches,” confirms Cornelius Pompe, vice-president R&D at Leukocare. “The most obvious advantage of outsourcing is the opportunity to increase the likelihood of success. Thereby, the sponsor’s

specific knowledge about the drug is combined with the formulation expertise of the service provider that is able to leverage from a high project throughput."

Accelerated formulation projects

"With more molecules in development than ever before, huge productivity challenges are arising. Consistent increases in molecules with challenging drug properties have created hurdles when trying to achieve successful delivery, which also aids in the high attrition rates of molecules before Phase II," notes Vanessa Zann, senior drug development consultant, Quotient Sciences. "If accelerating development timelines is the goal, drug developers must characterize their compounds sufficiently to allow intelligent formulation strategies to be adopted, and for contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) to be able to provide meaningful data quickly."

When moving away from traditional industry silos and using an integrated approach for projects with a single outsourcing partner, it is possible to gain significant cost and time savings, explains Zann. "Outsourcing to a fully integrated service provider also allows for the opportunity to access the specialist knowledge of drug substance, drug development, and clinical experts that are dedicated to the provision of these services, often having experienced many valuable case studies that can provide great benefit for the customer," she says. "This integrated consultancy approach can offer additional value when accelerating formulation strategies to achieve first-in-human and proof-of-concept milestones."

In addition to a lack of expertise, which creates a hurdle to successful formulation strategies by pharmaceutical companies, other common issues include the appropriate amount of resources and time to be able to choose and apply orthogonal approaches to understanding the formulation design space, specifies Paul Kippax, Pharmaceutical Sector director at Malvern Panalytical. "Working in partnership with a contract service provider that provides both expertise and instrumentation can add exponential value to any formulation development workflow," he says. "By offering consultancy on and access to the plethora of analytics and associated methods available, an experienced team will supply the clarity needed to answer your questions and accelerate your development."

A best-case scenario, when outsourcing a project to a CRO, would be for the sponsor company to gain rapid access to the wide range of instrumentation and experience that is required for an orthogonal approach, Kippax emphasizes. “[This scenario would] allow sponsors to effectively define the design space without introducing noise and unnecessary complexity,” he adds. “And selecting a services provider with deep experience developing the dosage forms most relevant to your product can be the ultimate fast-track to success.”

“Accelerating a formulation strategy is all about continually asking and answering the questions that enable you to narrow the design space,” Kippax states. “Like the beams of two torches crossing in the dark, applying the right combination of analytics to validate—or even dismiss—a particular formulation will quickly shine a light on the optimal product preparation.”

Alexander Faude, director Process Science, downstream processing, Rentschler Biopharma concurs that sponsors can benefit from the expertise that a CDMO can bring to the table, as well as the flexibility a partnership can offer. The reasoning being that not only are CDMOs, such as Rentschler Biopharma, experts in high-quality manufacturing, but they also follow holistic approaches to product development, he notes.

“At the same time, [a holistic] approach is tailored to the needs of the client and molecule in question,” Faude continues. “The collaborative exchange between the sponsor and service provider continuously enhances this foundation of knowledge and can be leveraged for project success.”

“The experience and track record of outsourcing providers plays a defining role in contributing towards the success of accelerated formulation strategies,” specifies Marvin Kadisch, director Process Science, upstream processing, Rentschler Biopharma. “[These attributes] ensure the alignment of material supply and quality with formulation development activities that are critical to the success of the strategy. Moreover, expertise, especially with respect to in-silico approaches but also wet-lab activities, is a defining factor.”

Particularly for accelerated formulation strategies, partnering with an outsourcing service provider that has formulation expertise for a great variety of modalities is advantageous because the partner will be agile

toward the specific needs of the client's molecule, adds Pompe. "Accelerated formulation strategies are largely built on cutting-edge technologies like machine learning, which require skillsets (e.g., software development experience) that are not necessarily available on the sponsor's side," he notes.

Technological advances

"High-throughput, automated analytics have been critical to enabling strategic formulation development, providing extensive and detailed measurements that rapidly expand understanding of critical material attributes," emphasizes Kippax. "Combining a highly automated approach with visualization and data analytics that provide high data density can really catalyze the sample-centric workflow. And to ensure your data [are] relevant, precise, repeatable and connected, it's important to have the right expertise available at the right time, to interpret analytics, support with data interpretation, and oversee the overall picture painted."

Firstly, Pompe emphasizes that the decision as to whether or not new molecules may even be eligible for accelerated formulation strategies, partially depends on the molecules' intrinsic liabilities. "At very early project stages, these liabilities can be addressed during developability assessments aiming for the identification of most promising lead molecules. Here and during later development phases, in-silico tools like molecular modeling, biostatistics, or machine learning are increasingly leveraged," he says. "In combination with predictive time-independent analytics (e.g., biophysical methods), these tools are able to expedite informed decisions on final formulations and allow for a more efficient utilization of lab resources."

Partnering with a service provider that encompasses the whole bandwidth of aforementioned technologies and is highly experienced in applying them to a broad range of modalities is beneficial, stresses Pompe.

A method that can be employed to accelerate both small and large-molecule formulation development is the integration of clinical trial manufacturing and clinical testing, points out Chris Roe, senior research fellow, Quotient Sciences. "With this approach, a number of formulations can be rapidly manufactured in small batch sizes with limited stability, and assessed in the clinic in quick succession (sequential dosing in a

small cohort of subjects) to inform of the best performing formulation to move forward with," he says.

Furthermore, the use of modeling and simulation software has added another tool to assist in accelerating formulation optimization, continues Roe. "Future innovations from artificial intelligence and machine learning tools, will enable organizations to leverage a prior experience to enhance formulation design and selection, based on input molecule properties and a target pharmacokinetic profile," he states.

"Outsourcing accelerated formulation strategies in the context of process development and manufacturing is a collaborative process that brings together the right mix of knowledge, expertise, and experience to guarantee project success," concludes Faude. "Ultimately, acceleration programs for highly coordinated process development and manufacturing followed by sophisticated approval strategies enable shortest clinical and commercial entering."

Reference

1. Market Research Future, *Formulation Development Outsourcing Market: Information by Services (Pre Formulation Services [Formulation Discovery, Pre-Clinical Services, Analytical Services], Formulation Optimization [Phase I, Phase II, Phase III, Phase IV]), by Dosage Form (Injectable, Oral, Topical, Inhaled, Others), by Application (Oncology, Genetic Disorders, Neurology, Infectious Disease, Respiratory, Cardiovascular, Others), by End User (Pharmaceutical and Biopharmaceutical, Government and Academic Institutes), and Region (Americas, Europe, Asia-Pacific, and the Middle East & Africa)—Forecast till 2027*, Market Report (January 2021).

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