

INDUSTRY application

Speedy delivery: Manufacturer gets specialized capsule filler in record time

In December 2014, the head of R&D process engineering at a major pharmaceutical manufacturer was presiding over a meeting with representatives from ACG North America, a South Plainfield, NJ, supplier of empty capsules, capsule fillers, tablet presses, and other solid dosage equipment.

"The executive committee had decided to take on a challenging product," said the R&D head, who asked that neither he nor his company be identified. "It was a very smart decision, because this is a niche product where we can go in and stay without competition for a long time." But the executive committee was withholding its full approval until the R&D staff developed the process and located all the machinery needed to make the product.

The first part of that challenge—process development—was met quickly, and most of the equipment was already on site. Just one critical component was missing: a capsule filler to dose the product's micro-tablets. So the R&D head expanded the search and learned that his company had manufactured similar products at a European site. Could those machines be modified to handle the new product?

"We knew a few people and companies that could do the work," he said. But none of them could furnish the new change parts quickly enough to meet the company's ambitious schedule. It called for filing an abbreviated new drug application (ANDA) before the end of 2015. For that to happen, the company needed to launch 6-month stability tests by late June 2015. Waiting months for change parts wasn't an option.

"So we asked, 'Is there anybody else who has this equipment available



ACG customized its AF90T capsule filler to manufacture a challenging new product. The machine underwent FAT in India 6 weeks after the purchase order was received. Three months later, it was manufacturing the product at a facility on the East Coast.

The team beat the deadline by 10 days and all three dosage strengths were ready for stability testing.

and can deliver on time?' It was very tight, 3 to 4 months." That's when the R&D head contacted ACG.

Plan the work

At the December meeting, the manufacturer described the product and explained to ACG what it required. "They would have to transfer the equipment from wherever it was, customize it to manufacture the product, plus perform the trials and qualification and everything else." It

was a lot to ask, but ACG's sales manager said his company could do it and offered a plan to complete the job. "He came to the rescue," the R&D head stated. "Nobody else could commit to bringing this equipment this quickly to the site and make it happen.

"For my management, it was like 'Wow, can they really do it in that time?' I was skeptical from my end as well because it was really a tight timeline. This was a full machine—entirely brand new with customization and everything—to fill micro-

tablets into capsules of three different sizes. This is a huge undertaking." But according to ACG's timetable—which spelled out what had to be done each day—it was doable.

Work the plan

On February 1, 2015, ACG received the purchase order for the machine, an AF90T tamping-style automatic capsule filler, which was to be built at ACG's facility in India. By

March 17, it was ready for 4 days of factory-acceptance testing (FAT), which two people from the pharmaceutical manufacturer attended. Next, the half-million-dollar machine was expedited to the manufacturer's site on the East Coast. In addition, ACG dispatched two of its engineers to the site to help install the machine, qualify it, and provide other support. The site team worked around the clock to ensure the product would be ready on time. And it was.

In fact, the team beat the deadline by 10 days, and on June 19, 2015, all three dosage strengths were ready for stability testing. "There were not any major issues that delayed our project. Everything worked. They set up and executed in the shortest possible time. It was a great coordination. They took the challenge just as we took it from our executive committee and they were committed to it."

The R&D head had never done a project so quickly, and admitted to occasional bouts of concern. "You always think that something may break. One night you sleep and another night you don't. But I was less worried than I could have been because I found the ACG guys had a very similar mentality, and we complemented each other. I think that came from their experience working with the generic industry. They understood where they could help us."

In addition to the capsule filler, ACG provided draft SOPs and qualification documents so the manufacturer's people could populate the fields quickly. "That saved a lot of time. ACG gave us a very hard commitment that they would be able to deliver and they did. It was a very good experience working with those guys." T&C