FINEST QUALITY SERVICE

Jet Pulverizer Meeting GMP Demands Through Investment in Infrastructure and Personnel

APPLICATION NOTE *GMP & ISO 8 ROOM | July, 2017*

INDUSTRY: *PHARMA, COSMETICS & PERSONAL CARE*

LOCATION: *MOORESTOWN, NJ*

KEY CHALLENGES: *MEET GMP REGULATIONS IN JET MILLING FACILITY*

SOLUTION: *INCREASE INTERNAL KNOWLEDGE, INVEST IN PEOPLE*

BENEFITS: *COMBINE 75 YEARS OF JET MILLING EXPERIENCE WITH FDA APPROVED ISO 8 ROOM*

Since 1946, Jet Pulverizer has been responding to customer demands with high quality, engineered solutions. Over the past half-decade, increasing demands in the pharmaceutical and personal care space to meet GMP processing has led Jet Pulverizer to increase its presence by investing in its personnel and infrastructure.

The Challenge

Austin Fay, President of Jet Pulverizer explains the need, "over the years, as market demands changed, so has our expertise; we've gotten into a lot more technical work that involves pharmaceuticals. Jet mills 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."*

What did GMP regulations mean?

- *The FDA has established minimum Current Good Manufacturing Practice (cGMP) regulations for preparation of drug products for human or animal use. The FDA has defined these requirements within Title 21 Code of Federal Regulations (21 CFR).*

To summarize the challenge, Fay put it this way: "Jet milling, by definition, makes fine particulate and a cleanroom is designed to reduce free particulate below a certain threshold. There are definite challenges in combining the two technologies that we've had to overcome."

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The Solution

There were two key hurdles Jet Pulverizer would have in meeting these challenges: infrastructure and procedural knowledge. On the infrastructure part, Jet hired consultants and spoke directly with its customers to understand what threshold would be acceptable. Jet fulfilled its promise by investing in an ISO 8 clean room and controlled storage area which met the following:

- *The cGMP suite is a certified ISO 8 controlled environment. ISO 8 is the newer term for the Class 100,000 designation. Certified ISO8 air quality means that the air may contain a maximum of 100,000 particles that are >=0.5µm per cubic foot.*
- *FDA inspected manufacturing suite and processes.*
- *Containment of (non-potent) API products using isolator or portable glove box.*
- *Complete air exchange/filtration greater than 20 x per hour.*
- *Temperature and Humidity controlled.*
- *DI water for cleaning.*
- *Sanitary jet mills and sanitary hammer mills.*

*On the procedural and knowledge side, Jet Pulverizer hired two new experts, **Jehad Elsaadi**, our new GMP Manager, came to Jet with a pharmaceutical background and an industrial engineering degree and **Richard Hare**, Jet's new EHS and Quality Manager comes to us with over 25 years of experience in bringing companies up to standard in the fields of GMP and GLP.*

The Impact

Austin Fay put it best: "By combining 75 years of dry powder processing history and expertise with a quality system that incorporates GMP, we are already unique amongst toll processors; the technical addition of the ISO 8 space sets us that much further apart."
Further, Jeff Conn, Vice President of OEM states: "Jet Pulverizer can help GMP interested customers through our process development; starting with our pilot or R&D production, then commercial production, at which point they could either ramp up or purchase a sanitary Micron Master® mill. Our customers will keep the benefits of our internal knowledge wherever they end up processing their dry powders."

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