Versatile drum coater helps Metrics secure rush project

Metrics Contract Services is the contract development and manufacturing (CDMO) division of Mayne Pharma. In 2018, the CDMO opened a new 126,000-square-foot solid dosage manufacturing plant at its Greenville, NC, location. The company designed and built the facility to meet or exceed the standards of all major regulatory authorities and provide comprehensive services from concept to commercialization at a single FDA-registered site.

The facility has multiple flexible production suites, including commercial-scale, solvent-capable, fluid-bed processing and film coating capacity. Specifically designed for containment, the plant can readily manage commercial-scale manufacturing of potent compounds and is engineered to meet stringent manufacturing demands for mitigating cross contamination. Features include segregated product corridors, 100 percent HEPA-in and HEPA-out filtered air, and dedicated quality-control laboratories.

Despite all of the facility's state-of-the-art equipment, a new customer recently contacted Metrics with a rush project that required a nimble adjustment to the plant's tablet coating capabilities.

“The client was completing registration batches for a film-coated tablet,” said Troy Woelfel, Metrics' vice president of operations and general manager. The client requested a 16-week turnaround for the project, but the product's batch size was too small to be coated in the production equipment currently installed at the plant.

Planned for flexibility
When the plant was built, the company had installed a Flex 500 production-scale tablet coater to handle its commercial tablet-coating projects. The versatile coater from Thomas Engineering, a coating equipment supplier based in Hoffman Estates, IL, handles aqueous and solvent coatings and supports film, sugar, functional, and drug-layering coating processes.

One of the coater's most appealing features was its ability to accept

Photo 1: Changing the coating drum using an interlocked trolley docked to the front of the machine takes just 15 minutes and requires no special tools.
a number of interchangeable drums with diameters ranging from 48 to 65 inches and capacities ranging from 190 to 920 liters.

The system includes a unique adjustable airflow feature that provides a process airflow range of 10 to 100 percent or 700 to 7,000 cubic feet per minute. This wide airflow range allows the system to effectively run batch sizes from 40 liters up to 920 liters.

“The Flex 500 was a solid choice for us because of its solvent capability and the flexibility of the drum sizes,” said Woelfel. “It also had a respectable price point.”

“The Metrics system was specifically designed for aqueous or solvent coating,” said Jim Roemer, senior sales engineer at Thomas Engineering. “This included compliance with all necessary operator and equipment safety requirements. The control system also includes integration with the site’s thermal oxidizer for solvent emissions abatement and environmental regulation compliance.”

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The coater’s interchangeable drum design also aids in cleaning.

“Cleaning validation is an increasingly critical part of manufacturing operations,” said Roemer. “The ability to completely remove the drum from the coating chamber permits a much higher level of access for swabbing and complete surface inspection.”

Thomas Engineering first introduced removable-drum coaters in the early 1990s, with the original models primarily being used for R&D and pilot plants. The Flex 500, which Thomas introduced in 2010, was the first production-scale coater to feature removable drums.

“Thomas allowed us to get a hands-on inspection of the Flex 500 at their facility,” said Woelfel. “We were able to remove and install the drum right there and measure the area required to change the drums to ensure that we allowed adequate space when we installed the coater at our facility. It certainly helped us feel confident that the machine would fit our needs.”

**Going smaller**

Metrics initially purchased one 48-inch-diameter cylindrical drum with a 270-liter capacity for the coater, but because this drum was too large for the new client’s project, the CDMO contacted Thomas for a solution. The supplier determined that a 48-inch-diameter bi-conical drum with a 190-liter capacity would be appropriate for the project’s 100-kilogram batch size. According to Roemer, the 190-liter drum has been installed and validated for production in hundreds of locations.

“The correct drum size was essential in keeping to the client’s timeline,” said Woelfel. “The Flex 500 coater enabled us to meet their requirements and also allowed them to stay at a scale equivalent to registration.”

Installing an entire new coating system would have been a complex and costly process. Simply purchasing a new, smaller drum for their existing coater drastically shortened the project’s lead time and reduced costs.

“We were able to deliver the new drum and trolley in less than 12 weeks, whereas a complete new coating system would require six to eight months for delivery and site installation,” said Roemer. “It’s easy to see that the addition of a new drum greatly accelerates the project time frame.”

One operator can easily exchange the drums in 15 minutes. First, the operator docks an interlocked trolley at the front of the machine. Then, after removing two hub bolts, the operator simply pulls the drum from the coater onto the trolley. The process is the same for any size drum and does not require the use of any special tools.

“We have past experience with Thomas Engineering and value the company’s outstanding reputation,” said Woelfel. “They’re responsive in their communication and meeting availability. In this case, the procurement process was smooth from start to finish.”

According to Woelfel, Metrics’ project pipeline suggests that smaller batch sizes are turning out to be an increasingly frequent client request.

“We acquired the smaller drum specifically for this particular project. However, other similar opportunities have followed, so we expect to employ it more broadly.”

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