outsourcing

CALL IN THE EXPERTS: THE BENEFITS OF OUTSOURCING PRODUCT TESTING AND ANALYSIS

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In this article, experts explain why contract testing is a logical choice for many pharmaceutical manufacturers and discuss common formulation and process issues, as well as what to look for when choosing a company to perform contract testing services.

The demand for contract pharmaceutical analytical testing is on the rise. By 2025, the global market for pharmaceutical analytical testing outsourcing will be worth $9.6 billion, according to a report by Grand View Research [1]. Analytical testing may comprise a variety of services including but not limited to bioanalytical testing, method development and validation, and stability testing. Contract research organizations (CROs) specialize in analytical testing, but contract development and manufacturing organizations (CDMOs) also

have these capabilities and may even have dedicated analytical testing departments.

"Many pharmaceutical companies, particularly those in the small to mid-size range, do not have the expertise or laboratory capabilities in-house to perform all the necessary analytical tests," said Richard Sidwell, vice president and chief scientific officer at Recro Gainesville, a Georgia-based CDMO. "This is especially true for new development projects, which often stretch their organizations into new technologies or analytical areas."

Even larger manufacturers with in-house testing capabilities may still choose to have a contractor perform these services. The Grand View Research market report states, "Not all companies have an infrastructure that is compatible for all types of analytical testing. Hence, outsourcing these operations is the most suitable option, which also helps save time and cost," [2].

"For solid dosage formulations, having the right equipment is essential to properly test materials and solve formulation and manufacturing problems," said Robert Sedlock, director of technical training at Natoli Scientific, Telford, PA. "A solid dosage lab like ours has all the equipment necessary to characterize materials, run compaction simulations, and alter the formulation if needed." Should a manufacturer decide to invest in testing equipment, they will have to account for the time it takes to buy, install, and validate the units. This can slow a product's entry into the market.

According to Kerry Johanson, chief operating officer at Material Flow Solutions, Gainesville, FL, even if you have analytical testing equipment, your employees may not have the expertise to apply the results to real-life situations inside a plant. "It's important to understand the materials of a formulation before you can solve a formulation problem or optimize a manufacturing process. Analytical testing can also ensure that instruments and equipment you purchase for a project will work with the particular material you're manufacturing."

Another issue is space. Consulting firms and contract organizations have dedicated labs and facilities to perform analytical testing and troubleshooting, which can be difficult and risky for pharmaceutical manufacturers to achieve. "Adding permanent capacity to accommodate new development projects can be quite expensive and time-consuming," said Sidwell. "When the uncertainty of project success is still high, it is often more prudent to leverage someone else's capacity. If the project is unsuccessful, clients can simply end their contract, instead of having to repurpose or unwind added capacity of their own."

Sidwell also points out that manufacturers who are already outsourcing other aspects of product development may find it more convenient to outsource analytical testing to the same organization. "Conducting analytical testing and other services at separate locations opens the door to a range of risks, logistical problems, and delays, such as shipping, communication, and contract and vendor management."

Common issues

Although solid dosage pharmaceutical products come in many forms and target a variety of different health issues, there are common problems manufacturers encounter during development that require a level of expertise that companies don't always have in-house. "The most common problems our pharmaceutical clients bring to us are early phase chemistry, manufacturing, and controls (CMCs) for small molecule pharmaceutical development," Sidwell said. CMCs are necessary to submit a new drug application (NDA), and the quickest way to get the information needed to speed a product to market is to outsource the testing. According to Sidwell, CMCs can include analytical method development for stability-indicating chromatographic methods, excipient compatibility studies, feasibility formulation development and stability testing, and clinical supply manufacture.

Another prevalent pharmaceutical product issue is segregation, where a formulation's components do not remain uniformly distributed," Johanson said. "In addition, our pharmaceutical clients are experiencing caking, hang-up, and flow problems. Sometimes the material must be engineered properly to optimize the manufacturing process, and sometimes the system needs to be redesigned to meet the needs of the product.

Often, problems don't appear until a manufacturer attempts to run the formulation at production scale. "Our clients regularly experience problems when they scale up a formulation," said Sedlock. "For example, a tablet formulation that ran well during R&D suddenly starts experiencing capping, lamination, or sticking and picking on the high-speed tablet presses. All these problems can be traced back to the formulation." At that point in the manufacturing process, however, changing the formulation is not an option. Contractors can assist manufacturers by modifying the tooling, coatings, tablet design, or equipment setup so the formulation will run successfully.

Qualities of a good contractor

Once you've decided to outsource testing and analysis, be sure to pick the right contractor for your testing needs. "Make sure that you agree on the quality standard required for your project," said Sidwell. "Misalignments here can be trouble. The difference in time and effort between a good-enough experimental chromatography method and a validated method suitable for testing pharmaceutical registration stability is tremendous."

According to Sedlock, whether it's a new or existing product, a company performing contract analytical testing should characterize all the raw materials used in the formulation, not just the API. "The company should also have the equipment to characterize a formulation's mechanical deformation properties. Understanding how a material deforms under compression can help you avoid scalability issues."

To address problems with an existing formulation, the contractor must be able to identify what could potentially cause a process to fail. "If you're seeking a contract

researcher to fix a formulation issue, they should have a breadth and depth of experience," Johanson said. "They should be able to ask the right questions. Does the formulation segregate? Is it friable? Is the material fine? Is it fluidizable? Does it have erratic flow? The answers to these questions should then guide their process design or product engineering."

The future of contract analytical testing

"The future of outsourcing contract development services in pharmaceuticals is bright," said Sidwell. "Contract development, testing, and manufacturing organizations enable small companies to access expertise, capabilities, and capacity much faster and cheaper than they could by building those things for themselves."

Johanson expects to see a higher demand for outsourcing of design of materials, where the contractor characterizes the material under process conditions, providing the necessary information to design a suitable product. "In situations when a manufacturer has minimal amounts of starting materials and doesn't know a lot about those materials, a set of characterization tests using small amounts of material can allow them to move forward quickly and also help them design successful pilot studies."

Sedlock believes this is also an opportunity for the industry to set guidelines and standardize requirements going forward. "If done right, there should be a set of standards for what type of studies should be performed during the development process," he says. "For example, product characterization during the R&D stage and a standard set of processes to follow will raise quality standards during the development process, which will hopefully cut down on headaches during manufacturing and scale-up." *T&C*

References

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Richard Sidwell, PhD, is vice president and chief scientific officer at Recro Gainesville. He is responsible for analytical, formulation, and process development activities for the organization, as well as clinical supply manufacture, testing, and stability assessment. Recro Gainesville has expert staff in analytical development, formulation development, and clinical supply manufacturing. The company can prepare formulations and clinical supplies ranging from simple powder-in-bottle or powder-in-capsule supplies for Phase 1 testing through full production-scale batches of final formulations for large-scale Phase 3 studies.