The Advantages of Using Peristaltic Aseptic Filling Machines With a 'Single Use' Production Philosophy

Watson-Marlow Flexicon

With injectable liquids taking the forefront of the field of new drug development, the market demands a cost-effective and safe way to produce drugs in small batches for specific populations. This article examines the benefits of single-use tubing as an efficient answer to these demands.

Today, new drug development is focused largely on bio-pharmaceuticals, rather than chemicals, which means the resultant drugs tend to be injectable liquids instead of solids. Furthermore, the new drugs are often designed specifically for smaller populations, leading batch sizes to be smaller. Alongside these two trends are ongoing pressures to increase efficiency, reduce costs, and minimize risks (such as cross-contamination between batches). Additionally, there is a need to reduce the time involved in validation procedures such as paperwork and man hours. Taken together, these factors make it clear that peristaltic pumps with single-use tubing or tubing sets are the future of 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 such drawback is the fact that piston pumps contain numerous contact parts that must be dismantled, cleaned, and sterilized between batches of different products. 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; a small risk of cross-contamination between batches always remains. 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 [1]. Part of Watson-Marlow Bredel, Flexicon offers single-use tubing sets, each of which is supplied 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, including 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 an excellent value.

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, maximized, and ramped down again. This reduces 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 pulsations 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 +/-1.0 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 subject to shear in the same way as it is 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. Single-use tubing sets are both practical and cost-effective. As such, peristaltic technology offers reliable, cost-efficient pumping that fits with the single-use production philosophy, without compromising the required pumping characteristics.

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