

Aseptic filling solutions

Ultimate flexibility for scalable aseptic filling

For more than 30 years, Flexicon has been established as the preferred choice for aseptic liquid filling for GMP regulated industries, such as biotechnology and diagnostics. Flexicon's products scale with your business. From the intuitive, easy-to-use design of our ergonomic pumpheads, through to the modular design of manual, semi and automatic systems, our products feature a grow-with-me concept to meet your fill/finish needs.

Our experience in engineering accurate and reliable filling machines for sensitive fluids in

GMP production and cleanroom environments, means we provide solutions to optimise your fill/finish processes.

As part of the Watson-Marlow Fluid Technology Group, Flexicon's engineering is backed by a global network of specialist and technical support engineers, who can help optimise your complete development and filling process, wherever you are in the world.

Experts in precision filling

At the heart of all our filling systems is the gentle pumping action of our peristaltic fillers, which ensure your valuable product is transferred without cross contamination or damage to viability and product quality.

Leveraging our expertise in peristaltic engineering has helped to optimise the performance of companies filling processes worldwide. Whether those companies are developing complex Advanced Therapy Medicinal Products (ATMPs) for testing, or looking to quickly—and safely—scale-up their batch production, we can help develop a system tailored to your needs.



A truly scalable filling solution

Flexicon offers a range of products that can be configured together to the level of automation and control as your needs grow. This scalable approach reduces validation costs and limits extra investment as your demand for capacity increases.



Tabletop units

- Fillers
- Screw Cappers
- Crimp Cappers



Semi-automated systems

- Filling
- Filling and capping



Fully-automated systems

- Automation of filling, stoppering, capping
- Modular filling and capping



Integration or retrofit solutions

- OEM fillers and controller
- Trolley solutions for OEM pump replacement



Lab - R&D

Clinical I

Clinical II

Clinical III

Small Production

Full Production

High Speed

Sterile, single-use fluid path - asepticu™ (page 23)

Tabletop Dispensing Systems - PF7+, PF7, 520Di, PF22 (page 7)

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Benchtop peristaltic filling machines—optimised for accurate, reliable and repeatable performance

Flexicon's high-quality benchtop filling range is the perfect centrepiece for your final filling process. Developed for accurate and reliable filling of sensitive fluids in GMP production and cleanroom environments, our range of benchtop filling machines offer a reliable, flexible and scalable filling solution.

PF7

PF7 is a flexible, reliable and versatile peristaltic filling machine. Developed to protect your valuable product in GMP production environments, PF7 provides a dependable, high-quality solution.

- Precision filling from micro-volumes
- Repeatability filling accuracies of better than ± 0.5 % to prevent costly overfilling
- No foaming, splashing or dripping between fills
- Simple, powerful user interface
- Designed for single-use fluid paths

Choosing the right product for your filling process

	PF7+	PF7
Precision filling from micro-volumes	•	•
Repeatability filling accuracies of better than ± 0.5 % to prevent costly over filling	•	•
No foaming, splashing or dripping between fills	•	•
User-programmable 'recipes' where users can define filling recipe parameters	•	•
Connects to a range of balances and printers for error-free calibration and batch reporting to help compliance to GMP and regulatory demands	•	•
Easy-to-clean surfaces with no entrapment areas, and an ergonomic design for operation on the bench or in isolators and LAF units	•	•
Clear and intuitive colour display with large keypad for easy use when gowned up in cleanroom environments	•	•
Zero waste start-up*	•	
21 CFR part 11 compliance	•	
eBatch Reports via USB or EtherNet	•	
100 % in-process weigh checking	•	
Dynamic recalibration	•	
Easy reject fill tolerance indicators	•	
Supported USB keyboard	•	

*Zero Waste—full accuracy after priming/calibration

PF7+

Enhance the performance of your critical process



The features of the PF7+ extend the established capabilities of the industry leading PF7. Developed for critical aseptic filling, PF7+ an intuitive peristaltic filling pump. When connected to the advanced filling kit the PF7+ provides:

- Zero waste start-up*
- Up to 100 % in-process weight checking
- Dynamic recalibration
- Colour fill tolerance for vial rejection

With improved process traceability through batch reporting and live audit trails via EtherNet, PF7+

removes the need to enter the cleanroom and provides access to a full audit trail with ease.

We have enhanced security through three user levels with unique permission, auto timeout locking and batch user password sign-off capabilities.

- 21 CFR part 11 compliance
- eBatch reports via EtherNet
- USB keyboard

PF7+ advanced filling kit

For a complete filling solution, Flexicon has worked with precision instrument specialists Mettler Toledo to develop a PF7+ advanced filling kit.

To ensure filling repeatability, the PF7+ advanced filling kit includes a Mettler Toledo analytical balance with wind guarding and an integrated, adjustable nozzle holder.



Tabletop screw and crimp capping

Consistent quality crimps and torque

When there is need to increase productivity, while minimising operator fatigue and the potential for repetitive strain injury, our cappers can be added to your process.

- Consistent quality closure
- Cap up to 1,000 units/hour
- Fast changeovers

Deciding which capper is right for the process depends on the capping needs.



Screw cappers

- No tools needed for changeover
- Handles caps up to 65 mm and bottle sizes up to 100 mm in diameter
- Adjustable closing torque

Crimp cappers

- High quality aluminium overseal
- Low particle release
- Easy to mount crimp heads and bottle tools in standard or customised sizes are available
- Collection of used compressed air



	Maximum cap size		Maximum bottle size	
	Diameter	Height	Diameter	Height
FC10 screw	50 mm	40 mm	55 mm	180 mm
FC32 screw	65 mm	40 mm	100 mm	240 mm
FS10 crimp	8–20 mm ISO 8362		73 mm	180 mm
FS32 crimp	13–32 mm ISO 8362		95 mm	240 mm

FlexFeed15 and FlexFeed20

Semi-automated benchtop filling and container handling system

As the need for more automation grows, FlexFeed series products use **PF7+** or **PF7** benchtop filling machines and introduce extended automation capabilities. The FlexFeed series meets the need of flexible production of small batches including contract filling and diagnostics operations where there are many different vials, bottled and microtubes.

The speed at which the vials/bottles are presented at the filling needle is fully adjustable, allowing light vials or bottles to be filled. Customised solutions can be designed to handle bottles with special shapes.

The **FlexFeed15** and **FlexFeed20**, used in conjunction with one of our crimp or screw capping machines, provides a simple and very flexible means of production and customers can achieve a fast return on investment.

- 12 mm to 50 mm (FF15) / 78 mm (FF20) diameter bottles without any format parts
- Complete changeover in less than two minutes
- Prevents repetitive strain injuries
- Small foot print and designed for cleanroom environments
- Excellent return on investment



FlexFeed20

Fast simple changeover

Changeover between different bottles or vials can be done in two minutes without format parts, tools or special operator skills.



FlexFeed15



Increase your throughput

The FlexFeed series meets the need of flexible production of small batches including contract filling and diagnostics operations where there are many different vials, bottled and microtubes.

FlexFeed30

Semi-automated filling and capping system for small batches

For a higher productivity, a more consistent screw capping and no more repetitive strain injuries, the **FlexFeed30** is the answer for contract manufacturers and diagnostic companies.

- Reduced production costs and increased productivity
- Consistent cap torque prevents leakage of liquid
- Up to 1200 units/hour
- Protects operators from repetitive strain injuries
- Complete cap and bottle change in less than five minutes
- Fills bottles from 12 mm to 50 mm in diameter



FlexFeed30



FP50

Fully automated filling and stoppering

Automating the key steps of aseptic filling cuts the risk of operator error and related contamination. The FP50 peristaltic filling system also eliminates the costs and risk issues of volumetric filling pumps.

- Up to 25 units/minute
- Excellent filling accuracy prevents costly overfilling
- From less than 0.2 ml to 100 ml fills of 2R to 100H vials
- Full or partial stoppering
- Quick and simple format changes
- Universal format parts reduce costs
- Small footprint for UDF bench or RABS installations



FPC60

Fully automated filling, stoppering and capping with optional inline check weighing

Built around our highly accurate peristaltic filler, the FPC60 is a uniquely configurable small batch aseptic fill/finish system with a wide variety of modules designed to work together to provide the ultimate filling solution.

The FPC60 system can be designed and built with a choice of optional solutions allowing adaptation of each stage of the fill/finish process including vial infeed, filling, stoppering, capping, auto-reject and product outfeed.

- Unparalleled value
- Increased batch consistency between operators
- Zero waste of highly valuable product in batch start up
- Pneumatic free
- No format parts for the entire vial range
- Reduce contamination sources and save time with hand-free initial calibration
- Highly accurate filling of better than $\pm 1\%$ from 0.2 ml up to 100 ml
- Up to 2700 vials per hour (45 vials/min)
- No tools and minimal setup between batches



To meet the needs of aseptic fill finish applications, Flexicon provides full turnkey FPC60 solutions for LAF and RABS systems. Integrated isolator solution for the FPC60 are also available through Flexicon in collaboration with our preferred partners.



Advanced optional features

- Auto reject for minimal operator intervention
- Independent validation of capping force
- No vial—no fill sensor prevents miss filling and contamination of the filling environment
- One-handed open/close pump design for easy change fluid-path in RABS and isolators



FMB210

Fully automated filling, stoppering and capping for medium sized batches

The FMB210 is perfect for fully automated filling and capping for aseptic drug, ophthalmic and diagnostic applications. It can handle a wide range of container and closure types.

A unique tool platform allows simple, fast and accurate format changes where multiple products need to be processed on a single filler. It can be configured for a choice of infeed and outfeed options or other peripherals.



- Ophthalmic and diagnostics: filling, dropper insert and precise electronic screw capping better than
- ± 10 Ncm (± 0.9 lbs/inch). Pneumatic screw capping is optional for higher throughput
- Aseptic filling of injectable drugs: filling, stoppering and roller closing of crimp caps

- Compact design means a small footprint that fits inside small cleanrooms
- Up to 75 units/minute: depending on type of cap, vial size and fill volume
- Completely closed peristaltic filling system ensuring no cross-contamination

Easy setup and changeover

Flexicon OEM system components

OEM pumpheads

Many filling machine manufacturers have successfully incorporated Flexicon solutions into their filling lines— adding value to their product and increasing their client satisfaction. Panel mount fillers from Flexicon are available in two sizes— QC12 and QC22—depending on your filling needs.

- Fully flexible filling volumes (between 0.2 ml - 5000 ml)
- Prevent spillage between fills, foaming and splashing
- Fast changeover
- High filling accuracy reduces fluid costs
- Global support and high quality filling accessories

OEM applications include:

- Existing filling lines where piston pumps need to be replaced
- New high capacity filling lines for the biotechnology and pharmaceutical industries
- Filling lines for awkward shaped bottles for the diagnostics industry



Mastercontrollers

Master controllers, such as the MC100 and the MC12, can control up to 16 pumps on a filling line. We supply stand-alone controllers, panel mounts and controllers for communication with filling line systems via PROFIBUS or DeviceNet. The MC100 relays communication directly from your system's PLC via industrial fieldbus optimising the values to provide precision performance of the fillers.

MC12 control unit with multiple PD12 and P22 fillers

The unit fulfils all the usual requirements and can be extended to include several filling stations, an electronic bottom-up fill system, a printer, a direct link to a balance for dynamic recalibration and more.

The MC12 master controller is capable of doing an automatic recalibration.

By connecting a load cell to the MC12, every data point is used to dynamically recalibrate without need for user input.

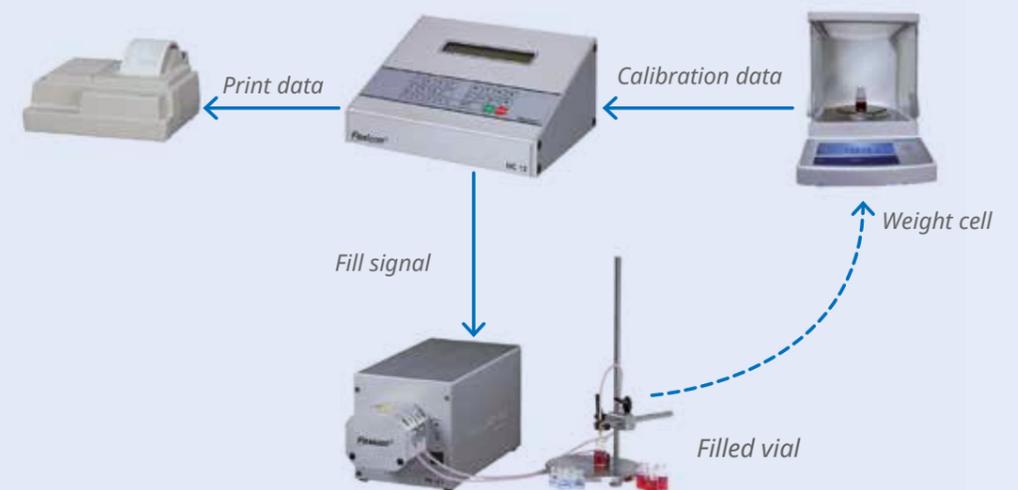
The PD12 and PD22 fillers are available in several versions as a stand-alone unit or for panel mounting. Panel mount versions can be ordered for vertical or horizontal integration and with a pump head in either anodized aluminium or in stainless steel.



Parallel Production Set-Up



Dynamic Recalibration Set-Up



Build custom production-scale filling systems of your own



\\ OEM trolley solutions for high capacity filling lines

- Flexibility of fill volumes from less than 0.2 ml to more than 250 ml
- High filling accuracy prevents costly overfilling—better than $\pm 0.5\%$ for most volumes
- Fast changeover between batches

The Flexicon trolley mounted filling systems are ideal for existing filling lines where existing pumps need to be replaced. Trolley designs are available for 2 to 16 filling stations with a master controller which can either be integrated into the trolley, or mounted on the control panel of the main machine.

Benefit from a fast validation process and obtain optimum capacity with no time-consuming stops due to splashing, foaming or dripping on the bottle track. Overfilling, lengthy cleaning and validation cycles are both eliminated, providing further savings.



Peristaltic filling systems and single-use fluid path from **one supplier**

Simplified validation and optimised pumping performance with Accusil tubing. We are the only peristaltic pump manufacturer in the world to manufacture our own tubing.

Accusil™ precision tubing

Prevents overfilling

Accurate and consistent dispensing requires having the right tubing inside the right pump.

Accusil™ is manufactured in our state-of-the-art extrusion facility to the highest quality, with a consistent wall thickness and a specific hardness for optimal tubing restitution.

- Full biopharmaceutical compliance with USP Class VI, Ph. Eur. 6.8 Chapter 3.1.9, ISO 10993 and FDA CFR 177.2600
- Industry leading validation pack available
- 100 % traceability with laser-etched lot number, product specification and use-by-date
- Manufactured in an ISO 14644-1 Class 7 environment at state-of-the-art tubing production facility
- Double-bagged for protection against contamination
- Laser etched for full traceability
- Post-cured after extrusion for superior purity
- Fully sterilisable by gamma radiation, autoclave or ethylene oxide
- Animal Derived Content Free



asepticsu™ single-use assemblies

A sterile and reliable fluid path

The combination of asepticsu and the gentle pumping action of Flexicon's peristaltic technology increases yield, lowers risk, and helps to reduce time to validation.

The USP Class VI single-use fluid path is fully traceable from end-to-end and is simple to validate. From the bag, to the tubing, through the pump, to the filling nozzle, asepticsu provides a fully assembled and lot traceable single-use solution.

asepticsu is manufactured in our ISO Class 7 cleanrooms then pre-sterilised using a validated gamma irradiation process and double-bagged ready for use.

asepticsu single-use fluid paths matched with Flexicon fillers guarantee:

- Lower cost and time to validation
- Elimination of risk of contamination
- Prevention of costly over-filling
- Efficient production of small batches of product



BIOTECHNOLOGY AND PHARMACEUTICAL SOLUTIONS



Watson-Marlow Fluid Technology Solutions

Watson-Marlow Fluid Technology Solutions supports its customers locally through an extensive global network of direct sales operations and distributors

wmfts.com/global

