

The advantages of using peristaltic aseptic filling machines with a 'single use' production philosophy

New drug development is today focused largely on bio-pharmaceuticals rather than chemicals, which means that the resultant drugs tend to be injectable liquids instead of solids. Furthermore, the new drugs are typically designed for specific populations, hence batch sizes are smaller. Alongside these two trends there are ongoing pressures to increase efficiency, reduce costs and minimize risks - including cross-contamination between batches. Additionally there is a need for a reduction in the time involved in validation procedures; paperwork and man hours, for example. Taken together, these factors point towards peristaltic pumps with single-use tubing or tubing sets as representing the future for bio-pharmaceutical fill/finish lines.

Traditionally, fill/finish lines have used piston pumps but, in today's bio-pharmaceutical production environment, piston pumps suffer from a number of drawbacks. One of these is that piston pumps contain numerous contact parts that must be dismantled, cleaned and sterilised between batches of different product. As batches become smaller, there is a need to shorten changeover times. Even if duplicate pumps are purchased to achieve faster changeovers, each pump still needs to be stripped, cleaned and sterilized - and a small risk of cross-contamination between batches will always remain. In contrast, the only component of a peristaltic pump that comes into contact with the product is the tubing. If the tubing is a single-use item that is supplied pre-sterilized, the need for cleaning and sterilization is eliminated, as is the risk of cross-contamination.

Extending validation periods in aseptic and sterile processes by providing single-use tubing sets and predictable pump service intervals is an important aspect of product development at filling and dispensing specialist Flexicon. Part of Watson-Marlow Bredel, Flexicon offers single-use tubing sets, each of which is supplied complete with a validation package. The DAFPA (disposable aseptic fluid path) sets are supplied double bagged and Gamma irradiated ready for use. Various single-use tubing set configurations are available. These include the required pharmaceutical grade silicone tubing for the pump and, depending on the application, a sterile filter, aseptic quick-connect fittings, pre-fillable product bag and filling nozzle.

Considering the time and resources that would otherwise be needed to clean and sterilize a piston pump, the single-use peristaltic pump tubing sets represent excellent value for money.

Production managers switching from piston pumps to peristaltic pumps are often surprised at the high-accuracy, pulsation-free flow that state-of-the-art peristaltic pumps achieve. In addition, sophisticated electronic control of the pump motor enables the flow rate to be ramped up, maximised and ramped down again, thereby reducing aeration and foaming so that very short cycle times can be maintained. It is not unusual for peristaltic pumps to be used on filling systems processing up to 150 bottles per minute.

Flexicon's pumps are normally fitted with a pumphead having two sets of six rollers, with the two sets of rollers offset from each other. Product is drawn through two parallel tubes and, after exiting the pumphead, the flows are combined via a Y-connector so that the pulsation from the two sets of rollers combine. The resultant smooth flow is comparable with that achieved using piston pumps down to micro fill levels. With appropriately sized tubing, peristaltic pumps can deliver volumes down to 0.5ml at an industry-standard accuracy of +/- 0.5 per cent; smaller volumes can be delivered with an accuracy of +/-1 per cent. Typical high-speed filling machines use in-process checkweighing to monitor the filling accuracy and, if necessary, the output from this can be used in a closed-loop pump control system.

Varying the pump speed is one way to change the flow rate, but peristaltic pumps can also operate with different sized tubing. This can be beneficial in applications where a facility produces a range of substantially different batches. Although it is an extreme example, a single peristaltic pump can fill volumes between 0.1ml and 250ml simply by changing the tubing size.

Some of today's bio-pharmaceutical products, such as live vaccines and organisms, are sensitive to shear and high pressure. Once again, peristaltic pumps offer advantages over piston pumps. In micro filling applications, for example, peristaltic pumps are calibrated to provide a maximum of 1.3 bar pressure. The smooth flow past the pumphead rollers means that the liquid is not subjected to shear in the same way as it would be when passing through the valves and small orifices of a piston pump.

Single-use technology is becoming popular in the production of injectable liquid bio-pharmaceuticals. While it would be impractical to have a single-use (piston) pump, peristaltic pumps offer a significant advantage in that the only contact part is the tubing. And single-use tubing sets are both practical and cost-effective. Peristaltic technology therefore offers reliable, cost-effective pumping that fits with the single-use production philosophy without compromising the required pumping characteristics.

For more information on Watson-Marlow Flexicon, please visit <http://www.flexiconamerica.com/>, or contact Watson-Marlow Flexicon directly at 1-800-282-8823 or by email at support@wmbpumps.com.

About Watson-Marlow Flexicon

Watson-Marlow Flexicon is the world leader in accurate peristaltic dispensing specializing in aseptic, diagnostic and ophthalmic filling applications. The full product range includes benchtop dispensers for liquids and viscous products, semi-automatic filling and capping machines, fully automated fillers and OEM peristaltic dispensing systems.

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