Vial Processing Advances Reducing Contamination and Damage

Sponsored Content by SP Scientific Dec 10 2019

Vials with chipped rim surfaces have been the cause of at least one recall for parenteral products and glass particles found in vials have resulted in several US Food & Drug Administration (FDA) 483 notices issued to pharmaceutical manufacturers. This is a critical event for parenteral product manufacturers, but it can sometimes go undetected. If the vial manages to reach filling and is stoppered and capped before inspection then this defect will be difficult to identify.

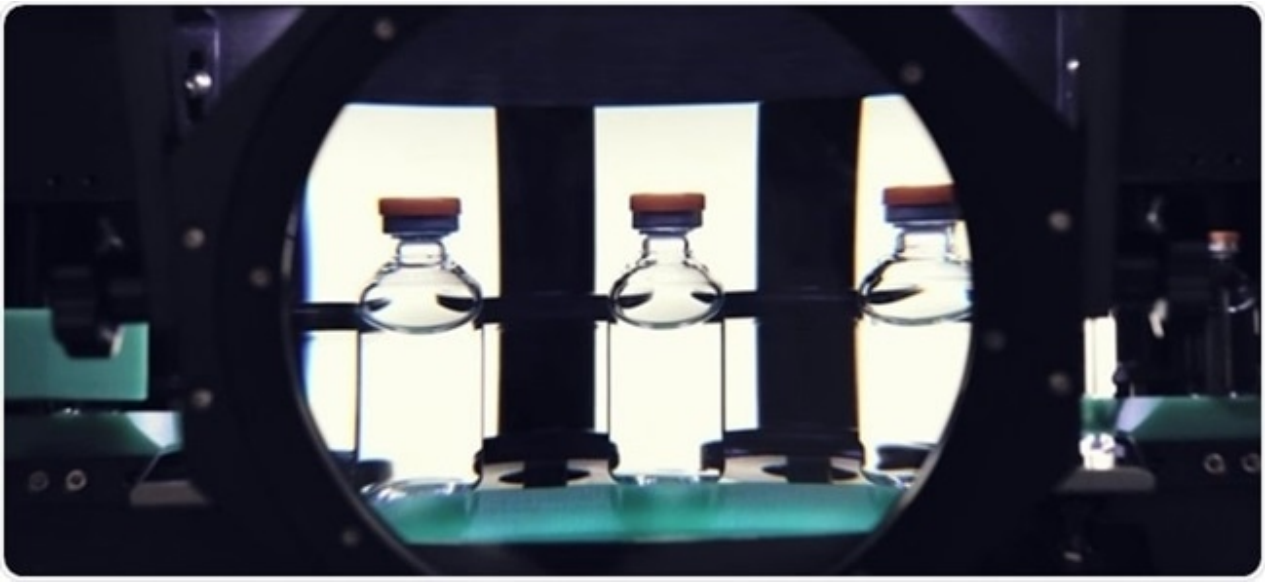

Image credit: SP Scientific

Rear-source lighting is used with manual inspection and most automated inspection systems to search the product for particles. Black spots appear where particles block the light but this process can easily miss glass particles. Bottom-source lighting is being used in new, more advanced inspection systems. These use reflectance measurement to help identify fiber and glass fragments but such methods are costly. As such, a better approach would be to address the issue of glassware damage at its source.

Sources of Glassware for the Filling Line

When large batches of vials require filling it is typical to source glass vials

then wash and sterilize them before filling as part of a continuous process. In such scenarios, any loose particles will be removed from inside and outside of the glass vials by washing them. The vials will then be sterilized by being put through a depyrogenation tunnel before entering the most sterile area of the facility ready for filling.

Figure 1: *Chipped vial rim and resultant particulate generation. Image credit: SP Scientific*

With smaller-scale applications, a cost and space-saving solution is to use sterilized glass supplied directly to the filling station as this bypasses the need to operate a washing and sterilizing line. The supplier will ship pre-sterilised glass vials to the end-user, which have been double bagged and gamma irradiated. While convenient, this may introduce additional risk to the process.

Inconsistent vibration and manual handling during shipping mean that the glass is not under full control. The glass is sealed to protect against contamination and the vials are tightly packed together in a formation or pack. However, damage can occur when vials rub against each other or collide. This results in the creation of glass particles. It is not possible to protect the vials with dividers or another packaging as this could compromise the sterility of the vials or create dust particles.

Another solution for throughput processes of 50 vials per minute or less is a vial washer and tunnel. As shown in Figure 2, these systems are compact

(occupying under 9ft) and provide drug manufacturers with complete control of the process, which in turn minimizes the risks of human intervention and contamination.

Figure 2: *Modern washing and depyrogenation installation featuring washing needles. Image credit: SP Scientific*

Eliminating Vial Damage During Washing

Operators have the opportunity to identify damage or debris when the vials are unwrapped by hand and loaded into vial washing machines. However, the washing machines themselves can cause damage to the vials. Many washing systems use stainless steel needles, which enter the mouth of the vial and transfer the washing media.

Rotary washers have dozens of needles entering the vials multiple times throughout the washing process and some linear washers have hundreds of needles. As shown in Figure 3, there is sometimes very little clearance between the needle and the vial opening. For example, a 2cc vial may have an opening as small as 7mm diameter and the needles can be up to 4mm thick.

Figure 3: *High Pressure Washing Jet Manifold for Vial Washing Without Needles. Image credit: SP Scientific*

It is very easy to accidentally bend thinner needles during storage or installation, meaning that the needle may hit the rim of the vial and cause the mouth to chip, which in turn will cause glass debris. When this occurs, it is virtually undetectable. As the vial is filled, stoppered and capped almost immediately, it may not even be detected during the final inspection process.

The use of needles has been eliminated in more advanced vial washers while still achieving a 3-log reduction of particles during vial washing as required by the FDA. This is achieved using a washing manifold with precisely machined orifices to generate high-velocity water jets which the vials are then positioned over. As shown in Figure 4, the risk of misalignment of needles, and therefore damage to the vial, is eliminated with this design as it creates a water stream that maintains its convergent nature until it impacts the base of the vial.

Summary

Drug manufacturers have little control over the process when using pre-

sterilised glass, which inherently means a risk of glass particles and unassured sterility. Vial washers that do not rely on needles should be chosen to minimize the risk of chipped glass and debris. Pre-sterilized glassware needs no longer be depended upon now with the availability of smaller systems that fit within smaller facilities.

About SP Scientific

SP Scientific is the synergistic collection of well-known, well-established and highly regarded scientific equipment brands — VirTis, FTS Systems, Hotpack, Hull, Genevac, and most recently PennTech — joined to create one of the largest and most experienced companies in freeze drying/lyophilization, centrifugal evaporation and concentration, temperature control/thermal management, glassware washers, controlled environments, vial washing and tray loading machines.

More than a scientific equipment supplier, SP Scientific represents brands that distinguish themselves by thoroughly assisting customers in matching equipment to particular application needs. Fortune 500, pharmaceutical, aerospace, automotive, medical device, diagnostic kit and biotechnology companies — as well as government facilities, universities and colleges are among the organizations served on a daily basis.

SP Scientific is part of SP Industries, Inc., a leading designer and manufacturer of state-of-the-art laboratory equipment, pharmaceutical manufacturing solutions, laboratory supplies and instruments, and specialty glassware. SP's products support research and production across divers end user markets including pharmaceutical, scientific research, industrial, aeronautic, semiconductor and healthcare.

SP's three flagship brands -- SP Scientific, SP Scienceware, and SP Ableware--represent over 400 combined years of experience, quality, and innovation. Headquartered in Warminster, Pennsylvania, SP Industries has production facilities in the USA and Europe and offers a world-wide sales and service network with full product support including training and technical assistance.

Sponsored Content Policy: News-Medical.net publishes articles and related content that may be derived from sources where we have existing commercial relationships, provided such content adds value to the core editorial ethos of News-Medical.Net which is to educate and inform site visitors interested in medical research, science, medical devices and treatments.

Last updated: May 13, 2020 at 3:17 AM

SP Scientific

Address

935 Mearns Road
Warminster
PA, 18974
United States

Phone: +1 (800) 523-2327

Visit Website

Download PDF Copy

SP Scientific is the synergistic collection of well-known, well-established and highly regarded scientific equipment brands — VirTis, FTS Systems, Hotpack, Hull, Genevac, PennTech and most recently i-Dositecno — joined to create one of the largest and most experienced companies in freeze drying/lyophilization, production fill-finish lines, centrifugal evaporation and concentration, temperature control/thermal management, glassware washers and controlled environments.

More than a scientific equipment supplier, SP Scientific represents brands that distinguish themselves by thoroughly assisting customers in matching equipment to particular application needs. Fortune 500, pharmaceutical, aerospace, automotive, medical device, diagnostic kit and biotechnology companies — as well as government facilities, universities and colleges are among the organizations served on a daily basis.

SP Scientific is part of SP Industries, Inc., a leading designer and

manufacturer of state-of-the-art laboratory equipment, pharmaceutical manufacturing solutions, laboratory supplies and instruments, and specialty glassware. SP's products support research and production across divers end user markets including pharmaceutical, scientific research, industrial, aeronautic, semiconductor and healthcare.

SP's three flagship brands -- SP Scientific, SP Scienceware, and SP Ableware--represent over 400 combined years of experience, quality, and innovation. Headquartered in Warminster, Pennsylvania, SP Industries has production facilities in the USA and Europe and offers a world-wide sales and service network with full product support including training and technical assistance.