INDUSTRY application

Parsolex expands manufacturing capabilities

Parsolex is a contract development and manufacturing services organization (CDMO) that works with clients involved in the research, development, and commercialization of non-sterile pharmaceutical products. The company's clients include small, large, and virtual pharmaceutical companies; research universities; clinical research organizations; and hospitals.

Parsolex operates an FDA-registered cGMP facility in West Lafayette, IN, in the technology-driven Purdue Research Park, just north of Purdue University's main campus. The facility was designed to maximize flexibility and serve a broad range of needs, with multi-purpose suites and portable equipment supporting unit operations such as blending, wet granulation, tablet compression, and encapsulation.

"This flexibility has allowed us to maintain tableting, liquid, and automated capsule-filling technology to support both clinical and commercial production," says Alfonso Chang, CEO of Parsolex. "For example, since 2004 we've produced well over 2.5 million commercial capsule doses."

The facility also includes a production viewing corridor that allows visitors to view production activities without having to gown and enter the cGMP area.

Investing in the future

Recently, Parsolex began a capital investment program that includes expanding the total volume of cGMP processing space by 33 percent to accommodate larger-scale process equipment, including vertical lifts for intermediate bulk containers and closed transfer of blends into tablet presses and capsule fillers.

As part of the expansion, several cGMP suites will be dedicated to specific unit operations, such as granulation, tableting, coating, and encapsulation. This proactive shift from the historical setup is designed to enhance operational efficiency and support increased capacity. At the same time, several suites will continue to exist as multi-purpose suites to retain flexibility to serve clients and address unique needs.

The expansion will increase the analytical laboratory's footprint by approximately 50 percent; include two new, fully dedicated product-development suites, totaling approximately 1,000 square feet; and increase the total pallet capacity of cGMP

Photo 1: A Pilotmix high-shear mixer/granulator (left) and Pilotlab fluid-bed system (right) are located in a new dedicated granulation suite.

warehousing to more than 80 pallet locations, leveraging a CAD-designed vertical racking layout to optimize material and work flows.

The expanded facility will feature all the prominent process technologies for cGMP manufacture of solid oral dosage forms for clinical trial material and commercial drug products. The company selected processing and packaging equipment supplier Syntegon Pharma Technology (formerly Bosch Packaging Technology) to provide much of the new equipment for the expansion.

"We conducted an extensive diligence exercise on equipment suppliers, exploring topics of expertise, capabilities, technologies, and service arrangements," explains Chang. "Ultimately, we selected Syntegon due to their reputation for quality, advancements in pharmaceutical manufacturing technologies, breadth and depth of expertise, and cooperative and collaborative approach to a partnering relationship."

Expanded manufacturing capabilities

The new Syntegon equipment includes granulation, fluid-bed coating and drying, tableting, drum coating, and capsule weight checking technologies. This equipment was selected to complement the company's existing capabilities and provide a diverse range of solid dosage technologies for a range of manufacturing programs.

"We're excited to partner with Syntegon to offer our clients access to the latest solid dosage technology innovations," says Chang. "This access enhances our capability to work on even more complicated and diverse issues that are challenging our clients today."

A Pilotmix high-shear mixer/granulator and Pilotlab fluid-bed system provide high-shear granulation and fluid-bed spray granulation, coating, and drying capabilities. The units are configured as an integrated system, allowing for enclosed, automatic vacuum transfer of material from the mixer to the fluid bed.

A TPR 200 tablet press produces up to 230,000 tablets per hour, more than doubling the company's tableting capacity and allowing for greater flexibility, improved yields, and faster changeover times. The press features versatile options, such as integrated die technology and the ability to combine B and D tooling stations in a single turret, along with an advanced data acquisition system for measuring and collecting a wide range of compression data.

"The flexibility of their tablet presses makes them ideal for R&D to medium-sized production batches," says Chang.

A Solidlab 2 drum coater handles batch sizes from 0.8 to 18 kilograms and provides easy scale up of production parameters for cosmetic and functional film coating, including controlled-release applications. A KKE 1700 capsule checkweigher enhances the company's existing capsule-filling capacity by providing precise gravimetric weighing of up to 102,000 capsules per hour. A Mycromix lab-scale high-shear granulator handles batch sizes from 0.1 to 3.5 kilograms.

"Parsolex had a clear plan to target certain areas of the market, focusing on where their experience lies," says Simon Cashmore, business development manager for

Photo 2: The dedicated tablet compression suite features a TPR 200 tablet press with an IBC lift for closed product transfer.

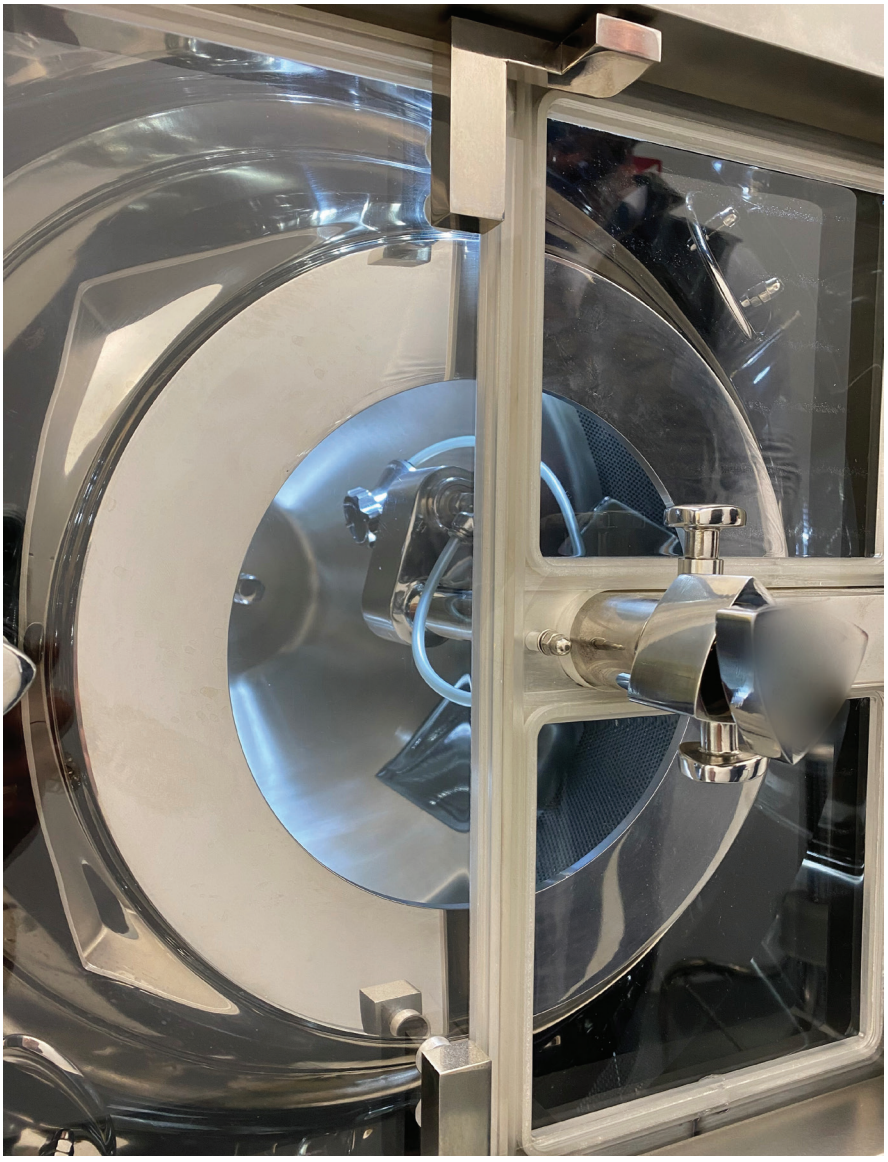

Photo 3: A Solidlab 2 drum coater in the new film-coating suite provides easy scale-up of production parameters for cosmetic and functional film coating.

pharma solids at Syntegon. "After meeting with them, we were able to come up with the best possible solutions to give them the utmost flexibility for manufacturing a range of batch sizes and different drug delivery technologies."

The data collected by the new equipment provides valuable information to enhance a formulation's success during scale up and commercialization—for example, enabling process parameters that enhance tableting robustness while maintaining bioavailability.

"The modular data acquisition systems record every parameter within a batch, which can then be evaluated for root-cause analysis," says Chang. "Recording many process parameters allows us to define critical and non-critical events during development. Collecting as much data as possible during development usually leads to a more successful scale up."

Partnering for success

Parsolex's relationship with Syntegon will go beyond just the purchase of equipment. Parsolex anticipates the collaboration between the two companies will advance pharmaceutical development and manufacturing as well as help address its clients' needs. While the nature of the partnership continues to evolve, discussions have included research collaborations and technical meetings and conferences, with planning for the first conference at the facility already underway.

"Our strategic partnership offers the possibility for both companies to take advantage of state-of-the-art equipment and a wealth of shared knowledge," says Cashmore. "It creates a unique opportunity, where we are able to carry out joint research projects throughout the manufacturing process, and we hope to launch our first publications later this year."

Positioned for growth

The capital investment program was intended to meet both existing and emerging client needs. The increased efficiencies and capacities will support existing client projects, while the new technologies, such as the granulation suite, will attract new projects.

"This positions Parsolex as a top contract manufacturer in the pharmaceutical industry and allows them to deliver a high degree of quality to their customers as well as providing a great showcase facility for us," says Cashmore.

Implementing the expansion while preserving cGMP capabilities to ensure that existing client projects could continue uninterrupted has required a high degree of coordination between Parsolex and vendor partners such as Syntegon. The company plans to recommission the site by the end of the second quarter of 2020.

"Feedback from our existing clients has been overwhelmingly positive," says Chang, "with a significant increase in new collaboration requests received in 2020. Both existing and potential clients are interested in scheduling site visits."

Parsolex
West Lafayette, IN
765 464 8414
www.parsolexinc.com

Syntegon
Minneapolis, MN
763 424 4700
www.syntegon.com