Design for Media Fills: Considering Sterility from the Ground Up

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18 October 2023









Media Fills

 Aseptic Process Simulation (APS)

Design

 to devise for a specific function or end

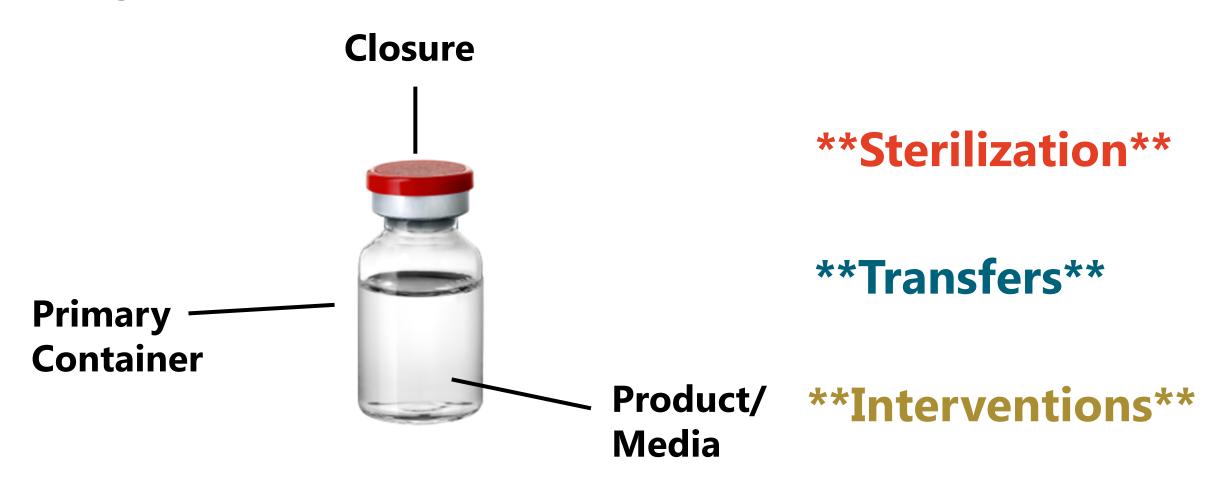


10,000 Foot View



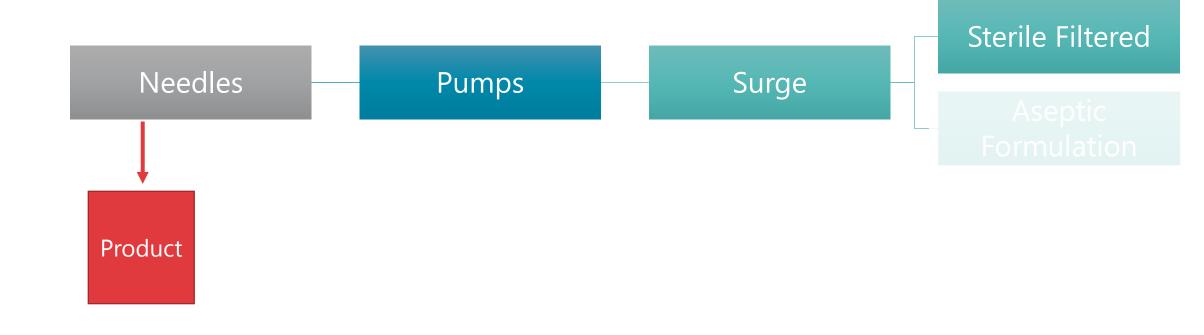


Pulling Threads from the Inside Out





Product Path Thread





Product Path - Pumps

Peristaltic Pump

Rotary Piston Pump

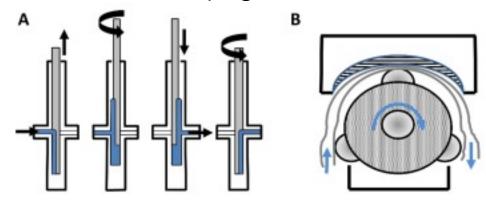


colanar.com

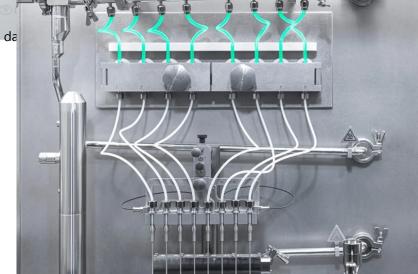


Time/Pressure System

Pumping Flows

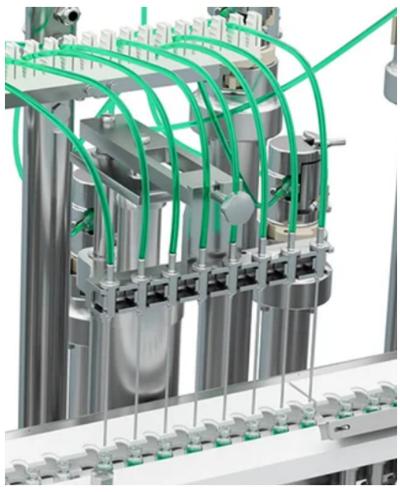


Tim Dreckmanna, Julien Boeuf, Imke-Sonja Ludwig, Jörg Lümkemann, Jörg Huwyler Low volume aseptic filling: Impact of pump systems on shear stress https://www.sciencedirect.com/science/article/pii/S0939641119313177





Product Path - Needles



syntegon.com



Product Path – Surge Vessel

Single Use Surge Bag



Stainless Steel Surge Vessel

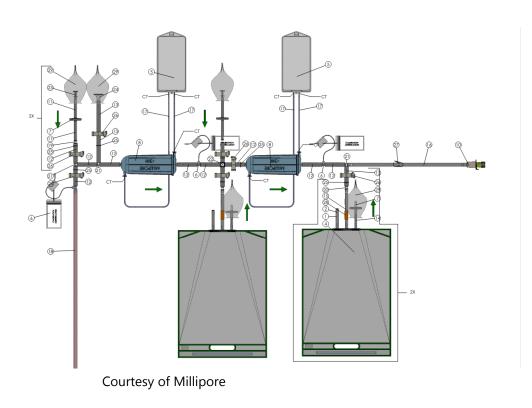


syntegon.com



Product Path – Sterile Filtration

Single Use Filter Assembly



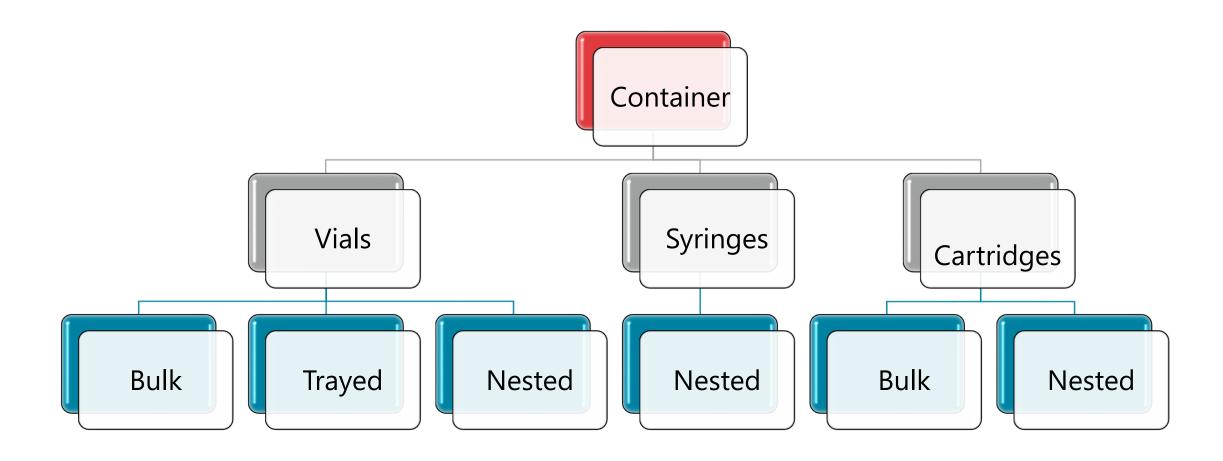
Fixed Filter Skid



Suncombe.com



Primary Container Thread - Presentations





Container – Presentations





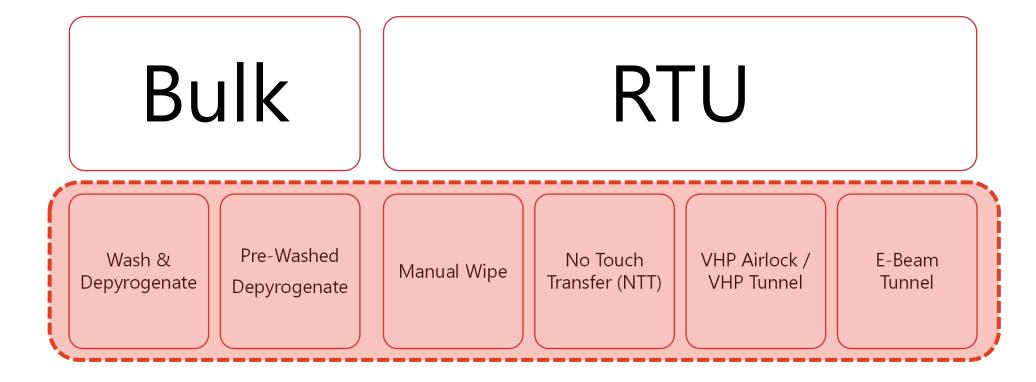
Ready To Use (RTU)





Primary Container - Sterilization

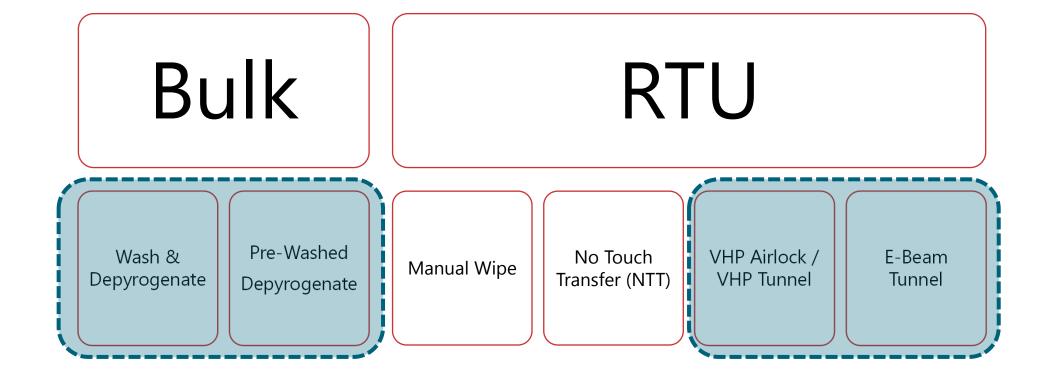
Sterilization





Primary Container - Transfers

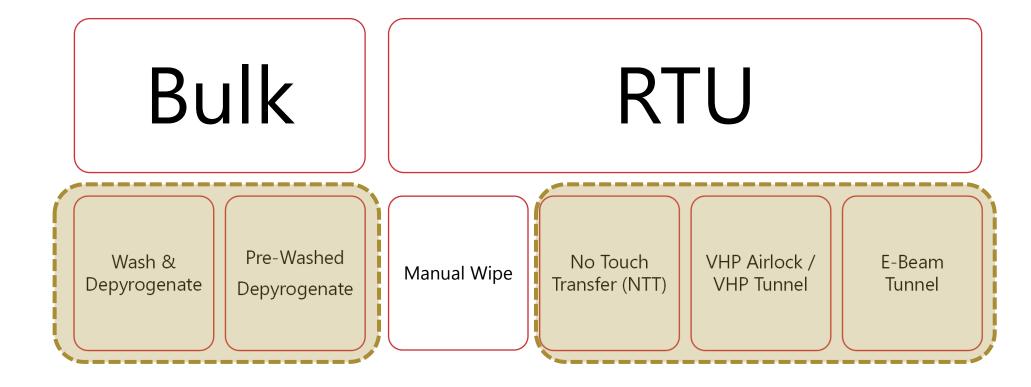
Transfers





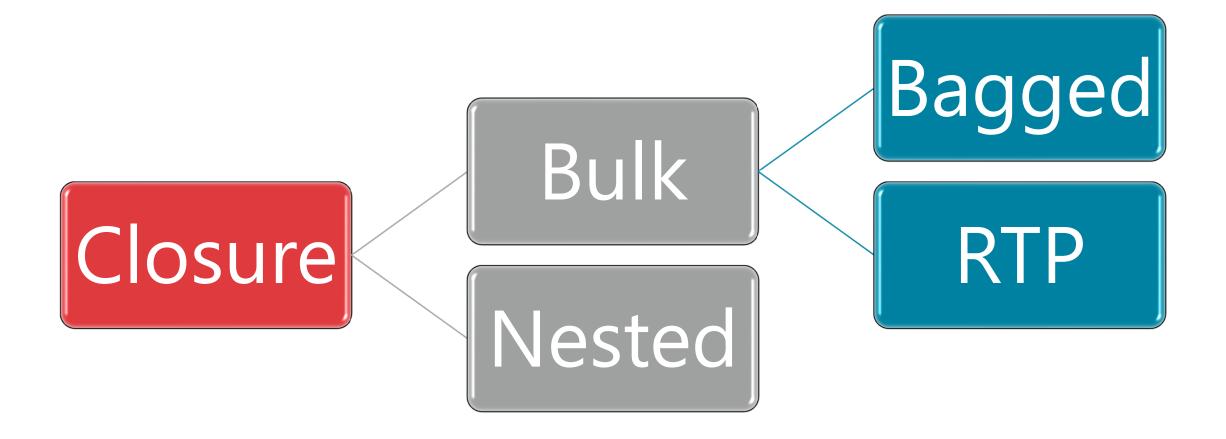
Primary Container - Interventions

Interventions





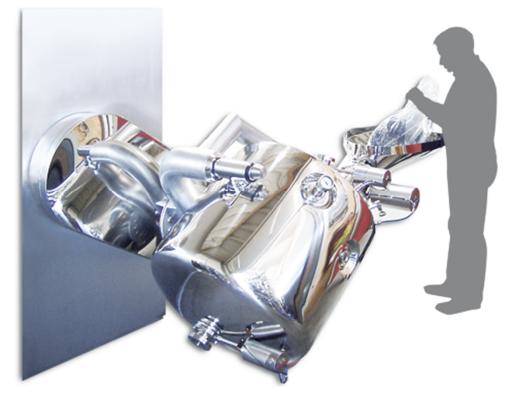
Closure Thread





Closure Thread

Stopper Processor



atecgroup.de

RTP Transfer



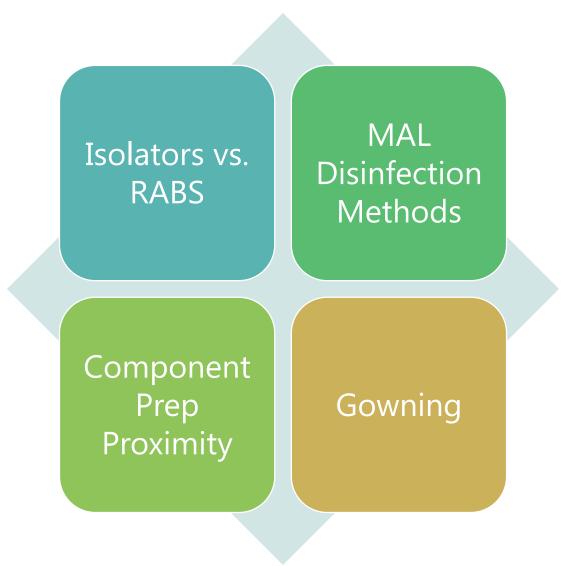
getinge.com



Autoclave Bag

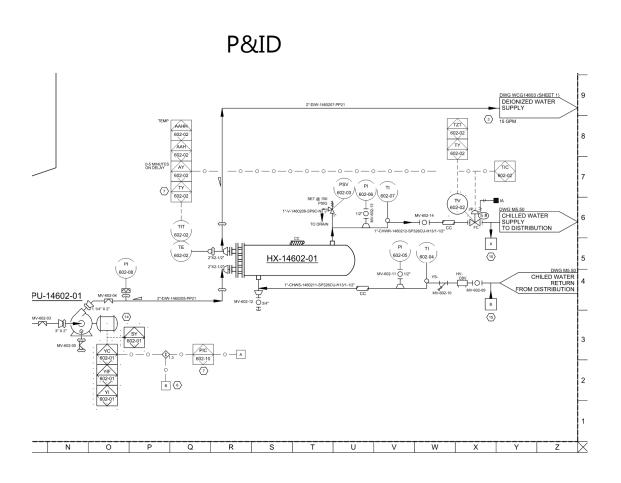


Broader Facility Links





Design Outputs



Product Quality Risk Assessment

4.0 Identification of Potential Failure Modes with Possible cGMP Impact												
Identify Where A Failure Would Affect Each Of The Operational Phases And Assign A Severity Level – Once an item has been identified as having an impact on the product or process complete Table 5.0 for each instance.		ransfer Plate nfeed Rotary Table	Infeed Rotary Table	Fare / Gross Weigh	Filling Station	Stopper Station	Cap Feeding / ransfer Station	Crimping Station	Reject Station	Discharge	CIP[/SIP	Dry Cycling
Tag#:	Description:	1	1		Ŧ	Ste	C Tre		- R			
-122U3	Dosing Vessel Pressure (Transducer)				Н							
-122B2	Dosing Vessel Pressure (Probe)				Н							
-122U5	Dosing Vessel Pressure Sensor Power Supply				Н							
-130N2	Needle Movement Motor Controller		L	L	Н	М	L	М	L	L		L
-130M1	Needle Movement Servo Motor		L	L	Н	М	L	М	L	L		L
-130V6	Needle Movement Suppressor-Diode											

0 Identifica	tion of Potential Effects	of Failure Mode		·		
Tag #:	Device:	Expected Result :	Severity Of Failure Mode:	Current Design Safeguards:	Recommended Additional Risk Mitigation:	Qualification Activities For Design Safe Guards
-95B4	Pressure Too Low Compressed Air	Equipment would hard stop. CIP/SIP would abort.	L, M, H	Alarm to indicate low compressed air pressure. Normally high logic.	N/A	10.9 Alarms & Interlocks
-96G2	Tare Weigh Load Cell Power Supply	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-96A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms 8 Interlocks
-97A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-98A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale fault(s).	N/A	10.9 Alarms & Interlocks
-99A2	Tare Weigh Load Cell	Equipment would hard stop.	L, M, H	Alarm to indicate scale	N/A	10.9 Alarms 8



Conclusion

