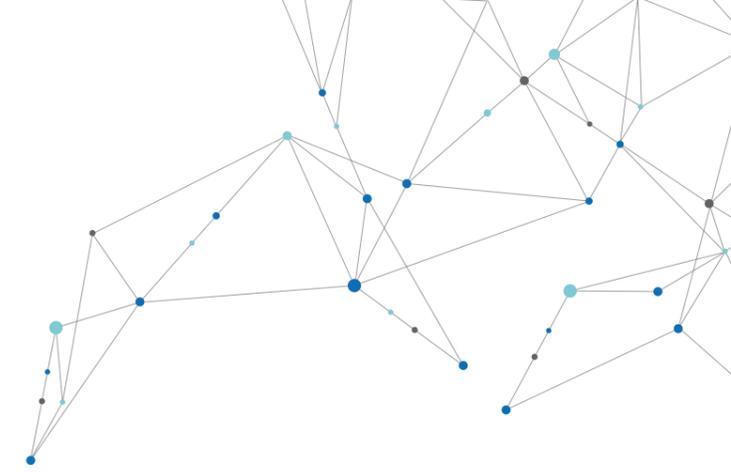




WM architect
single-use solutions

Your partner for
fluid path excellence

WATSON
MARLOW Fluid
Technology
Solutions



Your partner for fluid path excellence

Optimise your process with a wide range of fluid management innovations from WMArchitect™ single-use solutions.

An experienced, collaborative approach

Our experienced, bioprocessing specialists offer customised designs from an extensive component library to meet your specifications, as well as a selection of standard, ready-to-use single-use assemblies.

We follow a flexible, open architecture approach to improve efficiency in your production and support solutions with rigorous validation studies and tailored regulatory and compliance packages.

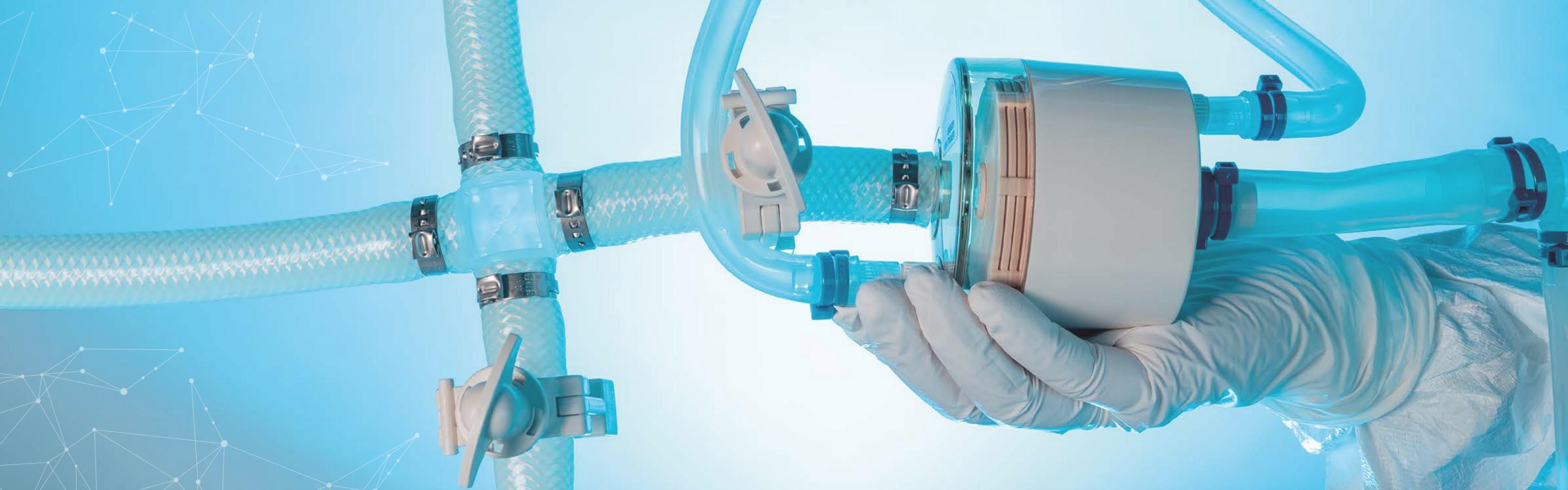
For an end-to-end fluid management solution from one supplier, WMArchitect single-use solutions can be used in combination with our best-in-class BioPure components, Watson-Marlow and Flexicon peristaltic pump technologies and filling solutions.

Confidence in quality

As your trusted partner and a highly skilled extension of your quality system, we work with you to ensure complete confidence in product quality and sterility.

For confidence in quality and trust in supply as you scale-up, all WMArchitect single-use solutions are manufactured, pre-assembled and packaged at our global network of state-of-the-art Class 7 cleanrooms.

- Complete confidence in product quality with our team as a trusted and skilled extension of your quality system
- A global manufacturing and supply network to ensure robust lead times and supply security
- With an open architecture approach, our specialist team design customised, single-use assemblies ensuring flexible integration throughout your process
- Reduce your regulatory burden with our expert team which manages regulatory compliance and validation testing



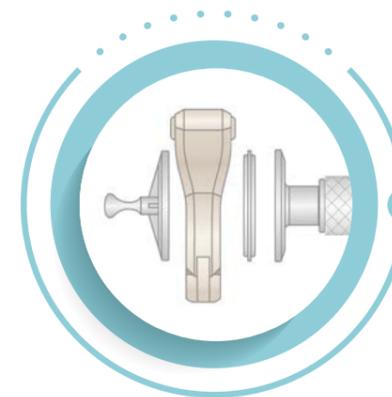
Customised Designs

Optimise your process with custom-designed assemblies to meet your specific requirements. The open architecture model allows full flexibility and compatibility with existing fluid-contact materials used in your process.

We understand that often, off-the-shelf products are merely a starting point. We customise our standard products to provide a complete and tested solution from a single supplier that is tailored to meet your specific requirements.

- Complete confidence in product quality
- Flexible integration with an open architecture approach
- Support of internal validation protocols
- Designed to reduce your validation burden
- Product quality assurance with 10^{-6} SAL (Sterility Assurance Level)
- Use in combination with Watson-Marlow peristaltic pumps or Flexicon filling systems for an end-to-end fluid management solution
- Supply security with Watson-Marlow's global manufacturing and supply network

STEP 1



Design consultation

Technical drawings of Customised Designed assemblies from an extensive component library as well as a selection of standard, ready-to-use Fluid Transfer assemblies.

STEP 2



Assembly

Manufactured, pre-assembled and packaged in Watson-Marlow ISO 14644-1 Class 7 cleanrooms, all lot traceable and available with 10^{-6} SAL.

STEP 3



Documentation

Provided with certificates of conformance, irradiation certificates and full validation packages (specifically engineered for Customised Design assemblies).



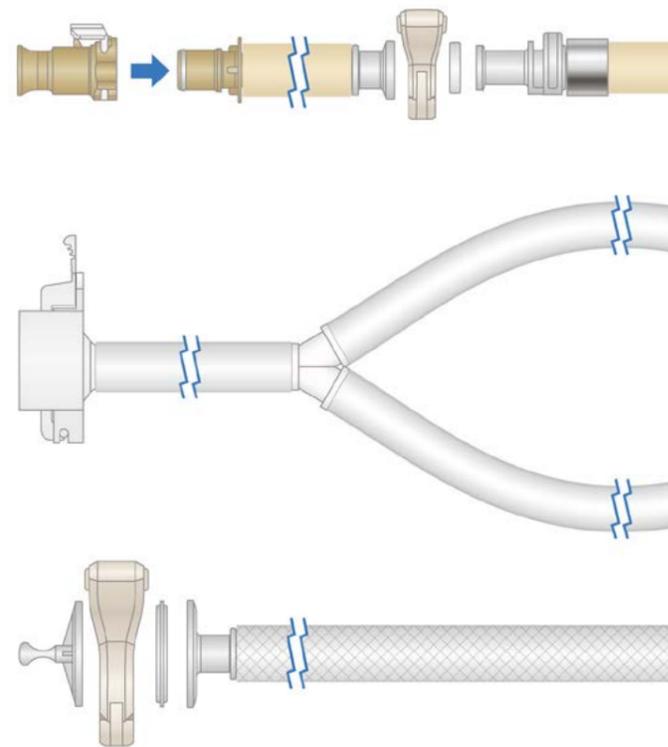
Fluid Transfer

Optimise fluid transfer between equipment and process steps.

Our specialist team has designed and standardised a selection of ready-to-use, pre-designed assemblies, all with lot traceable tubing and components. The ready-to-use, pre-designed assemblies use various connection formats and can be selected from a menu of validated components.

Standard Fluid Transfer assemblies include:

- Extended Loadsure elements
- Extended Double-Y elements
- Tubing and hose sets



Standard/pre-configured Fluid Transfer assemblies are available non-irradiated for quick turn-around times. Irradiated solutions with a 10^{-6} SAL are available on request.

- Complete product traceability
- Large component library to choose from
- Support with internal validation protocols
- Standard configurations available for reduced turn-around times
- Non-irradiated or irradiated assemblies for process flexibility (sterility assurance optional)
- Flexible integration with an open architecture approach
- Use in combination with Watson-Marlow peristaltic pumps for an end-to-end fluid management solution
- Supply security with Watson-Marlow's global manufacturing and supply network



Complete confidence in product quality



Fill/Finish

Safeguard your therapeutic during the filling process with a wide range of sterility-assured assembly configurations.

Representative assemblies are routinely tested for bioburden, particulates and endotoxin. Where further security is needed, our validation experts can provide lot-release testing to meet your quality requirements.

- Complete confidence in product quality
- Designed to reduce your validation burden
- Support of internal validation protocols
- Product quality assurance with 10⁻⁶ SAL (Sterility Assurance Level)
- Flexible integration with an open architecture approach
- Use in conjunction with Watson-Marlow peristaltic pumps or Flexicon filling systems for an end-to-end fluid management solution
- Supply security with Watson-Marlow's global manufacturing and supply network

For fill/finish fluidpath to full cGMP compliant automation, Flexicon is the preferred liquid filling choice for GMP regulated industries



Validation Testing

The WMArchitect single-use solutions range is fully supported by our experienced validation testing specialists.

We offer bioprocessing expertise and tailored validation packages to help reduce your regulatory burden.

Our validation testing team will design your validation studies using the most up-to-date, industry-recognised standards alongside our fully qualified testing partners. We provide a bespoke results assessment to ensure your specific quality assurance requirements are met.

Our decades of expertise in biopharmaceutical equipment manufacture ensure that your validation data analysis is rigorous and can be trusted.

Protocols can cover one-off testing or lot-release testing, and include standards such as:

- Endotoxin (USP <85>)
- Particulate (USP <788>)
- Bioburden (ISO 11737)
- Leak/integrity (pressure decay) (ASTM F2095)
- Extractable and leachable (BPOG/ USP <665>)
- Sterility (10⁻⁶ SAL/ USP <71>)
- Nitrosamine (USP <1469>)
- Chemical compatibility
- Functional, for example pressure rating
- Other, tailored to your specific validation needs



WMarchitect
single-use solutions

Delivering security in life-saving therapies

We are a trusted partner for biopharmaceutical companies worldwide, delivering solutions that enable confident scaling-up from pilot to production.

A Cancer Research facility is among a growing contingent of clinical trial sites that have adopted WMArchitect fill/finish single-use assemblies.

The Biotherapeutics Development Unit (BDU) is a modern, MHRA licensed, fully GMP-compliant facility with their own sterile filling lines for development and production of novel Investigational Medicinal Products for phase I clinical trials.

Used in conjunction with two Flexicon FP50 automated filling and stoppering machines, the fill/finish solution helped the BDU eliminate the need for cleaning validation and simplify

traceability of applied product contact components.

"In terms of traceability, all the documentation is provided with the validation pack, which makes our job much simpler. Previously, we were either performing manual pipetting or using external resources. We order using a single part number, which simplifies inventory management, and the system arrives pre-configured so we are ready to go. Everything is fully integrated with standard connections, so set-up time is virtually zero."

said John Emerson, who was Deputy Production Manager at Cancer Research BDU at the time.

Integrate effortlessly with...



Our range of peristaltic Watson-Marlow pumps are scalable, robust and developed to Optimise the performance of processes that demand sterility and precision.



Watson-Marlow Fluid Technology Solutions is the only peristaltic pump manufacturer to make its own tubing, engineered to work with our pumps as a complete solution. Manufactured in our ISO 14644-1 class 7 cleanrooms, our validated tubing delivers accurate, repeatable and long-term pumping performance.



Flexicon's wide range of aseptic vial fill/finish systems offer class-leading precision, efficiency and flexibility. The low shear, gentle pumping action of Flexicon's peristaltic filling machines ensures valuable product is transferred undamaged with high accuracy and precision.



BioPure fluid path components allow you to connect with confidence. Manufactured in ISO Class 7 cleanrooms, components are lot traceable, reducing validation risk in contamination-free applications.

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



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