



The Future Lies in Partnering

Intimately knowing their products and customers is helping suppliers offer value-added formulation development services **BY SANGITA VISWANATHAN**

W

ITH A NEW FORMULATION IN THE WORKS, Company A's scientists have tried their in-house formulation technologies, but are not happy with the release profiles they are obtaining.

One scientist suggests a different polymer technology. However, none of these scientists have extensive experience in working with the new polymer.

The team proposes visiting the newly-created development lab at the excipient supplier's facility to observe scientists there using the excipient for formulating different molecules. Soon, four scientists from Company A travel to the supplier's lab to see how the latter uses the same formulation to modify the release and what experimental conditions are used. After learning the various techniques and conditions, they are able to repeat the process at their in-house labs.

Welcoming clients into labs to use their development services and high-end instruments, suppliers are increasingly forthcoming in working with customers and buyers of their products. Offering such services as part of their development activities seems to be a wise business strategy for many suppliers.

Degussa Rohm America LLC is one company offering such services in its 5000 sq. ft. lab located in Piscataway, N.J. The company has four more such labs in Darmstadt, Germany; Tokyo, Japan; Mumbai, India and Shanghai, China.

The benefits of such a lab are three-fold, according to Nasser Nyamweya, Ph.D., technical services manager, who says the labs are used for carrying out customer projects, training programs and internal research.

The main purpose of these labs is to provide customer service and support. Drug development takes a lot of time and the key constraint is that customers want to do the feasibility studies as soon as possible and many times, clients may not have the appropriate equipment, expertise or materials to do this in-house. The other option is to outsource these activities to a contract lab.

And that's where the services offered by suppliers such as Degussa come in. "We provide our customers an opportunity to come to our labs and get hands-on experience," points to Nyamweya, as their labs specifically deal with controlled release polymers to solve drug delivery challenges faced by scientists.

The benefit appears two-fold: every time a customer uses a company's product, it helps the company establish better relationships with the clients, understand what they want and help them achieve their objectives. For the client, they learn to overcome or avoid the formulation nightmares they might otherwise face.

Nyamweya says at Degussa's lab, clients work with scientists on formulation approaches for various drug products. If the client is not familiar with the technologies, they have the opportunity to see the recommended procedures first hand at Degussa's labs, and then go back and apply it in their own labs.

Customers range from big companies to small firms. In some cases, these clients may not have much experience working with specific polymers. Others, however, would like to work on a new formulation, and may not have the capabilities or equipment to do it internally.

Historically, the formulation groups and the chemistry groups haven't worked together to help solve each other's problems. "And when you outsourced your API and your formulation, this gap was wider; but this is changing," says Dave Hoffman, president of the U.S. business for Hovione. "At Hovione, we are pretty bullish about the supplier development services that we offer."

Hoffman says a sweet spot for Hovione is using spray drying technologies to help in the pre-formulation process or for the intermediate drug product. "We only started this 18 months ago, and we are already working with a dozen companies on this process so far," he explains. "We listen to and ask the chemistry group and the formulation group what they need from us as an API supplier to help move this product up the value chain."

INTERNAL CONSTRAINTS

Time is a common constraint for customers. "Our clients need to know quickly whether a specific formulation will work or not," says Nyamweya. "Working with dedicated labs reduces the time constraints that they may have internally," he explains. In other cases, clients may not have the required equipment or the expertise. Or, if they are working on several projects, they might not have enough time and capacity to manage the multiple projects.

At Hovione, clients approach its scientists with ideas of what they require. Some of these clients may have already tested these ideas, but faced little or no success. "What we really do with the client is we reduce it to practice," says Hoffman. "In some instances, the client comes not so prepared but has an idea, and our engineers work with them to arrive at a viable solution."

Ultimately the strategy for Hovione is to become a one-stop

shop for its clients. "Hovione was traditionally an API producer; now we also do formulation development," points out Hoffman. "Our goal is to become a one-stop shop, where companies can come for APIs as well as formulation development expertise. Almost all of our strategic investments have been in this area in the last 18 months."

Supplier development labs are also used for training purposes. Workshops and demonstrations are conducted in the lab.

USING NEW TECHNOLOGIES

"Scientists, traditionally used to working with certain sets of conditions for some polymers, need to understand the specific conditions required for specific polymers," says Andrew S. Honeycheck, sales and market communications manager for Degussa. "You don't need high temperatures for certain types of coatings; for instance, if acrylic polymers are used at high temperatures, there might be excessive stickiness of the coated product. At our labs, we train our customers and teach them how to use the polymers. After all, a picture is worth a thousand words," says Honeycheck.

Another important benefit that such a lab provides is in the area of life cycle management—to try out a novel formulation method using an excipient to extend the patent / exclusivity life of an existing molecule. When these molecules come off patent, clients realize that using new technologies or excipients is an options available to help them circumvent patent expiration.

Also, many of these companies, while having manufacturing equipment, may not possess lab-sized equipment; and hence find the services offered convenient.

"We undertake feasibility studies for our clients and establish the required timeframes. They can bring their scientists here, or we can go to their respective labs," says Honeycheck.

Several other companies such as BASF, Colorcon and Dow Chemical also offer supplier development services in dedicated labs. Honeycheck points out that enforcing confidentiality and making available reproducible results from lab to pilot plant and manufacturing are high priorities for most clients.

The response has been very encouraging for Hovione as well. Hoffman seems to prefer small projects which enable him and his team to have intimate relationships with the clients. "Some of our ideal partners are biotech companies, who need all of our services," he adds.

Though there is increasing competition in this area, Hoffman deems it a good thing. "Competition is always rewarding," he says. "It forces us to keep working harder and we have advanced ourselves significantly, and we will expand upon this in the future."
—PFQ

PFQ thanks the following experts for their time and inputs:

Dave Hoffman, president of the U.S. business, Hovione Ltd. (Loures, Portugal), dhoffman@hovione.com.

Andrew S. Honeycheck, sales/market comm. manager, Degussa, andrew.honeycheck@degussa.com.

Nasser Nyamweya, Ph.D., technical services manager, Degussa Rohm Pharma Polymers, nasser.nyamweya@degussa.com.