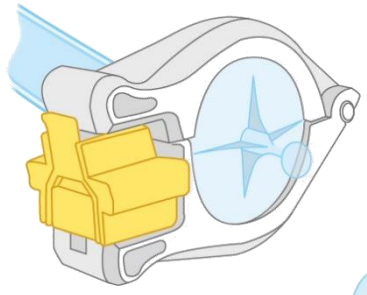
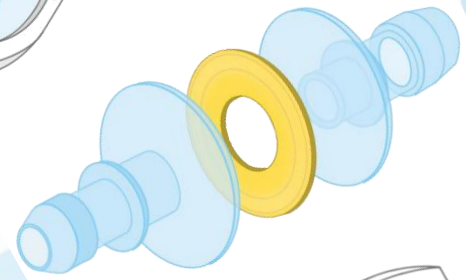
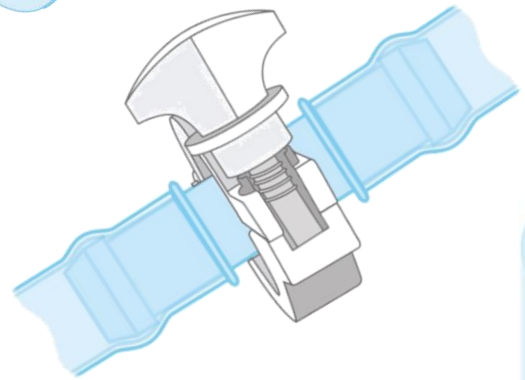
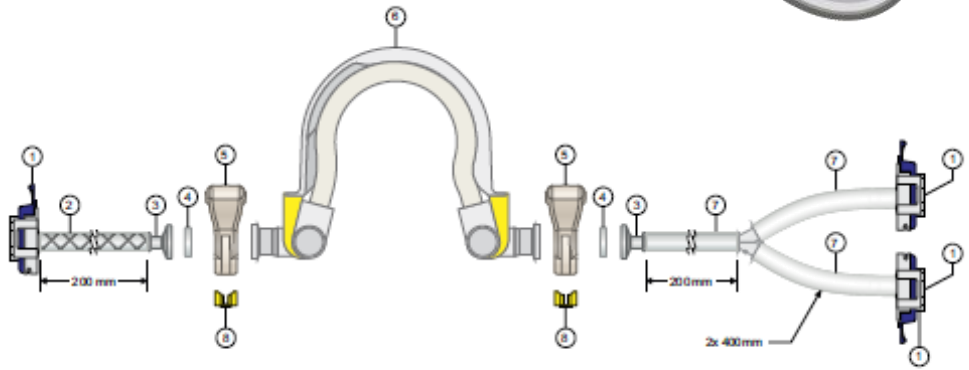
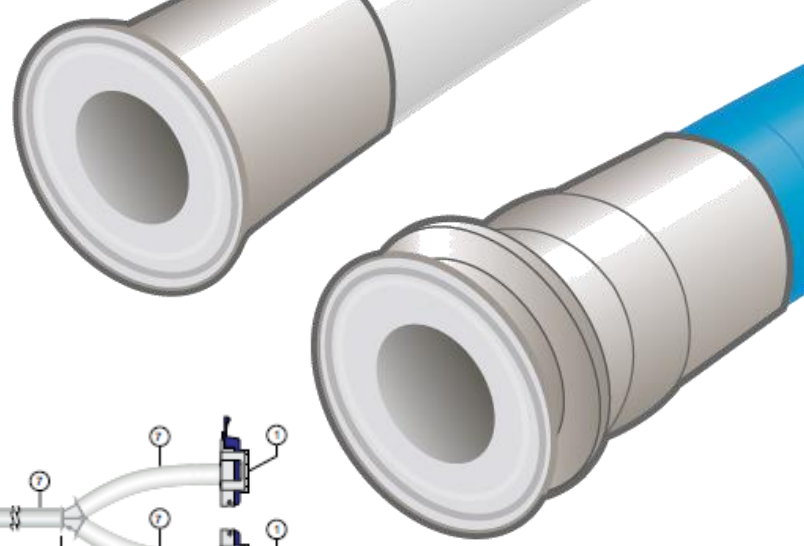
Fun Fact








200 mm
200mm
2x 400mm




Bredel
Hose Pumps
WATSON MARLOW

wm architect
single-use solutions

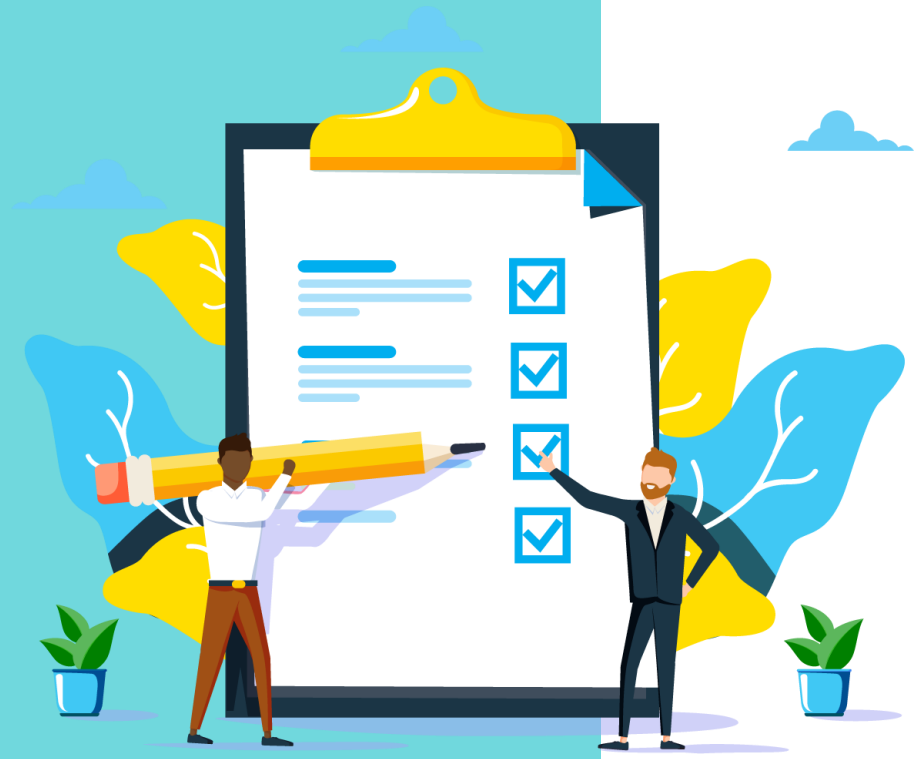
Requirements for Single-Use Systems

28. Swiss Cleanroom Community Event

Marco Renggli – Life Sciences SE

April 7, 2024

Spirax Group



Agenda

- Stainless Steel vs. Single Use Systems
- Requirements for SUS and its manufacturers
- Advantages
- Sterility

Stainless Steel vs. Single Use Systems

- Comparison
- Advantages
- Points to Consider

Picture: https://www.crbgroup.com/insights/biotechnology/sustainable-stainless-steel-or-single-use-systems

Stainless Steel

Requires CIP/SIP

- Water / WFI
- Detergents
- Steam
- Power
- Temperature & Time
- Cleaning Validation
- Room size and Infrastructure (Large Footprint)

Other considerations

- Capex projects
- Reduced Flexibility
- Hose Storage
- Changes are complex

Picture: https://www.crbgroup.com/insights/biotechnology/sustainable-stainless-steel-or-single-use-systems

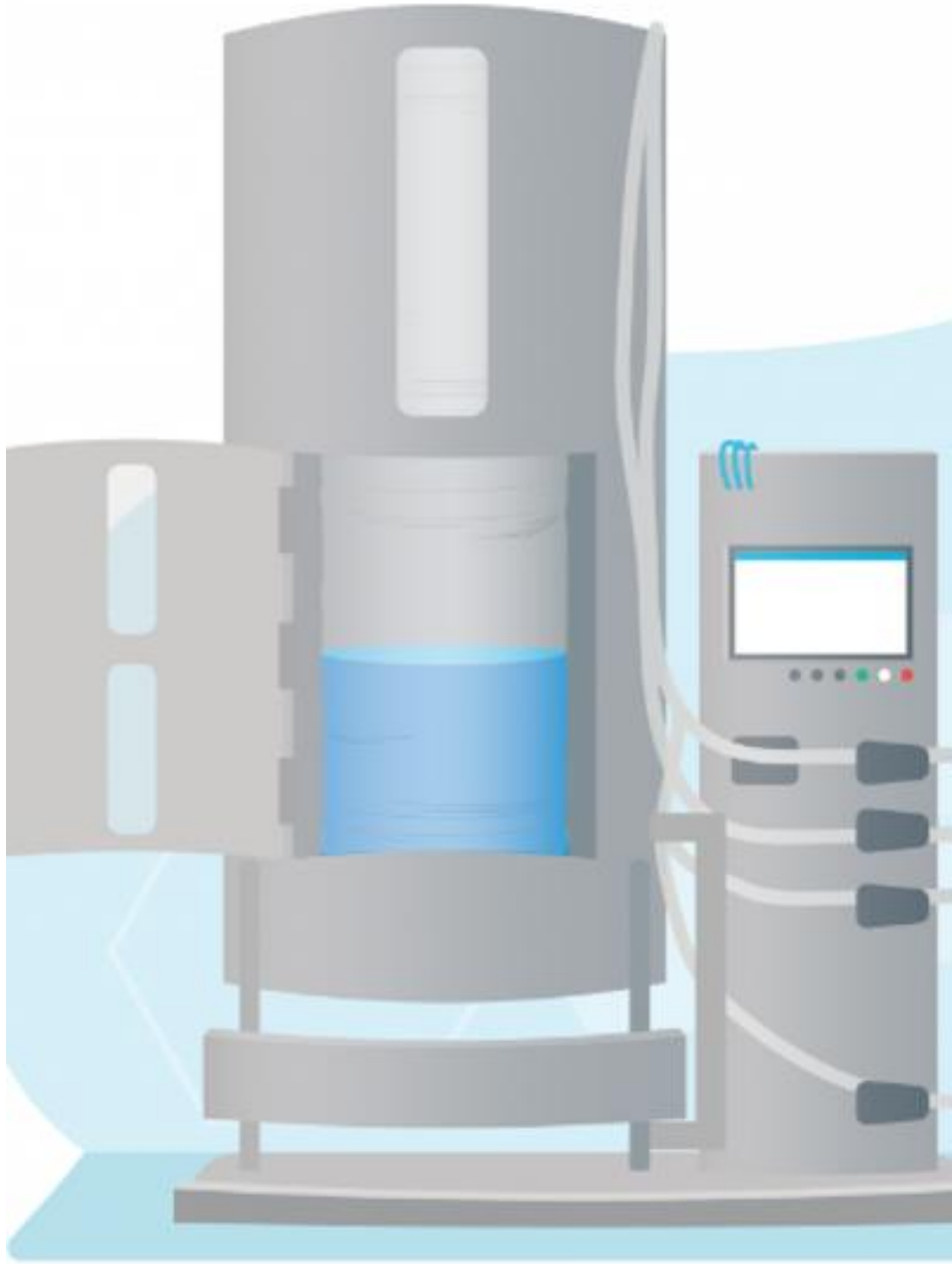
Single Use

Requires ~~CIP~~/SIP (Occasionally)

- Water / WFI (Greatly Reduced)
- ~~Detergents~~
- ~~Steam~~
- Power (Greatly Reduced)
- ~~Temperature & Time~~
- ~~Cleaning~~ Validation (Components,Fluid contact materials , Sterile product)
- Room size and Infrastructure (~~Large~~ Footprint)

Other considerations

- ~~Capex projects~~
- ~~Reduced~~ Flexibility (Increased)
- ~~Hose Storage~~
- ~~Changes are complex~~



Picture: https://www.crbgroup.com/insights/biotechnology/sustainable-stainless-steel-or-single-use-systems

Stainless Steel vs. Single Use Systems

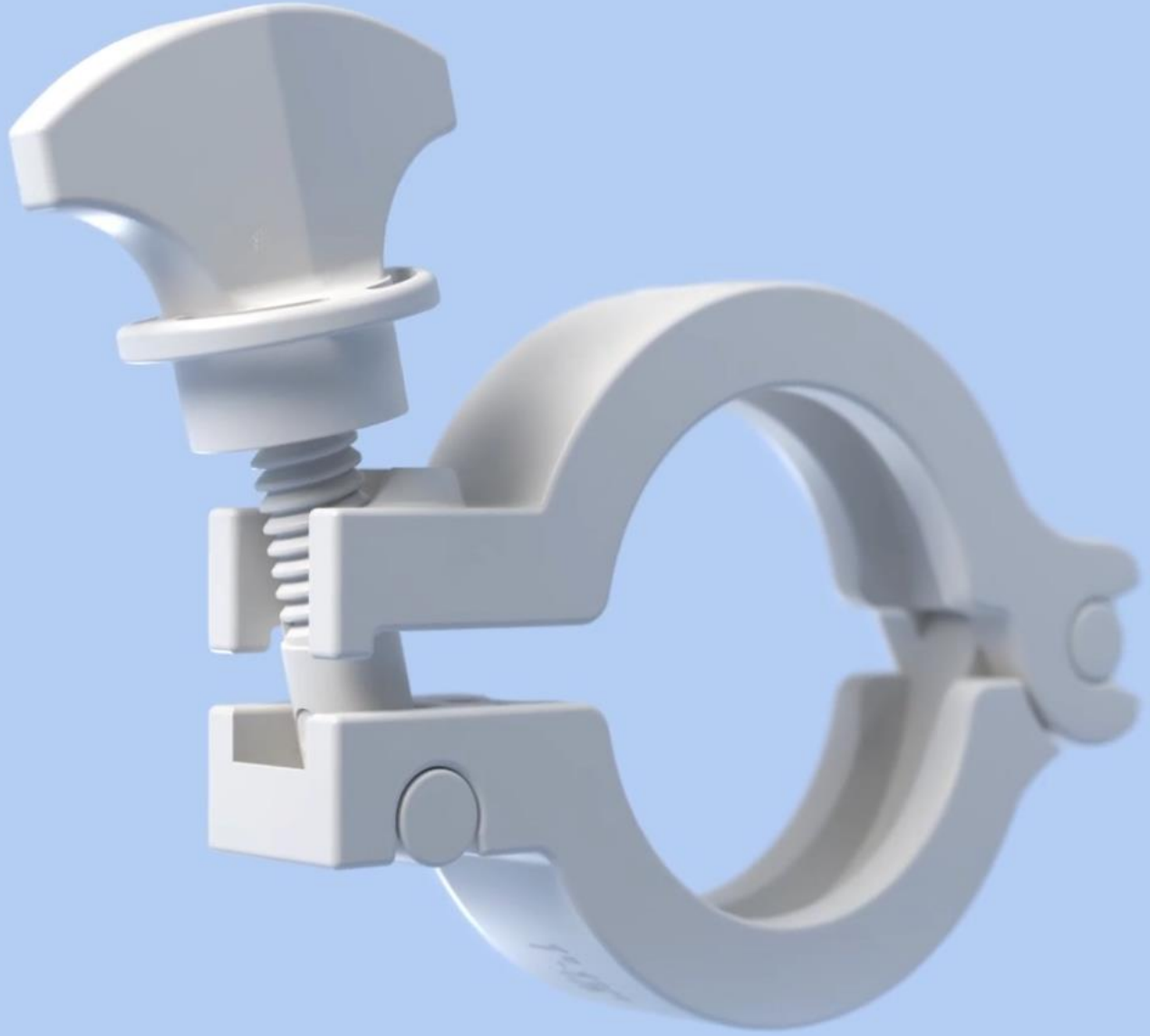
Sustainability / Environmental Impact

- Stainless Steel generates waste
  - Lots of contaminated water
  - Extensive energy usage

- Single Use Systems.
  - Recycling is difficult due to the potentially dangerous contact materials used.
  - Disposable of the SUS is currently via landfill or incineration
  - New materials are starting to be utilized in bags and component manufacturing in order to facilitate a recycling program or to reduce the carbon footprint of the product.
  - There are multiple industry studies proving that SUS have environment benefits compared to SS.

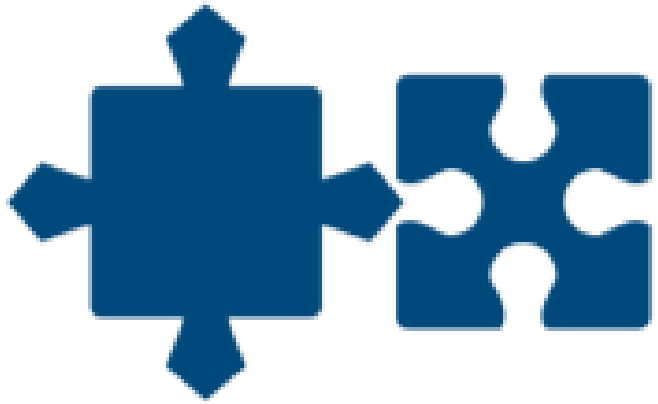
By re-engineering BioClamp's manufacturing process, we:

generate 22% less
CO_2 emissions



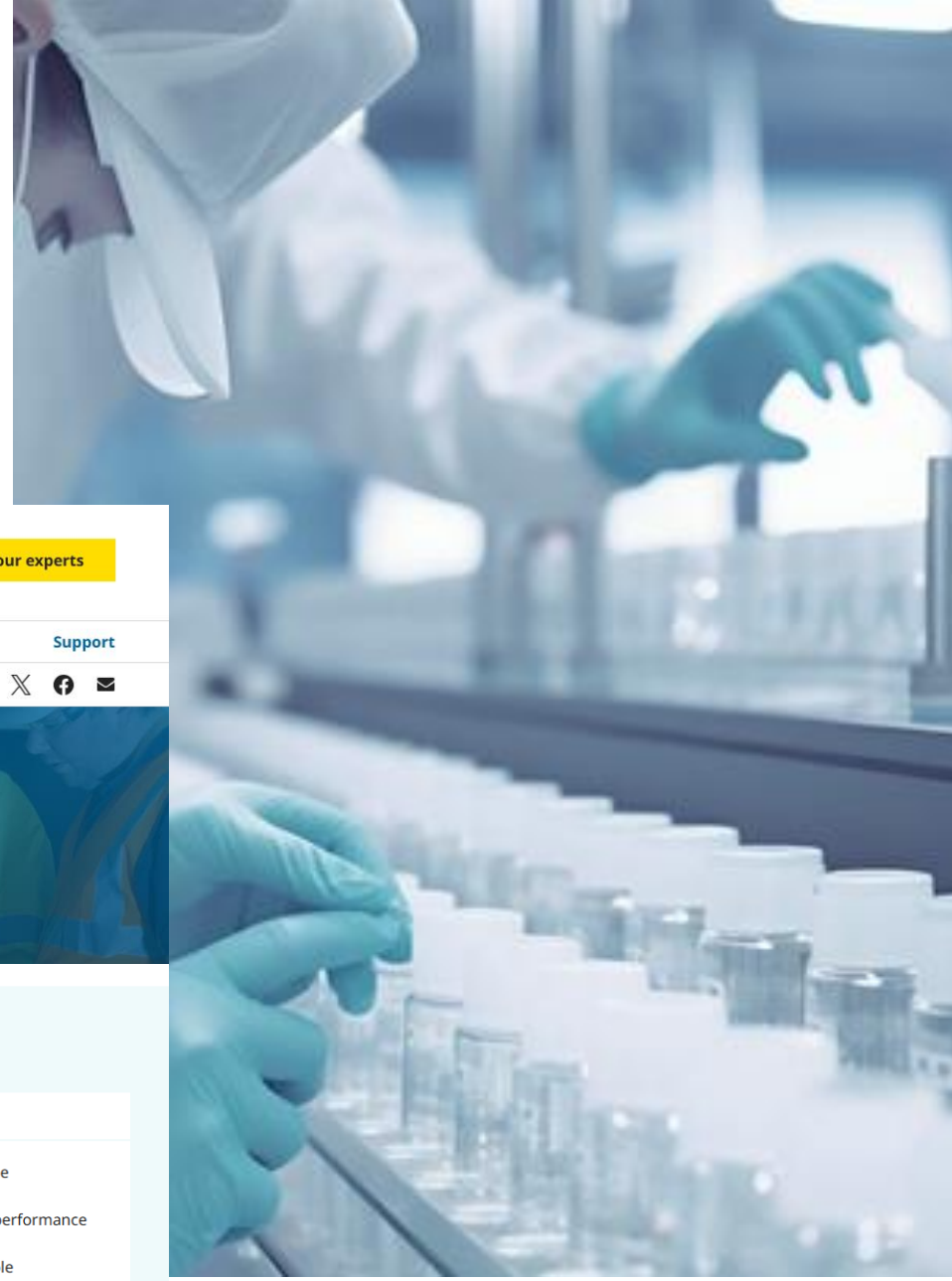
Requirements for Single-Use Systems

- **Mechanics (Seals, resistance, package integrity…)**
  - NO infrequent Assembly Errors
  - NO mis-sizing Tubing
  - NO mis-sizing Fittings
  - NO non-compatible Components
  - NO non-calibrated Closures



Requirements for Single-Use Systems

- Mechanics (Seals, resistance, package integrity…)
- **Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility…)**



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Home / Support / Chemical compatibility guide

Chemical compatibility guide

It is recommended that compatibility testing is always carried out to ensure the suitability of our products with your process chemical fluid. Actual chemical content can differ between suppliers and brands.

Duty fluid or chemical

Wine

WHISKY AND WINE

Material	Rating
ReNu Santoprene (Qdos)	-
NR Metering hose	A
NR Transfer hose	A
NBR-X	A
CWT FKM (Qdos)	A
ReNu SEBS (Qdos)	-
ReNu PU (Qdos)	-
CWT30 EPDM (Qdos)	A

Legend

- A — Compatible
- B — Reduced performance
- C — Not suitable
- - — No data

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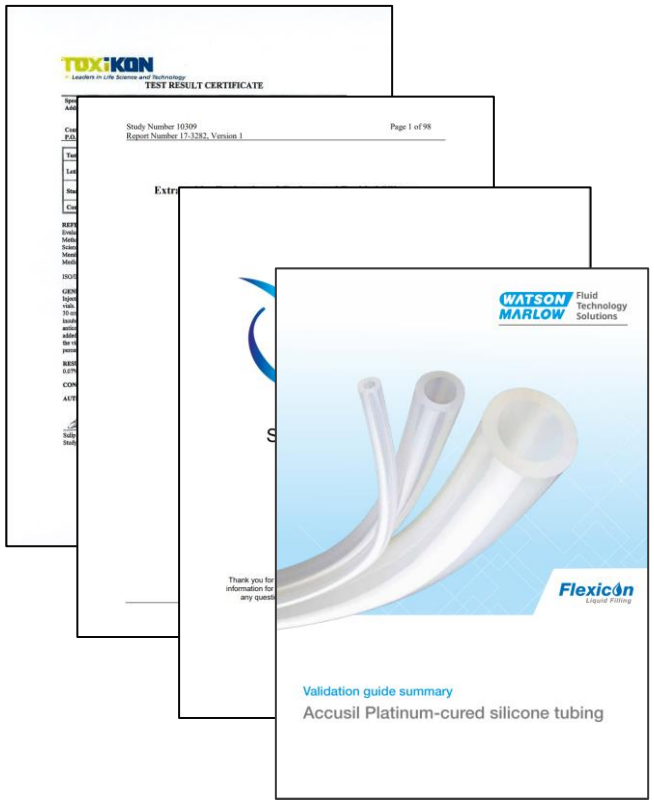
Requirements for Single-Use Systems

- Mechanics (Seals, resistance, package integrity…)
- Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility…)
- **Regulatory Requirements & Qualification**

- Endotoxin (USP <85>)
- Particulate (USP <788>)
- Bioburden (ISO 11737)
- Leak/integrity (pressure decay) (ASTM F2095)
- Extractable and Leachable (BPOG/ USP <665>)
- Sterility (ISO 11137/ USP <71>)
- Nitrosamine (USP <1469>)
- Chemical compatibility
- Functional, for example pressure rating
- Other, tailored to your specific validation needs

Documentation



Standard Documentation Package

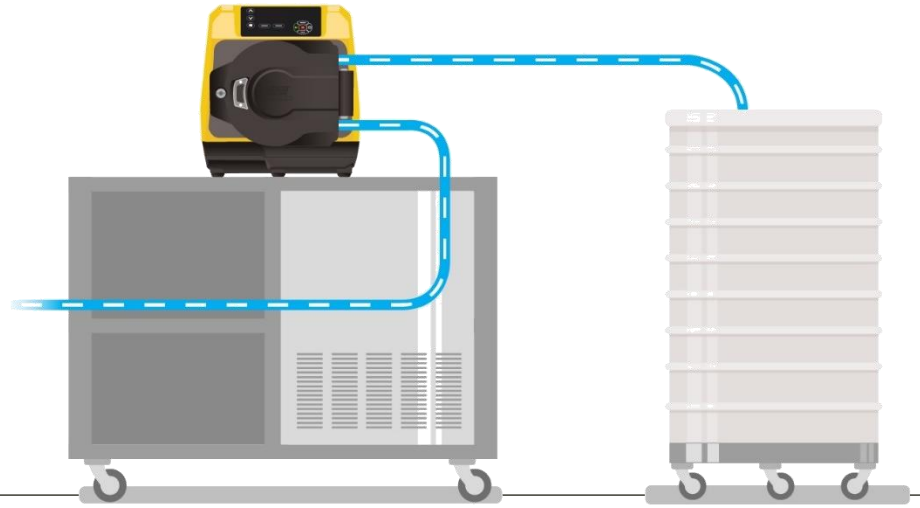
- Certificate of Conformance
- Certificate of Irradiation

Detailed Validation Packs

- Component CoCs, USP Tests, Extractables, Reach/Rohs Statements, Component Regulatory/Validation Guides

Requirements for Single-Use Systems

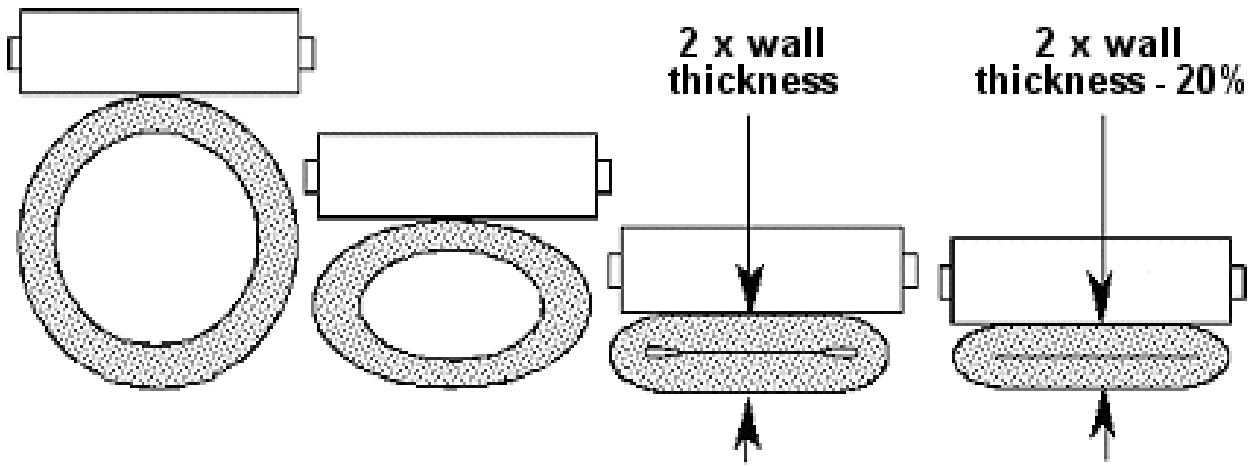
- Mechanics (Seals, resistance, package integrity…)
- Interactions (E&L, Biocompatibility, Endotoxins, Chemical Compatibility…)
- Regulatory Requirements & Qualification
- **Functional → don't forget the pump**



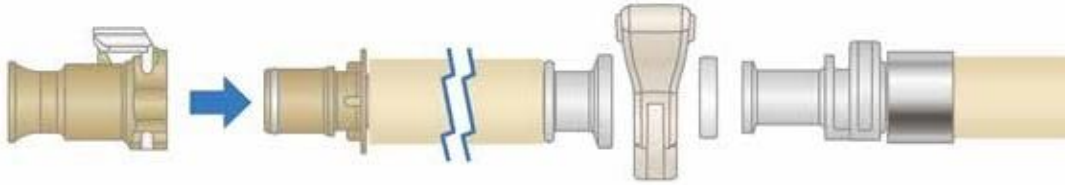
Don’t forget the Pump

Functional Requirement on Single Use Systems

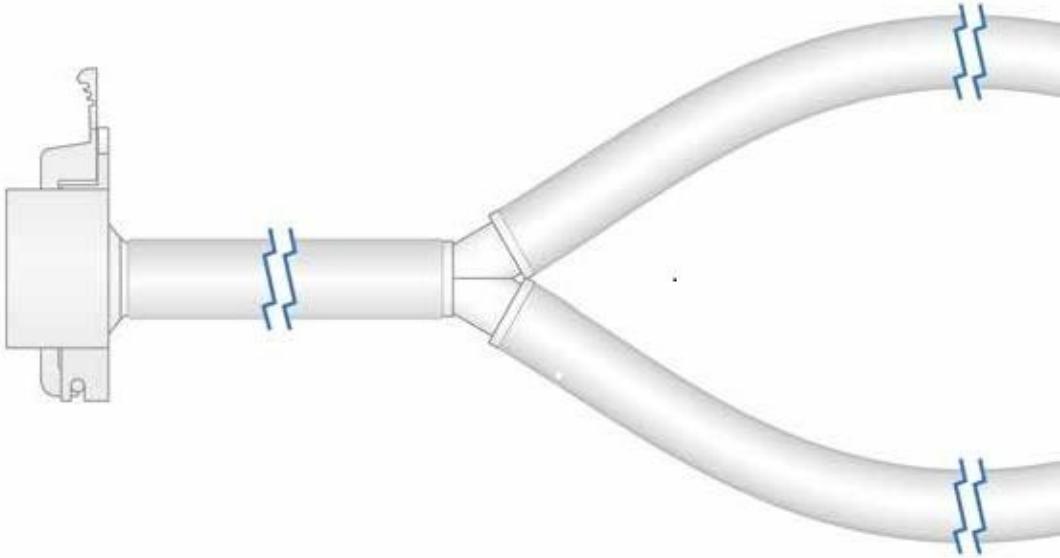
- Occlusion: Squeeze of tubing
- Restitution: Reinstating its original cross section



Standard Single Use Solutions



Select from hundreds of preconfigured and pre-priced assemblies with options for ***Triclamp, Aseptiquik and MPC connectors***



Straight Tubing Kits

- Pumpsil
- PureWeld XL
- Bioprene
- Silicone Braided Hose

Extended Y-Elements

- Pumpsil
- Bioprene
- STA-Pure

Extended Loadsure Elements

- Pumpsil
- Bioprene
- STA-Pure

Holistic Fluid Path Solutions

World-renowned Peristaltic Pump Family

WATSON MARLOW Pumps

&

Complete Fluid Path Management with expanded team and portfolio supported by a dedicated business unit

WM architect
single-use solutions

Anforderungen an Single use Systeme

Dienstag 02. September 2025 in Rheinfelden

Seminar-Themen

✓ Annex 1 - Anforderungen an Single use Systeme
✓ Sterilfiltration in der aseptischen Herstellung
✓ Anforderungen an Sterilfilter-Integrity-Testing (PUPSIT)
✓ SU-Flüssigkeitspfad und dessen regulatorischen Aspekte
✓ SU-Technologie mit Schwerpunkt auf Pumpen
✓ Single Use- Technologie in der Biopharma

Seminarprogramm

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