Filter bags and bonnets are critical components in fluid-bed processing equipment. This article explains how properly caring for your spare filters can extend their life and help you avoid costly downtime.

Pharmaceutical manufacturers make sizable investments in production equipment, GMP space, validation burden, and quality programs to ensure that they produce their drug products safely, efficiently, and profitably. Manufacturers simply cannot afford excessive downtime, so spare equipment parts are critical.

For example, fluid-bed dryer bags and bonnets must always be ready for immediate deployment, which means they must be clean, inspected, in good repair, properly documented, and fit for the intended use. Awareness and training in the proper cleaning, handling, and storage of filter bags and bonnets can help manufacturers realize the best return on their equipment and facility investments and help mitigate certain risks in fluid-bed operations. Imagine a $1.5 million production-scale fluid-bed suite sitting idle because a $1,200 spare set of bead coating bonnets was found to be damaged due to improper handling, storage, or cleaning and drying methods.

This article will discuss some best practices for managing fluid-bed filter bags and bonnets and ensuring that these critical spare components are available and ready for use when needed. With respect to fluid-bed dryers, the term “bag” typically refers to a filter with a patterned arrangement of multiple long tubes with sewn-on caps at one end stitched to a circular or semi-circular fabric base at the other end. This type of filter bag is sometimes referred to as an “octopus” bag, because the tubes resemble octopus tentacles. They are constructed from closed-weave fabrics and are most often used in drying and agglomerating operations.

Bonnets, on the other hand, somewhat resemble a gentleman's top hat, consisting of a single, large cylindrical chamber with a flat sheet of fabric sewn across the top and a skirted base. They are commonly made with an open-mesh fabric and are most often used in coating
applications with substrates such as beads and large granules. For the purposes of this article, I'll use the term ‘bags’ to refer to both fluid-bed filter bags and bonnets.

**Environmental effects on synthetic fabrics**

Like other organic materials, the polymer yarns used in filter bag fabrics and sewing thread are susceptible to damage from moisture, heat, and ultraviolet (UV) radiation. To optimize bag performance and life, your bag management procedure must mitigate the effects of these factors.

Companies often select filter bag fabrics for fluid-bed applications based on performance factors such as air permeability and nominal particle retention, along with criteria such as dimensional stability, strength, and chemical compatibility. Further limitations are found in 21 CFR Part 177, which includes a list of polymers acceptable for use in applications where materials are in contact with food and drugs, taking into consideration such factors as reactivity, leaching, and even the reaction processes used to produce the polymers. As a result, a limited number of polymers are suitable for filter construction.

For example, the combination of moisture and heat can affect the dimensional stability of polymer fibers. Polymers absorb and release water, which—along with changes in temperature—can cause the fibers to alternately swell and contract. As with other mechanical structures, the repeated stress of swelling and contraction may lead to cracking and eventual failure.

Extremely low temperatures can make the fibers brittle and increase the likelihood of cracking, especially at points where the fabric is folded or creased. In addition, swelling of the yarns can decrease the fabric’s porosity, essentially reducing the area of the openings in the mesh and even closing off the openings in closed-weave fabrics. This may lead to unacceptable changes in airflow and pressure drop and may cause filter blinding and poor process performance.

Continuous exposure to intense UV radiation may create unwanted chemical reactions, breaking down the polymer chains and reducing the fabric strength. In addition, these reactions often yield unwanted by-products that may leach and contaminate bags that are placed into storage after they are washed. In almost all operations, technicians remove the bags from storage and install them directly in the fluid-bed unit with no opportunity for removing contaminants in between.

**Mechanical factors affecting filter fabrics**

Folds and creases in the filter fabric are of special concern in long-term storage, where the creases might "set" into the fabric. Sharp bends and folds may create localized areas of mechanical stress concentration that can cause yarn failure during operation and especially during the repeated abrupt mechanical shaking action of the filter cleaning process, which can lead to localized wear, fraying, and tearing of the filter fabric.

Bonnets present their own challenge due to their geometry and the fact that the open-mesh fiber density is low, making them prone to damage from abrasion at the site of a crease or fold. When storing bags and bonnets, ensure that the fabric doesn’t always fold at the same place to prevent fatigue and other damaging effects.

Creases can also encourage the concentration of static charge. This is especially true in nonconductive fabrics but can also occur in conductive (anti-static) fabrics where the bag has not been constructed to fully ground a static charge through the hangers and skirt. Static charge buildup in the filter fabric can cause the particles in the fluid bed to adhere to surfaces and each other, offset the attractive forces of sprayed binders for agglomeration, cause bed channeling, or otherwise disrupt the gas velocity profile across the fluid bed. Discharge of static buildup may cause small burn holes in the fabric from sparks, which can create residue that may ultimately contaminate the product.

**Washing and drying**

Most often, companies clean production fluid-bed dryer bags with commercial washing and drying equipment, similar to that used in commercial laundries. Technical fabrics woven from polyester and nylon fibers are strong and resilient and usually hold up well after many wash cycles using standard detergents.

To increase filter bag longevity, minimize the amount of time the filters are exposed to heat and mechanical agitation during the washing process. In many cases, pre-soaking the filter bags using a mild cleaning solution (slightly acidic for polyester, slightly alkaline for polyamides) or even just fresh water can help lift coarse material from the bag surface and dissolve stubborn residue.

Cleaning agents are selected based on the process materials and the residues they will leave on the fabric after the filtration process. Ideally, the cleaning solution and rinse water should be as close to pH neutral as possible. You may be able to use a single cleaning agent for both polyester and nylon bags but should avoid chlorinated agents for either type. Purified water is ideal. Don't use softened water, because the dissolved solids in the softening chemicals remain on the fabric after washing.

Try to wash bags promptly after removing them from the fluid-bed unit to prevent compounds from setting on the fabric surface and to ensure consistent washing results. Wash water temperatures between 105° and 110°F are common for conductive fabrics, but higher temperatures (not exceeding 130°F) may be used for nonconductive fabrics. For machine drying, a temperature of 140°F is common. In general, use the lowest possible wash and dry temperature to get the job done.

It's a good idea to use chart or electronic records to provide a basis for validation and ensure that the machines aren’t using excessive temperatures. When using commercial laundry services, confirm that their drying equipment uses some form of indirect gas heating.
or air-steam heat exchanger, as direct heating may lead to hot spots that can scorch or weaken fabrics.

Use washing and drying machines that are appropriate for the size and geometry of the filter bags. No established correlations exist between washing-machine drum size and bag diameter, tube length, or number of tubes, but using the largest practical wash drum helps minimize how packed the bags will be in the machine and allows them to move more gently during agitation. Also, avoid tying the tubes together during washing, since it can lead to premature abrasion where the tubes rub together continuously.

Some companies prefer to hang-dry the bags, in which case it's a good idea to have a drying room where the bags can be suspended using a rack and hangers with the same geometry as in the fluid-bed dryer. Other companies reinstall the washed bags in the fluid-bed dryer and then dry them using unheated air at a high flowrate. Use a risk-based approach when considering either of these methods, as you need to think about validation and possible cross contamination, especially when drying bags that are dedicated to one specific product.

Fluid-bed filter bags will shrink over time with repeated use, washing, and drying. Innovative weaves and polymer choices in fabrics can help mitigate this, but some shrinkage is inevitable. Properly manufactured filter bags are sized large enough to allow for nominal shrinkage and will usually remain within the equipment’s tolerances. Evaluate the fit during each installation. Bags with excessive shrinkage will be difficult to install over the mounting ring and/or may become distorted at the caps once attached to the hanger. Either of these conditions can lead to mechanical stress and tearing. Also, if the tubes become too short and taut, they may fail prematurely from stress during shaking.

Inspect the bags regularly. When the bags are dirty, it's easy to miss small holes that may have formed during operation. Current GMPs suggest thorough inspection after cleaning and again just prior to use. Once holes form, they tend to propagate with repeated use and during washing and drying cycles. It's important to closely inspect filter bags that contain stainless steel wires for conductivity because damaged wires can “pick” at the fabric, forming tears and causing yarns to unravel.

Storage and handling

Proper storage and handling are important to prevent environmental and mechanical influences from damaging the filter bags. Storage systems and handling methods are largely a personal preference, and there is a lot of deviation between sites. Some companies rely solely on plastic bags for storage, with the sealed plastic bags often stacked or crammed onto shelves or even into drawers to fit limited storage space. This can put unnecessary compression force on the filters at the bottom of the stack and may cause undue stress and result in stubborn creases or other damage, especially during long-term storage.

A better practice is to store filter bags in robust plastic containers with lids, as shown in Photo 1. The plastic storage container protects the filter bag and allows you to stack the containers without putting additional weight on the bags inside. Some companies will first line the container with a plastic bag, then lay the filter into the bag and tie it off with a closure before putting the lid on the container. The benefit of this combined method is that it allows the technician to remove the sealed plastic bag from the container, bring it to the production suite, and open it in the suite without having to deal with the extra step of bringing the container back to the storage area.

The best storage containers are made of sturdy plastic, seal with airtight lids, and prevent transmission of UV light. The plastic can be the same as that used for totes, IBCs, drums, and other containers that regularly come into contact with drug products. The size of the storage containers will depend on the filter size and geometry, fabric stiffness, and whether they are bonnets or multiple-tube bags.

Where practical, gently “drape” the filter bags into their storage containers, letting the bags naturally flow into the containers under their own weight. Some pressing and compacting may be necessary, but avoid sharp folds and creases in the fabric, especially when storing the bags for several weeks or longer. Generally, you should store full-round bags individually to prevent compressing one bag under the weight of additional bags. This also helps to keep the container weight manageable for large bags and is more in line with GMPs since it
Some users set up a strategy that uses an expiration date before which the bags remain suitable for use in production followed by the usual wash process. If the bags reach their expiration date and haven’t yet been used, they’re inspected, washed, inspected again, and returned to storage until they’re needed for use or reach their next expiration date, whichever occurs first.

Identification, inspection, and record keeping

Several sections of 21CFR Part 211 provide guidance on equipment identification, cleaning, maintenance, and record keeping. In this context, you can regard fluid-bed filter bags and bonnets in the same way as other product-dedicated change parts such as tablet press punches and dies, encapsulation tooling, and packaging line items such as blister dies and manifolds.

Section 211.105 pertains to equipment identification using a “distinctive identification number or code that shall be recorded in the batch production record to show maintains the unique identity of each bag and storage device throughout handling and storage. Pairs of half bags (or “sets”) may be stored together if the container is large enough and the bags are not too large or heavy, but for very large half bags, you may want to store each half in a separate container.

In many GMP facilities, conditions in the storage area may already be suitable for storing filter bags. Even when using airtight storage containers, it’s beneficial to minimize the bags’ exposure to moisture during handling and inspection. Keeping the relative humidity in work areas steady in the 50 to 60 percent range helps prevent the fibers in the bag fabric from repeatedly swelling and contracting as they absorb and release moisture.

Keep storage temperatures well above 32°F (0°C) to minimize condensation and prevent expansion of any trapped moisture due to freezing, but temperatures shouldn’t exceed 75°F. Large windows and bright sunlight may be good for employee morale, but prolonged exposure to intense UIV radiation and heat can be harmful to filter bag fabric.

Lastly, factor filter usage against expected shelf life. Some users set up a strategy that uses an expiration date before which the bags remain suitable for use in production followed by the usual wash process. If the bags reach their expiration date and haven’t yet been used, they’re inspected, washed, inspected again, and returned to storage until they’re needed for use or reach their next expiration date, whichever occurs first.

**Figure 1**

Fluid-bed filter bag labels

<table>
<thead>
<tr>
<th>a. Embroidered</th>
<th>b. Ultrasonically embossed</th>
</tr>
</thead>
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**Figure 2**

Common types of filter bag wear

<table>
<thead>
<tr>
<th>a. Sewing thread wear—typically caused by abrasion</th>
<th>b. Torn seam—typically caused by poor handling</th>
<th>c. Hole in fabric due to abrasion</th>
</tr>
</thead>
</table>

[Images of fluid-bed filter bag labels and common types of filter bag wear]
the specific equipment used in the manufacture of each batch of a drug product.” For this reason, fluid-bed filter bags should be uniquely identified in a manner that distinguishes each bag from any other bag in the store room. Good practice is to include the same identification scheme on storage containers and log books.

Suppliers typically offer some form of embroidered cloth label that’s stitched onto a portion of the bag where it is not in direct product contact, as shown in Figure 1a. On fluid-bed filters, this label is commonly attached to the skirt. An alternate method is to use ultrasonic technology to emboss identifying characters onto the label material which is then sewn to the bag, as shown in Figure 1b.

The most common label identifiers are: the date of manufacture, supplier name, sales order number (or customer purchase order), and asset “tag” number. Companies that run a very large portfolio of drug products may also show the product name or formulation. In many cases, CMOs include the product brand name or the name of the client, which can be helpful to clients during site visits and audits.

Unique bag identification is critical for precise traceability, especially where materials of construction are concerned. End users usually maintain a file with their filter cloth specification sheets, but these sheets only state how the material is “supposed to be.” Continuous monitoring and certification on a per-bag basis permits robust validation and ensures that the bags are as specified and are traceable and compliant with the materials of construction guidelines in 21 CFR Part 177. Best practices suggest that certificates for uniquely identified bags should either accompany each item in a shipment or be emailed at the time of shipment or both. Electronic documents have the advantage of being directly linkable to electronic batch records, which supports compliance with 21 CFR Part 11.

The FDA provides some guidance on individual equipment logs in 21 CFR Part 211.182. For filter bags, log books should maintain records of usage and cleaning, observations of condition, and any remarks pertaining to the bags’ fit or function for use. Each bag should have a log, which should use the same identifiers found on the bag and its storage container. Beyond the usual references to batch records, the logs may include:

- the inspection date and time;
- the inspector name(s) and/or the name of the supervisor signing off on the entries;
- the number of batches (or hours) run on the bag;
- which machine the bag was used on;
- the name of the technicians dispensing the bag and returning the clean bag to storage; and
- information pertaining to cleaning, such as the date and time of wash, equipment used, a description of the wash and dry cycles (most sites use a reference to documented SOPs), and the name of the operator handling the wash.

Entries should be timely and in chronological order, and the information should be adequate to present a robust audit trail in the event of a deviation or inspection. The log book is the tool for reconstructing the entire bag management cycle and knowing who did what, when, and how, along with any comments on unusual observations or issues that require corrective action.

Many companies choose not to repair bags and instead set criteria for how much damage is acceptable before a bag must be removed from service.

Bag inspection is largely a qualitative process of evaluating the bag’s condition and fitness for use. Wear, shrinkage, and other damage is inevitable. Look for pin holes, rips in the fabric, splitting or parting seams, threads unraveling, and abrasion to the fabric surface. Figure 2 shows some common types of bag damage.
wear, while Figure 3 shows a microscopic view of bag thread abrasion. Because the degree of damage is somewhat subjective, it's a good idea to have a second technician also examine the bags.

The question of whether to repair or replace a worn bag often depends on the preference of the individual site. Sites can create policies to guide technicians when determining acceptable levels of wear or damage. Any small defects in the fabric and stitching may propagate and contribute to material loss or even a complete rupture and batch failure. Determining what can and cannot be repaired is largely done by the site technicians and operators that routinely work with the filter bags. Sharing onsite observations with your bag supplier, either in photos or by sending the damaged bag to them to evaluate whether or not repair is appropriate can help educate your site's technicians, so that they can eventually make repair decisions on the spot.

Photo 2 shows a typical patch made to close a tear in a fluid bed dryer bag. Such repairs can make predicting the repaired bag's expected usable life challenging. For example, a repair made to patch a hole, stitch a rip in the fabric, or close an open seam will do nothing to prevent failure from an abraded surface or the opening of a loose stitch elsewhere in the bag. For this reason, many companies choose not to repair bags and instead set criteria for how much damage is acceptable before a bag must be removed from service. Companies that do allow bags to be repaired and returned to service will sometimes assign different part numbers to the repaired bags to distinguish them from bags that have never been repaired. This helps with tracking a repaired bag's performance and remaining usable life.

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