

CONTRACT

PHARMA

For Pharmaceutical & Biopharmaceutical Contract Services & Outsourcing

Outsourcing Analytical Testing

Price is less important than quality

By Cindy H. Dubin
Contributor



Outsourcing Analytical Testing

Price is less important than quality

By **Cindy H. Dubin**
Contributor

QUALITY TOPS THE LIST OF PHARMA'S expectations from an analytical testing provider, according to industry insiders. Whether it's method validation, microbiological testing, tech transfer or method development, analytical labs — estimates indicate about 100 in the U.S. — are enlisting top-tier scientists and sophisticated equipment to address industry needs, from virtual organizations to Big Pharma.

"Quality results are what pharma wants; rarely do we hear complaints about cost," said Michael Crowley, Ph.D., M.S., B.S., vice president business development for PharmaForm, a full-service analytical support CRO.

Randall Guthrie, vice president, Xcelience, LLC, a formulation development and clinical supplies service business, agreed: "The key to everything in our industry is quality. Not only does this refer to the quality of the data, but also the quality and reliability in delivery; the quality of the relationship as well as trust; quality associated with regulatory adherence; quality associated with communication; quality of the science and people; and quality in working through problems and issues."

"Price rarely comes up in conversation with clients," said Frank Santillo, Ph.D., senior director of research services for Bilcare Global Clinical Services. Bilcare focuses on end-to-end services in the clinical supply chain, including method development, method validation, scale-up and transfer, and stability

testing. Dr. Santillo and his colleague Joe Morris, vice president of operations, contend that Big Pharma understands the need for quality when it comes to usability of data. "Small pharma firms and virtual organizations tend to be more price sensitive," said Mr. Morris. He remarked that the value of quality is better appreciated as the relationship develops.

Companies may have limited budgets depending on the situation, and clearly Big Pharma is under pressure to control costs, explained Tim Oostdyk, Ph.D., chief operating officer of Lancaster Laboratories. "From Big Pharma to virtual, there is no question that analytical testing is complex and that quality is at the forefront of everyone's mind; and price is not the decision maker. However, once companies are confident that quality and service are consistently being delivered, they expect it to be delivered in a cost-effective way."

That attention to quality has the analytical testing market growing strong at a rate between 20-40%, say some experts. The large CROs continue to get larger, while the small CROs continue to emerge and gain success. Overall, there is such pressure in the industry to qualify and advance potential drug

Cindy H. Dubin has written about the pharmaceutical industry for several different magazines. This is her first contribution to **CONTRACT PHARMA**. She can be reached at bdubin@earthlink.net.

candidates into the pipeline that outsourcing becomes a necessity. "Couple this with a reduction of headcount in pharma, aggressive strategies in the biotech industry, and continued emergence of virtual development companies, outsourcing and partnering activities will continue to grow," said Mr. Guthrie.

Pharma's Needs

Experts agree that pharma is seeking expertise and typically does not have in-house resources to perform analytical testing on its own.

According to Mr. Guthrie, many of Xcelience's clients outsource as an overflow activity from their own capabilities, having the contractor perform repetitive tests such as stability programs. Some firms are "virtual in nature" and do not have the required capabilities. "For these companies, we are called upon to perform method development, method validation, manufacturing support, release testing and stability," he said. "In many cases, outsourcing is a means of accelerating the process, and for many companies it saves them money by not having to build their own infrastructure of laboratories."

Some pharma companies take what Mr. Guthrie calls the "parallel development" approach. This is where a company outsources the entire development program in parallel to other development programs ongoing inhouse. This is an attempt to accelerate compound activities and get more into the pipeline faster, usually involving formulation development and early-phase manufacturing.

He added that many clients seek a "packaged service" model that ties together activities such as formulation development, manufacturing and analytical.

Baxter Healthcare Corp.'s clients typically seek testing to support final product development, including development stability. QC laboratories perform testing to support manufacturing as well as formal stability studies, explained Wendy Saffell-Clemmer, a manager with pharmaceutical development at Baxter.

It's not just small pharma and virtual companies in need of analytical testing

providers. PharmaForm works with several top 20 Big Pharma companies that do not have the required GMP equipment necessary to perform the studies, Dr. Crowley pointed out.

Pharma also looks to analytical labs to help them reach the market faster. "In the competition to get products to market, we are required to operate under generally very tight limits, so we need to get things done right the first time," says Seenu Srinivasan, Ph.D., senior director of analytical sciences at DPT Laboratories.

Dr. Oostdyk agreed, saying that the pressure on Pharma to get to market faster has raised the bar for analytical labs, "requiring them to have a higher level of expertise."

The Evolution of Analytical Testing

Ten to 15 years ago, contract labs were seen as merely a set of hands: "Do as I say and never deviate from the methods and procedures," was often the norm. The perception was that contract labs were often sweatshops for processing many samples. With the recent downsizing of Big Pharma and the wealth of talent now residing in most contract labs, there has been a major shift in the industry, with quality taking center stage.

For example, Ms. Saffell-Clemmer said that in recent years, there has been a dramatic shift in the number of biologic products manufactured in Baxter's contract facility. "Protein products typically require more complex analytical methods as well as multiple orthogonal methods to demonstrate purity and stability," she said. Baxter has been enhancing its capabilities for protein analysis by improving its analytical instrumentation: "Detection of aggregation of proteins is currently a hot topic because of the increase in high concentration formulations of large proteins such as monoclonal antibodies. Thus, the increase in the manufacturing and biopharmaceuticals has changed the types and variety of test methods that contract analytical laboratories must now offer to stay competitive."

Dr. Oostdyk commented that Lancaster Labs has also broadened its range of analytical services to support compa-

nies that develop small and large molecules, as well as the companies that may formulate both. "We've deliberately positioned our business to address the needs of both pharmaceutical and biopharmaceutical products. Our objective is to be the most comprehensive provider of analytical services in the industry," he said.

Another offering that some labs boast is extractable and leachable testing.

It's not just small pharma and virtual companies in need of analytical testing providers.

"Requests for extractables and leachables testing for bulk containers and disposable systems have been increasing," says Jennifer L. Riter, associate director, Analytical and Testing Services, West Pharmaceutical Services. From this perspective, West provides analytical testing that is focused around packaging, devices and administration systems, such as container closure integrity testing, compatibility studies, stability studies, process development/validation tests (Karl Fisher, silicone oil analysis) and other chemical and functional testing. "With E/L analysis, it is important to understand that, for the most efficient analysis to occur, a provider should be experienced with materials and specific analytical techniques to develop and validate methods and studies. This analytical work is different than the normal drug product assay development that most labs are used to," says Ms. Riter.

Dr. Santillo of Bilcare says that Process Analytical Technology (PAT) is a hot issue for many pharma companies as they try to ensure the quality of their data. He said, "The whole idea behind PAT is to understand the manufacturing process and use analytical testing to provide feedback about that process. Understanding the process ensures that quality is built in right from the start."

Additionally, Ramanspectroscopy is now available and being used by analyt-

ical scientists to examine structural changes and the environment of the drug. "What scientists learn from Ramanspectroscopy cannot be learned using other types of technology," says Dr. Santillo.

It is this type of expertise, talent and science that has attributed to how pharma perceives analytical labs; expertise, talent and science that Mr. Guthrie says is "top notch." He added, "In many cases, the industry has evolved from 'fee for service' and overflow activities to full development support and partnering activities."

Managing the Relationship

To ensure both a quality relationship and quality data, CROs say clients should expect open, responsive communication from their analytical testing provider as soon as the project is initiated. Both parties must agree on the scope of work, understand technical details, and agree on all quality requirements, such as how data will be documented and reported and how failing results will be investigated. Clients should also expect timely communication in the event of unexpected results or changes to projected timelines.

Some relationships are simplistic while others support complex partnership models. The former is more of a "fee-for-service" model while the latter may incorporate partner activities directly into the development planning process.

Vincent Santa Maria, president of Bilcare, said that it is up to the contractor to add value to the project to ensure its success. "If a provider simply does what is asked of it, then it is just a commodity," he remarked. "But if the contractor can challenge the client to add value to the project, then that is a real service."

The common element in all partnership models is to have a single project advocate or point of contact at each end of the relationship. "Without this being in place and having the true support of senior management on both sides, pandemonium is certain to occur," said Mr. Guthrie. "These people are truly the key to expectations and deliverables."

"It is beneficial to have a single project manager handling the business relationship, but also essential for our scientists to communicate directly with the client scientists to ensure that all technical details are captured in the project protocol," said Ms. Saffell-Clemmer. "The technical contacts on the client side should be available throughout the lifetime of the project for guidance in deciding a path forward in the event of unexpected results."

Dr. Oostdyk agreed that multiple points of contact throughout the contract laboratory organization, as well as convenient access to project information, are critical to project success. Therefore, Lancaster Labs is working to take open communication to a new level. Beginning in September, the company plans to offer a web-based service called LabAccess that allows clients to view comprehensive project information, including the analytical data being generated. "This 'window' into the laboratory exposes the client to the analytical operation," said Dr. Oostdyk. "As the Quality group approves a test, the data becomes available online."

"I've seen so many relationships fail because they do not have the right people in the right job at either end of the relationship," said Mr. Guthrie. "Both sides must have advocates that are empowered by their respective senior management teams. Both sides must have advocates that mesh from a personality standpoint and understand drug development and the science. Those people are often tough to find."

What should not be tough to find is quality in analytical testing. "Quality is very important," says Dr. Crowley. "If a mistake is made in the analytical space, the company will not be around for long."

Mr. Guthrie agrees: "The key to growth for any company is delivering on promises and maintaining impeccable quality standards." ■