SPECIAL FEATURE

Outsourcing Formulation Development & Manufacturing: Going Beyond the Science to Become True Partners

By: Cindy H. Dubin, Contributor

Contract Development and Manufacturing Organizations (CDMOs) are critical partners for pharma and biotech companies when it comes to providing innovative solutions that advance the next generations of therapies. To that end, CDMOs are seeking to modify contracts to maintain competitiveness and maximize revenue growth. The top three contract modification priorities are adding more indices, extending contract durations, and ensuring adaptability to shifting market requirements.[1]

Small-molecule specialized CDMOs with expertise in complex formulations, such as (HPAPIs)are growing in importance. The global small-molecule CDMO market will reach almost $85 billion in 2032, up from $45 billion in 2022.[2] While not growing quite as significantly, the global large-molecule CDMO market was valued at $11.6 billion in 2023 and is expected to jump to almost $20 billion in 2029. This market revolves around biologics, monoclonal antibodies, therapeutic proteins, and biosimilars.[3]

Both play a critical part in process development, complex manufacturing processes, and regulatory compliance. "As we continue

Sterile vial filling in Eurofins' closed robotic isolator via filler.

to see the industry evolve post-COVID, 2023 continued to be a difficult year when it came to rising inflation impacting biotech funding and M&A," says Dr. Andrew Lewis, Chief Scientific Officer, Quotient Sciences. "One major takeaway from 2023 was evident: with the best science, it's possible to weather the storm and make truly ground-breaking advancements. We are already seeing turnarounds in 2024, with CDMOs increasingly viewed as strategic partners."

For instance, contractors are providing less off-the-shelf programs, and are instead going deeper to work on the science needed to enable all parts of a program. He says: "The scientific acumen of the outsourcing provider and quality of scientific output can be the deciding factor in a program's success or failure."

In this exclusive, annual report, leading CDMOs speak with *Drug Development & Delivery* about how they are adapting to bio/pharma client needs, their capabilities in handling complex molecules, and how they are transforming from specialist contractors to true partners.

Outsourcing Formulation Development & Manufacturing: Going Beyond the Science to Become True Partners
Singota Solutions

Publication
Drug Development & Delivery

Date
June 2024
Vol 24 No 5

Singota Solutions: Understanding the Needs of Small Biotechs

Singota Solutions specializes in providing formulation, analytical, and process development services to small biotech firms working in the injectables space. Singota understands the characteristics of its start-up clientele and has built its business structure to address these factors, explains Will Powers, Senior Director Business Development and Marketing at Singota. "Having a cGMP-compliant facility with storage, sampling and dispense, up-to-date analytical and manufacturing facilities are a must."

The use of robotics and the associated benefits of repeatability, increases in precision, and the reduction of human error increase the chances of project success and reduce timelines by avoiding delays caused by deviations. Manufacturing equipment designed specifically to minimize line loss, and techniques used in analytical methods and testing, can be devised to minimize the amount of API/drug substance/drug product consumed.

Singota Solutions of Bloomington, IN, specializes in aseptic filling, formulation, analytical, and process development services for small biotech firms in the injectables space. The cGMP-compliant facility features advanced robotics for precision, reduced human error, and minimized line loss, ensuring project success and faster timelines.

He says that personnel aligned with common goals across the organization, and competent, well-trained project managers who can inform and quickly coordinate a variety of moving parts from all sections of the organization helps move client projects along. "A predisposition to utilizing frequent and effective communication, and a collaborative, non-siloed approach to solving problems is important," Mr. Powers says. "The mindset and characteristics of the employees is critical. Having a team of smart, positive, disciplined, self-motivated employees with good interpersonal and teamwork skills at all levels of the organization makes for an organization that can get things done, and accomplish those tasks correctly."

One task that Singota recently performed was for a small biotech's formulation and process development project. A formulation change, which included adding a preservative, was identified by the client fairly late in the project timeline. This additive was identified as having compatibility issues with one of the polymers in use in the flow-path for aseptic filling. The Singota formulation and process development teams researched the problem, executed mixing and compatibility studies, and a workable solution was identified using the existing flow path. This enabled the project to be completed on time with the new formulation.