This article discusses the primary factors that influence capsule filler performance and provides tips for optimizing your encapsulation process.

Tablets and capsules are the most common oral solid dosage forms (OSDFs). Both deliver active pharmaceutical ingredients (APIs) to the body in small, easy-to-swallow dosages and can be produced with great accuracy and at high speed on modern tablet presses and capsule fillers. While tablets are currently more prevalent, forecasts for capsules are very aggressive in both the pharmaceutical and nutraceutical industries. According to manu-
facturers, approximately 400 to 450 billion hard capsules are produced per year, with an upward trend.

Each dosage form brings its own challenges for drug product manufacturers, but capsule filling is generally more complex than tableting because the formulation—typically in powder, pellet, or liquid form—must be inserted into the empty capsules. This involves feeding and opening the empty capsules, compressing (in the case of powders) and inserting the formulation into the shells, then closing and ejecting the filled capsules, all at high speeds, which is inherently more challenging and mechanically complex than tableting.

While the latest capsule fillers offer a suite of novel approaches, the overwhelming majority of capsule fillers currently installed and in operation are cam-driven machines that rely heavily on high degrees of synchronization. Each step in the process is inextricably linked to every other step, and any change to a particular movement can impact all the other movements. As complex as the encapsulation process is, paying close attention to a few key factors and machine attributes can effectively minimize the number of headaches that may otherwise arise. The following are just a few factors that can help you optimize your capsule filling operation and avoid undesirable occurrences, such as machine crashes.

**Storing and handling empty capsules**

Empty capsules are fragile, precise, and temperature-sensitive, and you must give careful consideration to their storage and handling. Each manufacturer of empty capsules offers its own guidelines on the temperature and relative humidity (RH) ranges most suitable for storage (generally between approximately 59°F and 77°F and 40 to 60 percent RH). Following these recommendations is imperative, as failure to do so can create unnecessary problems with capsule separation and closing. Careful handling is equally important, as seemingly small capsule defects, such as dings or dents can also create problems. The simple practice of treating empty capsules with the utmost care can pay big dividends.

**Handling format parts**

On a tablet press, product-specific change parts are generally limited to fill cams and tooling, whereas a capsule filler has a significantly larger number of change parts. These typically include:

- Sorting blocks;
- Push forks;
- Magazines and segments;
- Tamping pins; and
- Dosing discs.

Operators should handle all of these components carefully at all times to ensure that they retain their factory tolerances and to minimize the risk of damage—primarily due to impact—that can, and often does, prevent good capsule movement and accurate weight control. Carelessly tossing components onto a table during changeouts is a recipe for headaches down the road.

**Ensuring adequate vacuum**

Filling capsules efficiently is difficult if they don’t open easily. Effective capsule separation is critical, so pay careful attention to the machine supplier’s recommendations for vacuum pump settings and maintenance of all related system components, including filters, seals, and vacuum lines.

**Cleaning**

Simply keeping a capsule filler clean at all times will improve its performance. And other than in contained applications, where it may not be possible to open a machine mid-campaign, cleaning doesn’t need to be limited to between batches. Periodically wiping interior components and surfaces, vacuuming excess formulation, and maintaining optimal dust extraction can help ensure the free movement of all parts and sub-assemblies.

**Training**

While comprehensive operator training is important for any type of capital manufacturing equipment, it is critical for capsule-filling machines because they are so complex and contain so many moving parts. Still, drug product manufacturers often overlook this essential component of a successful capsule-filling operation. Many equipment suppliers offer training programs that can be tailored to a company’s specific needs, but all such programs should at least cover machine setup, operation, and maintenance. The most reputable suppliers retrain their own technicians regularly, and end users should capitalize on that progressive expertise. At a minimum, a good operator training program should cover the following:

- A basic overview of encapsulation processes;
- Capsule sizes and specifications;
- An introduction to major sub-assemblies and their functions;
- How to develop effective, comprehensive standard operating procedures for such tasks as machine use, cleaning, and tamping-pin station removal/installation (for machines that offer such capability);
- The user interface and how to make machine adjustments;
- Best practices for handling empty capsules;
- Format parts and wear patterns;
- How to create product recipes (for machines that offer such capability);
- Capsule separation and vacuum requirements;
- Dosing and how to use a slug tester;
- Key methods for alignment operations;
- How to troubleshoot process-related issues;
- Calibration methods, and
- Preventive maintenance procedures (see below).

It is impossible to overstate the importance of sound training; after the equipment investment itself, training should receive the highest priority in an encapsulation process.
Preventive maintenance

Considering the scope of investment that most modern capsule fillers represent, it would be surprising for a company to neglect to establish a preventive maintenance (PM) program to protect that investment. Fortunately, nutraceutical and pharmaceutical manufacturers are increasingly embracing this key consideration with conviction. Most capsule-filler suppliers have recommendations for maintenance intervals, but end users should adopt and implement their own checklists to remain proactive and prevent problems from occurring. Common issues such as bent or rounded tamping pins, elongated segment bores, or worn dosing disks are easy to spot but equally easy to overlook without a good PM program in place. Modern capsule fillers can operate at increasingly impressive rates with great precision but only if the machine is well maintained.

Ensuring that your capsule filler operates as intended and at optimal performance levels requires daily PM. There are many adjustments and settings that can drift out of specification if the operator does not watch them carefully and consistently. Also, until recently, most capsule fillers have utilized many sub-assemblies, which are mechanically coupled to each other, so if one thing goes wrong due to a lack of PM, it can cause many other things to go wrong or be damaged as well.

While capsule fillers don’t all operate under the same principles, your PM program should pay consistent and careful attention to the following key components if your machine uses them:

- Cams;
- Segments/bushings;
- Segment carriers;
- Tamping pins;
- Dosing disks;
- Sorting blocks;
- Alignment pins;
- Push forks; and
- Tamping springs.

Many capsule-filler suppliers can provide a preventive maintenance framework that will complement the program developed by the end user. Suppliers have the advantage of understanding exactly why their machines were designed in a particular fashion, and their employees often have an encyclopedic knowledge of subtle features and procedures. Suppliers also often offer service level agreements (SLAs), which generally include:

- Technical suggestions for improved yields and production rates;
- Creation of standard operating procedures and implementation of checklists;
- Identification and replacement of worn or non-working components;
- Implementation of various training programs;
- Team formation and goal setting for improved efficiencies and decreased changeover times;
- Focus on safety inspections and utilization of installed safety features; and
- Introduction of new enhancements, features, and upgrades.

Encapsulation machines represent some of the most significant equipment-specific investments an OSDF manufacturer will make, so the approach to operating and caring for them should be commensurate. By investing in good training and fostering a solid foundational understanding of how the machines work, you can minimize potential pitfalls in your capsule-filling operation.

Matt Bundenthal is director, sales and marketing at Fette Compacting America (www.fette-compacting-america.com, 973 586 8722).