Crossing Out Batch Contamination

Contemporary drug development largely focuses on biopharmaceuticals as opposed to chemicals; this means that resultant drugs tend to be injectable liquids rather than solids. Typically, these drugs are designed for targeted populations, thus shrinking batch sizes. Alongside these trends are pressures to increase efficiency, reduce costs and minimize risk—this includes slashing cross-contamination between batches and validation times.

All these factors converge to show that peristaltic pumps, combined with single-use tubing or tubing sets, can represent the future in biopharmaceutical fill/finish lines. While traditional equipment uses piston pumps, today's biopharmaceutical production environment demands more. Piston pumps can suffer from a number of drawbacks, for example, housing a number of contact parts that must be dismantled, cleaned and sterilized between batches.

As batches decrease in size, however, changeover times must be shortened. Even if duplicate pumps are available to quicken batch transfer, each pump must be stripped, cleaned and sterilized. The liability of cross-contamination between batches, though, still lurks.

A Shot In The Arm For Contamination Control
In contrast, the only peristaltic pump component that comes into contact with product is tubing. Add to that the potential to use pre-sterilized single-use tubing in the process, which phases out the need for continuous cleaning and sterilization, as well as the chance for cross-contamination to thrive.

Single-use tubing sets and regular pump service intervals can additionally help extend validation periods in aseptic processes. To that end, filling and dispensing equipment supplier Flexicon, furnishes each single-use tubing set with a complete validation package. Double-bagged and gamma-irradiated, these disposable aseptic fluid path (DAFPA) sets arrive ready to use.

With the flexibility to select from several configurations, the DAFPA offering also includes the pharmaceutical-grade silicone tubing required for pumps, and depending on the application, a sterile filter, aseptic quick-connect fittings, a pre-fillable product bag and a filling nozzle. Now simply consider the time and resources necessary to clean and sterilize a piston pump in contrast.

Those making the piston-to-peristaltic transition are often surprised by the precise, pulsation-free flow afforded by peristaltic pumps. Furthermore, electronic pump motor control permits the incline, maximization and decline of flow rates, reducing not only aeration and foaming, but cycle times, too. As a matter of fact, peristaltic pumps can fill systems processing up to 150 bottles per minute.

Normally fitted with a pump head integrating two sets of six rollers that are offset from each other, Flexicon peristaltic pumps draw product through two parallel tubes. Upon exiting the pump head, the product combines by Y-connector to take advantage of the pulsation produced by both roller sets. As a result, these pumps can compete with smooth piston-pump flows—even down to microfill levels.

With the right tubing size, peristaltic pumps can deliver 0.5-mL volumes at an accuracy of ±0.5 percent, whereas smaller volumes realize accuracies of ±1 percent. Most high-speed filling equipment, moreover, incorporates in-process checkweighing to monitor accuracy, thus granting the opportunity to enter data into a closed-loop pump control system to further optimize performance.

While varying pump speed is one way to change the flow rate, peristaltic pumps additionally boast compatibility with many tubing sizes, which can prove invaluable in operations involving batches. Although an extreme example, one peristaltic pump could fill volumes between 0.1 and 250 mL.

Some biopharmaceutical products, such as live vaccines and organisms, are sensitive to shear and high pressures. A smooth flow past the pump-head rollers, though, signifies that the liquids pumped by peristaltic technology are not subjected to shear. Calibrated for a maximum pressure of 1.3 BAR, peristaltic pumps can even accommodate microfilling applications.

Single-use technology is becoming increasingly popular in the production of injectable liquid biopharmaceuticals. Peristaltic pumps boast that only tubing comes into contact with product. Therefore, peristaltic technology delivers not only reliable, cost-effective pumping, but also a design dedicated to the philosophy of single-use production.

For more information from Watson-Marlow Flexicon, please call 800.282.8823, e-mail support@wmbpumps.com [1] or visit www.flexiconamerica.com [2].

Source URL (retrieved on *03/14/2014 - 5:24am*):
http://www.chem.info/articles/2009/04/crossing-out-batch-contamination?qt-most_popular=1

Links:
[1] mailto:support@wmbpumps.com
[2] http://www.flexiconamerica.com