Drug Development & Delivery

Analytical Testing

eBook

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Analytical Testing Providers Offer Versatile, Advanced & Expanded Services

By: Cindy H. Dubin, Contributor

The stringent regulatory guidelines for drug development and safety are increasing the demand for analytical testing. Additionally, the rise in generics and biosimilars is contributing to the market's growth (Coherent Market Insights).

Pittcon 2024 highlighted the role automation is playing in analytics at some Big Pharmas. For example, AstraZeneca demonstrated how automation is helping to boost analysis for preclinical and clinical drug candidates. GlaxoSmithKline is using automation and machine learning to create a combination of high throughput analytics.

Conducting in-house analytical tests can be resource-intensive and time-consuming. Outsourcing analytical testing to specialized laboratories allows access to state-of-the-art facilities, advanced technologies, and experienced scientists, enabling efficient and accurate analysis of drug products. Thus, the global pharmaceutical analytical testing outsourcing market was valued at $8.57 billion in 2023 and will practically double to $16.35 billion by 2031 (Skyquest).

Stevanato Group is an analytical testing service partner whose Technology Excellence Centers offer support from early-stage to launched combination products. These services include testing prototypes, method validation, design verification, and product validation.

LGM Pharma, a CDMO, announced earlier this year that it is investing more than $2 million in its analytical testing services and expanding offerings by 50%. This investment underscores the company's focus on being a valued CDMO partner. LGM is also adding suppository manufacturing capabilities as the delivery system gains traction in the industry because of the delivery systems's direct and efficient drug absorption.

Learn more about Stevanato Group and LGM Pharma in this exclusive *Drug Development & Delivery* annual Analytical Testing eBook.

LGM Pharma

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Address Three Common Challenges When Outsourcing Analytical Testing

By: Shailesh Vengurlekar, SVP, Quality & Regulatory Affairs

Drug development companies choose to outsource analytical testing for a variety of reasons, but they often boil down to necessity for those that lack in-house analytical capabilities, or as a strategic decision. The US Food and Drug Administration states that contracting can enhance speed and efficiency, provide technological expertise, and expand capacity.[1]

To fully capitalize on the benefits of outsourcing analytical testing, sponsors must rigorously assess their CDMO partners across three crucial dimensions: turnaround time, communication, and quality.

Turnaround Time

Slow or unreliable turnaround times can significantly impede your time to market. When evaluating analytical testing laboratories, consider several key factors to identify partners likely to meet agreed-upon schedules. Potential causes of delay include insufficient staffing with the necessary expertise, equipment outages or downtime, and an overload of business that leads to shifting priorities and impacts your project. Additionally, if the testing provider engages in contract manufacturing, this could divert resources and cause scheduling delays. Finally, out-of-specification (OOS) results can also extend timelines.

To ensure the testing provider can meet your timelines, discuss schedules in advance, including what will happen if they miss a deadline — and ensure a contingency plan is in the contract.

Here are eight key questions that will help you find an organization that is more likely to deliver results on time:

1. How many analytical chemists are in the facility?
2. What is the staff turnover rate?
3. If the laboratory has to prioritize jobs in the queue, would your project be treated as the most important?
4. How old are the facility's instruments, and is the preventative maintenance program up to industry standards?
5. What is the plan for ensuring laboratories are well stocked and prepared to handle potential supply chain delays?
6. Do they have good relationships with their qualified suppliers?
7. How do you manage laboratory resources if multiple projects are happening simultaneously?
8. What is your standard operating procedure (SOP) for handling OOS investigations? And communicating this?

Communication

Consistent, clear communication is vital to successfully outsourcing analytical testing, especially regarding any project scope or timeline changes. While laboratory partners may want to avoid delivering news of unexpected complications or delays, customers need to know this information as soon as possible so they can manage projects effectively. Establishing clear communication expectations at the outset ensures you are always well-informed. Find out when and how you should expect results. For example, labs often deliver routine weekly testing results via an email report. However, you may prefer to discuss the results of larger, more complicated projects in video calls.

Also, discuss how the laboratory team will contact you about any issues requiring immediate notification. Set a communications schedule, especially for larger projects. Your testing provider should address problems as soon as possible to mitigate the impact on the overall schedule. Bi-weekly meetings are often the ideal way to stay informed about progress and quickly answer questions from either party.

Quality

While communication and schedule adherence are essential, quality is the main factor in determining success. For instance, a testing error could cause you to miss your clinical trial schedule window, leading to financial penalties and costly delays to market. Ensure that the outsourced provider follows industry best practices: They should meet current good manufacturing practice (cGMP) and good laboratory practice (GLP) standards.

Before hiring an analytical testing laboratory, assess their experience, track record, and staff expertise. Once the work begins, conduct site inspections and audits or use consultants for quality checks. The laboratory should provide both raw data and interpreted results so you can verify the conclusions.

Partner Smart

To partner smartly with experienced, well-run analytical testing providers, ask questions to discern their readiness to meet scheduling demands, communicate effectively, and prove quality in their testing services. When evaluating potential outsourced laboratories, consider their capabilities, track record, and the systems they have in place to ensure quality. The right match will be a fruitful partnership that balances speed and quality to accelerate your R&D program, optimize your cGMP manufacturing process, or submit a successful NDA/ANDA application.

Reference

1. US Food and Drug Administration, Guidance for Industry, Contract Manufacturing Arrangements for Drugs: Quality Agreement (CDER/CBER/DVM, Nov. 2016) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract- manufacturing-arrangements-drugs-quality-agreements-guidance-industry.

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Choose one CDMO partner to accelerate safe, high-quality therapeutics to market. **That's smart.**

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Avoid significant challenges in outsourced analytical testing. Download our whitepaper.

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Navigating the Challenges of Commercializing a New Drug-Device Combination Product

By: Alan Xu, Product Manager for Analytical Services, Stevanato Group

Developing a drug-device combination product is a complex challenge to handle alone. Even though a variety of autoinjectors, pen injectors, and wearable devices already exist, each one may react differently to your drug product. So, careful review is required to develop an optimal Validation Master Plan.

A trusted industry partner, such as Stevanato Group, can make the difference between successfully completing design testing and costly product design revisions. **Stevanato Group's Technology Excellence Centers (TECs) are uniquely positioned to provide guidance through the various steps of a Validation Master Plan across product development and different clinical phases to help choose the optimal product and test methods to reduce risk and time to market**.

Testing may start with a head-to-head comparison between multiple brands or quality levels to see which container and device combination is optimal for the customer and how it compares with legacy products. Testing may then end with either Design Verification, Design Validation Testing, or method transfer testing to your final GMP manufacturing site.

We can help you develop your Validation Master Plan starting with your Technical Requirements Specification to determine which components are to be tested and what methods should be used.

Compendial method options are often the first to be considered to minimize the method validation efforts required by regulatory bodies. Often, we consider how we can implement non-destructive methods that produce variable data instead of destructive methods or methods that generate attribute data to require fewer samples to reach statistically significant results. Non-destructive testing also enables multiple tests to be performed on the same sample – reducing the overall cost to produce test samples and the volume of samples to store for stability.

Engineering Verification Testing (EVT) – Can we freeze the design?

The first step on the device testing journey is Engineering Validation Testing (EVT), a stepping stone to reach Design Verification. EVT aims to test prototypes with full or representative functionality using methods that may be later validated for design verification. A successful EVT typically confirms the product design is ready to be transferred to manufacturing so that commercial samples can be produced. A failed EVT typically identifies problems that need resolving before production.

Ideally, the actual drug product is used for EVT. However, if the drug product is too expensive for this stage of testing, it may be possible to use a placebo with the same rheological properties (such as viscosity) or chemical properties minus the Active Pharmaceutical Ingredient (API) to study the interaction between the buffer, container, and device. Accelerated aging – where samples are maintained at temperatures above their typical storage temperature – may also be used to predict long-term performance instead of waiting for samples to age in "real time."

Method Validation – Is the method suitable for that intended purpose?

Once EVT is completed, method validation occurs – including checking that the test method and test equipment are robust. For example, methods must be shown to be repeatable and to generate reproducible data regardless of instrument operator. Instrumentation must be properly installed, operate as expected, and performance qualified. Full method validation involving test samples filled with the customer's drug might not be necessary or may be streamlined, if the method is compendial (such as taken from ISO 11608-1, or ISO 11040-8), allowing cost and lead time to be minimized. Statistical techniques – such as t-tests – are then used to determine if the method is successfully validated.

Design Verification Testing – Is the product built correctly?

Once production samples are filled with drug and validated methods, Design Verification comes next. This specific testing confirms that the manufactured combination product will do what it was designed to do, that it meets its intended technical specifications.

If any failures are determined during EVT or DVT, an extensive root-cause investigation and ultimately design or manufacturing modifications may be required. Poor planning or insufficient testing throughout development may result in the incorrect container or product to be chosen. Should the product be changed, various validations performed at the manufacturer may also have to be repeated, increasing the scope of damage.

Production Validation Testing (PVT) – How will the product perform during mass production?

Ideally, EVT and DVT are successfully completed, so the final testing step involves transferring relevant test methods to the manufacturer and production validation testing (PVT) to ensure everything is in place ahead of mass production. Depending on In-Process Control (IPC) and the lot-release strategy, some of the design verification methods will be used by the quality control laboratory at the GMP manufacturing site. Potential differences between the Design Verification site and the manufacturing site will have to be carefully studied to generate an appropriate risk assessment. These risk assessments, along with technical requirements by the receiving site, will be critical in developing an appropriately robust method transfer protocol to demonstrate that that methods at both sites return comparable results.

Stevanato Group TECs – Compendial and Custom Methods

We have developed a variety of compendial and custom methods to help with the testing of drug-device combination products, ranging from the drug container to pen injectors, on-body wearable devices, and autoinjectors. TECs can also handle a wide range of drug products – including Schedule 2 controlled substances – and can produce viscous placebos to test the limits of device performance. The TECs have also developed and executed test method transfer protocols, such as between sites in the EU and the US. And, if there is a failure during the EVT or DVT process, the TECs have the forensic capabilities and experience to help identify the root cause. The TECs can also coordinate with specialist laboratories for activities such as extractable and leachable testing or biocompatibility analysis.

Stevanato Group TECs leverage the overall company's strengths, which include the design and manufacturing of both primary containers and drug delivery devices. Our services range from technical analysis to generating technical documents for regulatory submission. Reach out to Stevanato Group today to learn more about how we can help you accomplish your goals.

WE BRING SOLUTIONS TO LIFE, BACKED BY SCIENCE

Tailored analytical services and testing for your drug development journey

Selecting the right primary container for an injectable drug or **passing a device design verification test** are crucial steps in the product development process.

With our **Technology Excellence Centers** (TEC), located at our headquarters in Italy and in the biotech hub of Boston, US, we can offer analytical and device testing services to support our customers all the way, **from early-stage to launched combination product**.

We can cover a range of specialized fields including container closure systems and drug-delivery devices with the goal of assisting our customers to anticipate future challenges and help them navigate the regulatory landscape.

Stevanato Group

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