



Particle Processing | Delivery Technologies | Dose Manufacturing

Particle Dynamics completes another successful FDA inspection!

St Louis, MO, January 29th, 2019 - FDA Completes Successful Inspection on January 17, 2019

Particle Dynamics is pleased to announce another successful FDA inspection which again resulted in no FDA Form 483 observations. The January 2019 inspection was the second unscheduled FDA inspection of Particle Dynamics facilities in one month. This multi day inspection was a full API general cGMP audit of our St Louis, Missouri, USA manufacturing site which houses Particle Dynamics' Complex Granulation and Microencapsulation manufacturing technologies.

Particle Dynamics has a proud history of compliance to FDA drug regulations. Our St Louis facility has hosted the FDA four times since 2011; three for full pharma and one for food. The results of this audit affirms our commitment to quality as a foundational value to our company.

Rebecca Connors, VP of Quality, said "We are extremely proud of the outstanding result of the January 2019 FDA inspection, which directly reflects our cGMP regulatory compliance and the tireless dedication of our employees in their daily work. A second FDA inspection, in a month without any observations, is a testimony to our commitment to Particle Dynamics' principal value of providing our customers with world-class quality products."

Particle Dynamics operates all of its facilities to FDA 210/211, 110/111, and 117 standards to support the diverse range of products we produce for the pharmaceutical, nutraceutical, OTC, and Consumer Health markets

For more information please contact Brian Scanlan, Head of Commercial Operations at Particle Dynamics, at bscanlan@particledynamics.com.

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About Particle Dynamics:

For over 30 years, Particle Dynamics has supplied innovative technologies, quality ingredients and custom processing capabilities that deliver solutions to customers in the global healthcare market.

The company's longevity has been built on a foundation of innovation, expertise, and investment in technologies and equipment that have made a significant impact in the oral solid dosage forms arena. Since its inception, the company has made significant investments in particle processing and delivery technologies to ensure its status as an innovative market leader.

Particle Dynamics is organized around six key Technology and Service lines, including Spray Drying, Continuous Granulation, Microencapsulation, Iron Deficiency Technologies, Dose Manufacturing and R&D/Technical Transfer Services. In addition, the company holds leading global positions in Direct Compression products such as calcium and magnesium carbonates.

Today, Particle Dynamics continues to invest in technology, equipment, and people to maintain our industry leading position in all major technology and service lines. We are led by a group of industry veterans with extensive experience in running technology and service companies in the pharmaceutical and nutritional products industries. The company remains active in its pursuit of new opportunities and expansions.