

Insights On Solid-Dose Manufacturing Roundtable

In the October issue of *Life Science Leader* magazine, Barry Regan, director of manufacturing, Abbott Laboratories, Global Pharmaceutical Operations Division discussed key topics concerning solid-dose manufacturing. Abbott has been providing pharmaceutical contract manufacturing services for more than 25 years and is recognized as a global leader in biologics, potent and small molecule API manufacturing, as well as drug product manufacturing and packaging.

Highlights of this roundtable discussion with Regan include: solid-dose manufacturing evolution during the past 10 years, what the future holds for solid-dose manufacturing, common misconceptions with solid-dose manufacturing, and advice for those looking to purchase solid-dose manufacturing equipment.

Life Science Leader magazine (LSL): How has solid-dose manufacturing evolved in the past 10 years?

Regan: Technology plays a more significant role in solid-dose manufacturing than ever before.

- Equipment has become more sophisticated with integrated in-process controls requiring fewer manual interactions. These in-process controls and feedback from the equipment help ensure quality, efficiency, and consistency throughout the manufacturing process.
- Another trend in solid-dose manufacturing is the use of multi-use equipment on one platform. Quick changeovers allow one piece of equipment to replace what typically was three or four pieces.
- New technologies in formulation also continue to be seen, which expand the solid-dosage portfolio and give distinct advantages in ease of use, stability, and processing.

(LSL): What is the future of solid-dose manufacturing?

Regan: Solid-dose manufacturing will continue to be a prevalent method for delivering therapies. Customers are comfortable and familiar with solid dose tablets as a method of delivery for their medications. Consolidation and optimization of solid-dose networks will continue as LEAN principles are expanded to find the most efficient method for manufacturing.

(LSL): What are some of the most common misconceptions about solid dose manufacturing equipment?

Regan: One common misconception is underestimating the need for continued maintenance and engineering support for

solid-dose manufacturing equipment. Appropriate preventive and predictive maintenance needs to be performed on all solid-dose equipment to ensure it operates at peak levels. Continued engineering support ensures that the equipment's utilization can be maximized throughout its lifetime. Systems integration, control optimization, and productivity enhancements help ensure the performance of equipment for many years.

(LSL): What are some common mistakes pharma companies make when purchasing solid-dose manufacturing equipment?

Regan: When selecting equipment, one mistake is to think only about the immediate needs. Equipment is built to last for many years. Therefore, the value that the equipment can deliver years later must be considered. The design and maintenance needs of the equipment as well as support from the vendor, large or small, is a key factor in equipment selection and should be well thought out prior to purchase.

(LSL): How should a pharma company evaluate what type/size/quantity solid-dose manufacturing equipment they need?

Regan: The first point to consider is whether or not there's a need for solid-dose equipment based on what is available within the current manufacturing network. Current capacity, processing capabilities (long and short term) and regulatory requirements should be considered when determining what equipment is needed. When these questions have been answered, then the primary driver for equipment selection is the manufacturing process itself. The process, more than anything, dictates the type of equipment needed. The requirements of performance (speed, capacity, quality, longevity of the process, and return on investment) will ultimately drive the specific model and quantity needed.

(LSL): What advice would you give to end users searching for solid-dose equipment?

Regan: It's important to explore the options available before committing to specific equipment. Begin with understanding



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the technology available and defining the current and future process needs in order to match the equipment with the manufacturing needs. Consider whether an off-the-shelf or customized model is needed. Clearly defining the equipment size, capability, and controls will help optimize the equipment for current and future applications.

Leverage vendors' knowledge and the experience of their customers. Ask to visit sites where the equipment is installed and seek advice from current users about the value the equipment provides. Understanding users' experience with the equipment is a good measure to predict what your experience may be in the future as well.

Abbott Laboratories, Global Pharmaceutical Operations Division

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