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## Jet Pulverizer adds ISO 8 suite

Founded in 1946, Jet Pulverizer, Moorestown, NJ, designs and manufactures high-energy spiral jet mills in a variety of sizes. It also offers contract milling, which it performs using jet mills, hammer mills, or other mechanical mills. It also provides blending, screening, and packaging services.

In its early days, Jet Pulverizer processed industrial goods, such as titanium dioxide and toners, said Austin Fay, an engineer at the company. "But over the years, as we've grown and market demands changed. so has our expertise and we've gotten into a lot more technical work that involves pharmaceuticals. Jet mills and spiral jet mills in particular achieve the finest grind possible in dry powder processing." Particle size distributions are narrow, typically in a range of 0.5 to 44 microns, and the mills process as little as 1 gram of material. They also preserve product purity and generate no heat from attrition. "That's what makes this technology particularly interesting to the pharma segment," Fay said.

To build on that interest, Jet Pulverizer added a controlled-environment suite that meets ISO 8 standards. "[The addition] gives pharmaceutical customers a much higher degree of confidence that their material will be handled safely and at the appropriate hygiene level," Fay said. "We know a lot of these customers because we do test work for them, and they inevitably wind up buying a mill from us and doing their own processing. This is a way for us to maintain our relationship as a service provider."



Adding an ISO 8 room reassures customers that the company can perform high-level work on sophisticated products.

The company is also seeking to increase its role in product development, said sales manager Brian List. "If you're a pharma company and have your own mills, you can use us as a product development center because of our expertise and versatility in mill design. We can do the test work and then either keep it here as a toll contractor or sell you a mill. We're trying to accommodate our customers in three ways: Test work, toll work, and equipment."

The company has been registered with and inspected by the FDA for many years. The addition of an ISO 8-certified room "gives confidence to customers and potential customers that we have the ability to do highlevel work on more sophisticated types of products," List said. The company is not seeking to process high-potency APIs or DEA-restricted products. "It's for any dry product that needs size reduction or screen-

ing to be performed in a controlled environment."

The new area, also denoted as a Class-100,000 suite, includes downdraft ventilation, temperature and humidity controls, positive-pressure airlocks, and an isolated gowning room. It also offers Type III deionized water, desiccant- and HEPA-filtered compressed air, carbon-filtered/molecular-sieve compressed nitrogen, and high-purity liquid nitrogen for cryogenic milling. All processes can be conducted using GMP-level protocols and procedures, including cleaning, cleaning verification, and FDAcompliant documentation. The company's on-site analytical lab provides fast and accurate particle size characterization and reports. T&C

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