

Successful Solid Dose Equipment Training

Helping operators become technicians and building strong production teams requires training on machine set up, operation, cleaning, and maintenance. Empowering operators can reduce equipment downtime and impact the overall quality of your solid dosage forms.

The global oral solid dosage pharmaceutical formulation market is expected to grow from \$493.2 billion in 2017 to \$926.3 billion by 2027, becoming the most commonly used dosage form.¹ Their popularity can be attributed to their chemical and physical stability, cost-effective production, and ease of manufacturing. But like all manufacturing equipment, solid dose machinery is still susceptible to wear, breakage, and downtime. Having a well-trained manufacturing team familiar with the various aspects of the technology can ensure these issues are kept to a minimum.

Whether you have new or legacy equipment; new or experienced operators, well-trained operators make for stronger production teams. These teams should know how to set-up, operate, disassemble, inspect, repair, and perform preventive maintenance. Equipment that is not installed or maintained properly is subject to wear and damage—even during normal handling conditions. If operators are unfamiliar with the equipment or don't handle daily maintenance, they may misinterpret mechanical problems when they occur. In addition, downtime can cost upwards of half a billion dollars to pharmaceutical manufacturing, so operators may be under pressure to quickly make repairs, but these may not be the right repairs.

Be Prepared for Variation in Tablet Manufacturing

In solid dose (tablet) manufacturing, it is important to recognize that no two batches are exactly alike. Teams should be trained to expect variation in ingredients and excipient blends. When ingredients and conditions change, a manufacturing team must make needed adjustments and react to the

performance of the blended ingredients. Additional variables that impact ingredient performance are shipping conditions, storage, handling, and environmental factors. Combine these variables with inadequate machine handling, and the problems will compound.

Supervisors and managers must be trained to understand production variables. Making bad product faster is illogical. Each batch should be treated to perform optimally. Many teams don't understand that how long a blend sits affects its performance. Most blends need to settle at least 12 hours before they use, and most blends have a limit before they settle too much. Each formulation is different. Time and performance criteria need to be monitored and assessed on a case by case basis. Quality, not quantity, should drive production.

Operation performance can only happen if the set-up is robust: parts are maintained, cleaned, repaired, and replaced properly. Unfortunately, most procedures are not as robust as they need to be. Operators are the front line of defense. They see what is happening before anyone else. If they don't effectively communicate product or equipment variations, proper response may not ensue. Teams need to be trained to be more efficient and effective in identifying and explaining process changes.

Getting employees to achieve this level of success requires training procedures that are presented in short, clear bursts of information. If a procedure is too complex or too simple, it won't be followed. Writing a good procedure means developing a footprint that can easily be followed and repeated. During training, an operator must demonstrate that they can perform a procedure before being allowed to perform a task on their own. An operator must understand why they are doing something, or they will lack the confidence to make corrections. Knowing the "why" makes an operator a better troubleshooter.

Identify Wear and Tear

Equipment is only new once. The moment it is put into use, expect wear and tear. Worn parts need to be inspected and replaced. An operator must be taught the features of a machine, how they work, and how they impact product quality. For example, on a tablet press, the most important part to inspect and change regularly is a scraper blade. A scraper blade that is in poor condition will directly impact the quality of the tablet. For some abrasive products, the scraper blade must be replaced daily "as needed;" for less-abrasive products,

the scraper is replaced as needed—never on a set schedule. Consider using the replaced part as a training tool to set criteria for when a part needs changing in the future.

Conclusion

Properly operated solid dose manufacturing equipment is one of the most critical aspects to the overall quality of a finished product. Units of operations in solid dose manufacturing are driven by set up, operation, cleaning and maintenance procedures. Each operation is dependent on the one before and success is cumulative. Results come from understanding the complete process. Techceuticals popular training program is "The Manufacturing Process," a hands-on course designed to provide an in-depth understanding of solid dose operations. The course is designed for everyone involved in pharmaceutical manufacturing, regardless of skill level. Topics covered include formulation, blending, milling, granulation, drying, final blending, tableting, tablet press tooling, coating, and encapsulation.

We teach by troubleshooting, making sure that operators understand the bigger picture of what they're doing. We provide the why's and the how's, so that everyone we train cannot make a change without knowing *why* they are making this change. This practice makes them an inherent troubleshooter from the very beginning. We also make sure all trainers are confident, and that stems from information. We are able to teach years in a day, and at the end of our program, our operators and supervisors shine.

References

1. Oral Solid Dosage Pharmaceutical Formulation Market: Global Industry Analysis 2012 - 2016 and Opportunity Assessment 2017 - 2027, Future Market Insights, July 18, 2017, <https://www.futuremarketinsights.com/reports/oral-solid-dosage-pharmaceutical-formulation-market>.