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APPLICATION

FOCUS

HIGH PURITY PROCESSES

Thermo Scientific Maserflex® Pumps Ensure Precise. Repeatable, And Flexible Pharmaceutical Production

Challenge:

Besides requiring precise liquid metering, dosing and transfer, virtually all pharmaceutical and biotechnology research, development and production processes demand sterility, fluid isolation, and zero contamination potential to assure a high level of process and product security. The FDA also has significant concerns regarding contamination, including cross contamination of biotech products that could potentially alter the safety, identity, strength, quality, or purity of the product. Validation cleaning processes are required and often time-consuming and costly.

Solution:

Sterile liquid flow is paramount in pharmaceutical and bioprocessing applications, which is why Masterflex peristaltic pumps are highly-suited for these demanding processes. Whether it be pharmaceutical products, live cell cultures, nutrients, or bioreactor constituents, our validation-friendly, non-contaminating peristaltic pump systems are designed to ensure precise, sterile control and management of flow while providing longer process run periods and reduced downtime – all which translates to process optimization.

Benefits:

One major reason Masterflex peristaltic pump systems are ideal for facilitating aseptic and sterile processes is because, unlike rotary lobe, centrifugal and other pump designs, Masterflex pumps have no check valves, seals, diaphragms or other components in the fluid stream – the fluid does not come into contact with the pump itself, only inside sterile tubing. The result: fluid isolation – a completely closed system for contamination-free aseptic/sterile flow at a wide range of flow rates, making applications easy to clean and maintain.

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CLEAN PUMP TECHNOLOGY FOR HIGH PURITY PROCESSES

Maintaining the integrity of high purity liquid flows is essential in pharmaceutical and biopharmaceutical applications. Whether it be in research, clinical development, full scale production, or contract manufacturing, problems associated with instrument contamination can be very costly. In these processes, the control and management of high purity flow must rely on pumping systems that provide sterility and precision at all times.

Masterflex peristaltic pumps employ clean pump technology to provide a totally closed system for contamination-free aseptic/sterile flow. Cleaning the pump internals is never required because flows come in contact with only the inside of one uninterrupted length of silicone or special grade tubing that will withstand repeated sterilization. CIP/SIP (cleaning/sterilization in place) is easy. With a Masterflex Easy Load® pumphead, for example, the tubing can be sterilized in place after simply releasing compression on the roller.

FACILITATES SINGLE-USE, DISPOSABLE OPTION

Rather than sterilize the tubing, another option is to treat the tubing as a disposable material and simply re-place it when the process is completed. This can simplify cleaning validation, reduce the risk of contamination by personnel, cut costs, and speed up the process – an especially viable option in this era when pressure is mounting to reduce validation costs while increasing compliance with cGMP. Treating tubing as a disposable or single-use material can also be particularly useful for contract manufacturers, or in clinical phases of development, when a facility may handle a variety of drugs.

Validation-friendly, non-contaminative Masterflex pumps are designed to ensure precise, sterile control and management of flow in high purity applications.

STERILITY, FLUID ISOLATION, ZERO CONTAMINATION

Masterflex pumps provide a completely closed system for contamination-free aseptic/sterile flow control

With adjustable 650:1 resolution, **bi-directional flow and self-priming capabilities**, Masterflex pumps provide for smooth, seamless operation.

Masterflex pumps provide for sterile, precision liquid metering, dosing and transfer, with **an accuracy of ±0.5% or better**, flowrates from .006 mL/min to 33.000 mL/min, and repeatability of 99.5 percent.

Very gentle method of pumping **does not damage shear-sensitive products**, such as cell cultures.

Masterflex pumps are extremely flexible with product viscosities.

Masterflex pumps are CIP/SIP (cleaning/sterilization in place) capable.

Positive shutoff helps ensure precise metering, dosing and transfer while providing a high degree of process and product security.

Masterflex pumps are powerful and compact, making them **a perfect fit for clean room applications.**

Because Masterflex pumps are nearly 100 percent volumetrically efficient, **very little heat is introduced into the process**, compared to rotary lobe and centrifugal pumps.

A wide range of superior tubing material is available for most any application.

Peristaltic design means **no valves, glands or seals to wear out** or become clogged.

Requires very little maintenance to keep in peak operating condition.

PHARMACEUTICAL/BIOPHARMACEUTICAL HIGH PURITY SOLUTIONS

Some applications for Masterflex pumps include:

Filling and dispensing
Processing of fermentation products
Cell propagation
Biomass separation
Ultrafiltration processes
Aspiration of tissue culture medium
Bioprocess container transfer
Circulation of cell suspension in fermentation
Dispensing into petri dishes
Harvesting cell media
Nutrient supply for cultures

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