Reducing the Risks of Particles on the Outside of Vials

The pharmaceutical industry and safety regulators are putting more emphasis on using external washers to remove product particles from the outside of vials. This process minimizes the legal risk of long-term exposure for packaging operators and medical personnel who frequently handle toxic products.

**Historical justification for external washers**

The implementation of post capping external vial washing (decontamination) within the pharmaceutical industry has been increasing in recent years. Historically, powder filling installations were the most common applications to consider external washing. This was mainly for cosmetic reasons due to the obvious quantities of powder that were visible on the outside of the vials.

**Financial justification for external washers**

With the cost of drugs increasing, many pharmaceutical companies have found it financially advantageous to use external vial washers in front of automatic inspection equipment. All injectable products must be inspected for foreign particles and automatic inspection units are more reliable in identifying particles than manual inspections. These units provide a tremendous labor savings but, unfortunately the automatic inspection process can be sensitive to particulate that has attached to the outside of the vials. Therefore, many companies use external vial washing to reduce the risk of false rejects. Higher yields can easily pay off the capital investment within a very short time (especially for expensive products).

**Risk avoidance justification for external washers**

Another trend that has increased the popularity of external washers is the expanding market for cancer drugs and high potency products. There has become an awareness of the risk of long-term exposure for medical personnel involved with the day in and day out handling of contaminated vials.

**Sources of contamination**

As mentioned previously, Powder filling applications for antibiotics commonly use external washing as this is a very dusty process. However, it is surprising to see limited use of external washers for freeze-dried products. Freeze-dried products are filled as a liquid and then loaded into a freeze dryer and frozen. The product is sublimated by pulling a vacuum on the chamber so that the ice crystals turn into gas without going through the liquid phase.

In theory only moisture is drawn out of the vials but in reality there are particles of product that exit as well, contaminating the outside of all surrounding vials.

Another source of contamination occurs periodically at the end of the
freeze-drying cycle, during the stoppering phase. In a perfect world, all the shelves of products compress and the stoppers are seated without any damage to the vials. However, often there are many vials that are broken during this process which adds to the contamination of the entire batch.

Freeze-dried product will exit the freeze dryer and go to the capper where over seals are applied. Capping speeds are often 400 to 600 vials per minute, and if a vial is slightly out of tolerance, there can be breakage. This event can scatter product dust throughout the capping enclosure, again adding to the contamination of the outside surface of clean vials.

Many of these products may not be classified as high potency or Biologics but can still be harmful to humans due to allergic reactions or the cumulative buildup with frequent handling.

**Desirable technical features for external washers**

External washers have the positive advantage of removing or neutralizing actives that are on the surface of the vial; however, there can be an adverse effect if moisture from the washing process gets underneath the aluminum seal and promotes bacterial growth or mold. There are many external washers on the market which do not attempt to protect the cap from moisture during the washing process. However, I would recommend seeking out suppliers that use a soft durometer mold to provide a watertight seal around the cap during the washing cycle.

Many feel the need to wash vials to remove particulate from the outside of the vial and therefore, dissolving the dried product with water is sufficient. In reality regulatory agencies are more interested in neutralizing the effect of the drug. In the case of Biologics it’s important to use a chemical pre-rinse (detergent) to destroy or kill the live cells rather than using just a dissolution process.

It’s also important to remove product from the base of the vial as well as the sides. Many times a vial has a full wrap label but the base of the vials is always exposed and often the concaved shape of the vial base is the most difficult to clean and is the largest transferable surface. For this reason it’s important to select an external washer that does not use conveyors or rails that can shield the base from the cleaning process. Conveyors are also discouraged because they are designed with complex interlocking surfaces that are impossible to validate as clean. Conveyors can carry particulate well into the heart of the machine, contaminating vials that may have been previously cleaned. It is important to select a supplier that does not use any conveyors for the movement of the vials through the cleaning and drying process.

**Additional possible applications**

Many companies have installed external vial washers for either powder filling applications, high potency, liquid or freeze-dried products to minimize the risk of operator or end-user exposure to harmful products. To date, the industry mainly uses external washers for injectable products. However, many antibiotics and prescription products come in solid oral dose forms. Counting of soft tablets and capsules into bottles can make for extremely dusty conditions during the packaging process. These products can potentially contaminate the public and present similar risks as previously mentioned with the injectable products.

There has been very little attention focused on the need to clean the exterior of bottles in the solid dose segment of the industry. However, I expect this to change as additional legal cases arise from the overexposure to products by healthcare workers.