A Quadro Engineering & Fitzpatrick Co. Case Study

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Fully Scalable, Lab-Sized Pharma Milling Equipment - Now Easier To Operate and More Versatile Than Ever

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Formulation, R&D and Oral Solid Dosage pharmaceutical laboratories worldwide are being challenged with investing in equipment that affords more versatility while concurrently balancing diminishing budgets and compressed timelines to – safely and reliably – scale up from small lab and pilot runs to full production. Now, with the introduction of the SLS – SCALABLE LAB SYSTEM™, The Fitzpatrick Company and Quadro Engineering Corp. have combined decades of expertise in manufacturing lab-scale powder size reduction mills into a one-stop solution.

Today's Lab Equipment Considerations Versus Traditional Approach

For years, pharmaceutical formulation and R&D laboratories have been challenged to find a balance between investing in as many lab-scale technologies as possible and staying within their budget.

To add to the pressure of suitably equipping a lab, R&D spending budgets have slowly decreased over time in favour of very targeted and focused return-for-investment calculations and pay-back analysis; before a single penny is spent. The practice of having a complete proposal that would explain to senior management the benefits of a particular technology over another and "why" it is important to invest in said technology, is now followed more rigorously than ever. And rightly so, making the best choice really matters when available funds are continually dwindling.

Figure 1: SLS – Scalable Lab System™

Enter the SLS – Scalable Lab System™, a lab-sized drive platform that enables users to have five (5) different milling/deagglomerating alternate outcomes in one machine. Why? The answer is simple – flexibility, versatility and a reduction in capital investment. But that is not all. Having interchangeable milling heads with a single drive mechanism offers additional benefits such as a "reduced footprint, half the training, less documentation and an easy comparison of performance on mill types…[I am] really happy with this", as Dr. John Robertson, Senior Research Fellow at the University of Strathclyde, Glasgow, UK put it. In short, the SLS is a shift from traditional to avant-garde, from "one machine for one operation" to one core solution with multiple possibilities.

But the concept of interchangeable milling heads for a lab environment is not new. It was first introduced by The Fitzpatrick Company in 2003 and featured the combination of the L1A FitzMill™/FitzSieve FS75 conical mill. In 2011, as synergies between Fitzpatrick and Quadro Engineering grew stronger, the FS75 FitzSieve head was replaced with the Comil® Model U5.

Zoetis, USA describes the lab scale flexibility benefit as follows: "In our lab area, we often have to move pieces of equipment in and out of modules in order to complete a process. With a single unit, we can reduce the number of trips into and out of the module".

Dr. Robertson further notes, having swappable heads goes beyond the reduced investment benefits, "we have used this [L1A/U5 combination lab mill] typically weekly on average since installing it and across a wider range of applications than initially envisaged, having the two mill heads and ease of change etc. [enables] us to do more in a busy facility, with limited space".

Today, the milling head interchangeability concept has culminated in the SLS – Scalable Lab System™, which, as the name depicts– is truly a system whereby four (4) interchangeable heads enables five (5) different processing solutions (one of the milling modules serves a dual-purpose). With the ability to switch in seconds, from a FitzMill™ hammermill to a Comil® (or High Efficiency Comil®) to a deagglomeration/FlexSift security screener, or a High Speed H5 Comil® – the benefits are self-evident. (Fig 2)

Figure 2: Interchangeable Milling Modules Via Sanitary Clamp Connection

The Future of Lab Scale Equipment – Reducing Time From Concept To Production

Now, an operator can test the same product with five (5) alternate size reduction solutions and compare the performance, the particle size distribution, the granule's shape, the bulk density, the powder's flowability, and much more. In other words, it is now easier than ever to be able to narrow down the best milling technology available for a particular product, one that will ultimately help to make improved and more robust tablets.

But the benefits of the SLS – Scalable Lab System™ go far beyond the test results in the lab, as what good are successful lab trials if they cannot be easily and reliably scaled-up and transferred to a production environment. If the technology used for small sample sizes does not translate into predictable production-scale equipment, then all the tests need to be repeated and re-validated. This does not sound like a good strategy.

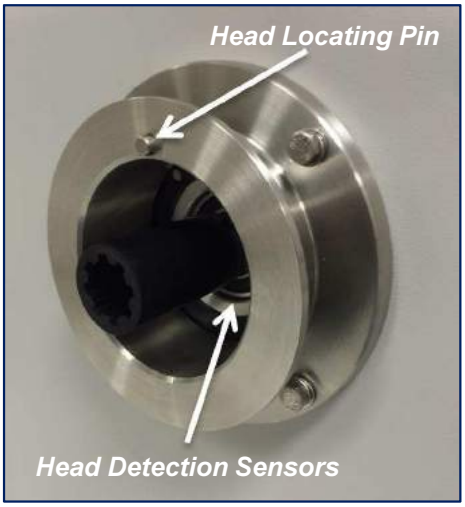

Figure 3: *Smart-Detect* System

Scalability – that is, getting the same particle characteristics in a production run as those obtained with small product samples, just at larger volumes – is something that needs to be the basis of lab equipment to make the investment really count. How does the SLS address this? Two words: *Smart -Detect* (Fig 3). How does it work? Simply put, as each head is placed and coupled with the base drive platform, the *Smart-Detect* feature automatically pre-sets the RPM range of the impeller or rotor inside the milling chamber, thus ensuring the tip velocities of the rotating element are the same as larger production machines.

Consistent tip velocities ensure that as the particles are processed in the lab-sized module, they are subject to the same influences as their larger production-sized counterparts. For example, when milling takes place, keeping tip speeds constant – regardless of model size – means the powder will be exposed to the same level of impact, shearing, compression and/or cutting size reduction forces. The operator cannot err and enter a speed into the SLS that cannot be duplicated with a production machine. That is smart.

Of course, other parameters also need to be maintained and transferred from lab to production to ensure scalability, such as screen-hole diameters and hole-type profiles (round holes, grater/rasp holes, etc.), impeller/rotor leading edge configuration and feeding methodologies.

Some Final Thoughts ….

Technology is constantly advancing, making the user's experience a more efficient and productive one – particularly at the lab-scale where frequent technology changes are the norm. "Until purchasing the L1A with the interchangeable U5 lab head ….we had a lot of waste and not much control. It is a very easy piece of equipment to operate, adjust, clean, and exchange heads. We are already trying to get approvals to purchase another unit" (Zoetis, USA).

Reducing the time required to scale-up milling results from lab to production, reducing the number of individual single-use machines, providing a wider range of size reduction technologies without increasing the overall footprint or breaking the bank in the process, are all at the core of what makes the SLS – Scalable Lab System™ so attractive. "I have used mills for 20 years and getting more integrated equipment just makes sense" (Dr. Robertson).

For R&D formulators and scientists weighing the pros/cons when choosing lab-scale equipment and consider what is best for the long-term…making the right choice… just makes sense.

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Quadro Engineering, and The Fitzpatrick Co. have been trusted partners of the world's top pharmaceutical, chemical and food ingredient processing customers for decades. Specializing in solid dosage and API milling, roller compaction and security screening, Quadro and Fitzpatrick are known globally for their quality services, application support and leading technology brands, including the Quadro® Comil®, Fitzpatrick's Fitzmill™ and Chilsonator® products. The Fitzpatrick Company was founded in 1934, and Quadro Engineering Corp. in 1976.

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