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## *The effective launch*

New products are the lifeblood of pharmaceutical companies, and launching one—be it an innovator or generic product—requires effective management across many areas. One of the most important areas is meeting the manufacturing requirements, and how that's handled can make or break the launch.

We recently helped a customer launch a capsule product for which we developed and manufactured both the active pharmaceutical ingredient (API) and the finished dosage form. It's an uncommon integration that, in this case, contributed to a successful launch. Two other critical factors were our flexibility and the customer-oriented perspective we maintained throughout the process. Here's how it worked.

First, we involved the staff of our finished dosage operations from the beginning of the project, thereby ensuring that we had the API well characterized. With that information, we knew that the API could be efficiently developed into a manufacturable finished dosage form. It also allowed us to run some API and finished dosage activities in parallel, shortening the timeline. This was crucial to our customer because other companies—our customer's competitors—were pursuing approval of products that used the same API. Needless to say, last-to-market status could have had a lasting impact on our customer's market share and profits.

Second, we collaborated with our customer on a manufacturing suite and process train that were dedicated

to this project. The suite met the quality and performance standards that our customer required and was sized to meet the launch requirements. This preparation gave our customer confidence that the product was to be reliably manufactured in a manner consistent with the customer's best practices, such as maximizing efficiency while ensuring accurate capsule fills. In addition to integrating new process equipment, we hired more skilled staff, which sounds sim-

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ple, but with so many activities moving in tandem, the additions had to be seamless. Our customer gave us the latitude to surmount the learning curve and incorporate the new equipment and people.

Third, we managed to provide additional data and information to regulators in response to their questions as part of the approval process. Our customer had 15 calendar days to provide adequate responses to these questions or they risked starting the approval process over again. We mobilized our resources and were able to deliver the required new data,

which included additional impurity profiles for the intermediates as well as the API. We had to work quickly through the requirements while ensuring that our contributions were scientifically sound and would meet regulatory expectations, which they did, and the product was approved.

### **Customer perspective**

The number and quality of competing products, how quickly you obtain regulatory approvals, selecting the right marketing partners, and pricing can all affect the success of new products. Furthermore, choosing the right CMO, one that understands the customer's perspective, can help minimize the impact of these factors and contribute positively to the launch process. Our quick and complete response ensured our customer had an approved product on time. Now our customer can focus on developing their expected market share in a competitive space. T&C

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