

Thermo Scientific Masterflex Pumps Ensure Precise, Repeatable, and Flexible Pharmaceutical Production

Gregg E. Johnson, Thermo Fisher Scientific, Fluid Handling, Barrington, IL, USA.

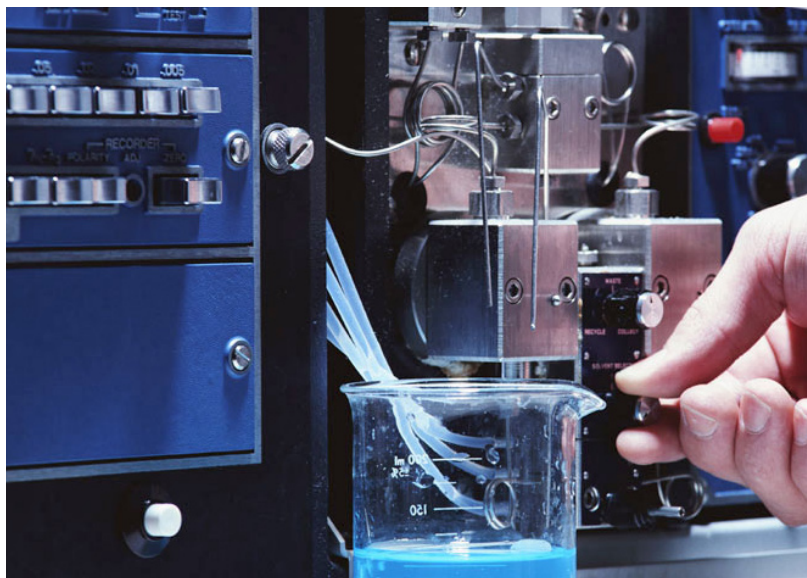
Key Words

- Masterflex
- Easy-Load
- Precision Liquid Transfer
- CIP/SIP
- Pharmaceutical
- Biotechnology
- Peristaltic Pump
- Fluid Isolation

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 Thermo Scientific 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-contam-



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.

Maintaining the integrity of high purity liquid flows is essential in pharmaceutical and biopharmaceu-

tical 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.

Clean pump technology

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.

Rather than sterilize the tubing, another option is to treat the tub-



inating 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.

ing as a disposable material and simply replace 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.

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 $\pm 0.5\%$ or better*, flow rates 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 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.

Masterflex B/T® Rapidload® direct drive peristaltic pumping systems provides for simple tubing changes.



- 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

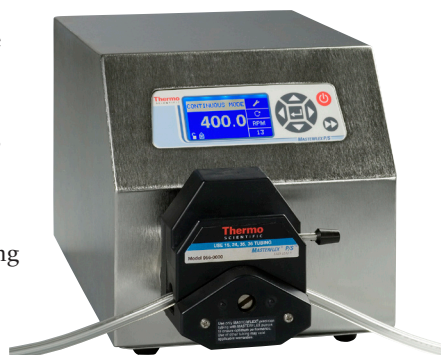
Bioprocess container transfer

Circulation of cell suspension in fermentation

Dispensing into petri dishes

Harvesting cell media

Nutrient supply for cultures



Masterflex® P/S.

In addition to these offices, Thermo Fisher Scientific maintains a network of representative organizations throughout the world.

Canada
+1 800 637 3739

USA
+1 800 637 3739

Worldwide
+1 847 381 7050

www.thermo.com/fluidhandling

Thermo Fisher Scientific, Barrington, IL USA is ISO certified

©2009 Thermo Fisher Scientific Inc. All rights reserved. Gore and Sta-Pure are registered trademarks of W. L. Gore and Associates, Inc. Norprene, Pharmed, Tygon are registered trademarks of Saint-Gobain Performance Plastics Corp. All other trademarks are the property of Thermo Fisher Scientific Inc. and its subsidiaries.

Specifications, terms and pricing are subject to change. Not all products are available in all countries. Please consult your local sales representative for details.