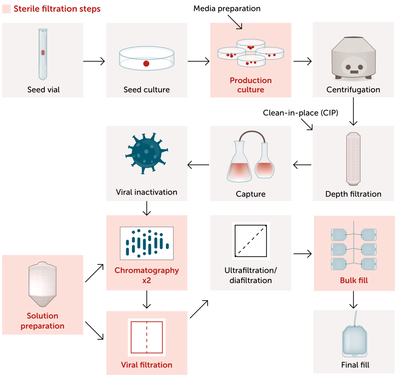
Sterile Filtration Solutions for Single-Use Bioprocessing Systems

Bioprocessing for monoclonal antibodies (mAbs) and other life sciences modalities relies on effective and efficient sterile filtration processes to remove contaminants that compromise product purity and yield in both small-batch systems and rapid large-scale manufacturing.



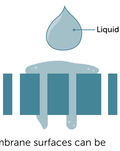
By leveraging filtration technology expertise, Entegris provides end-to-end engineered solutions for critical bioprocessing workflows. Here's how.

MATCHING FILTRATION TO THE WORKFLOW

Filtration must be used at multiple points in bioprocessing workflows for liquid and gas applications. At each step, the processing parameters for isolation of the molecule, the composition of the product, and the system/single-use design dictate the choice of filtration technology to integrate.

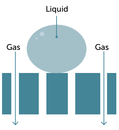
FILTRATION PARAMETERS THAT IMPACT SINGLE-USE INTEGRATION

Membrane Surface Chemistries: Liquid Filtration



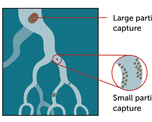
Membrane surfaces can be functionalized to become more hydrophilic, which allows the filter to wet-out more easily and allow for liquid processing.

Membrane Surface Chemistries: Gas Filtration



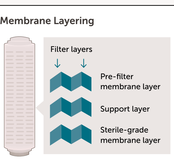
Conversely, membrane surfaces can be treated to be more hydrophobic, preventing liquid droplets from wetting the membrane and allowing for critical gas filtration.

Membrane Pore Morphology



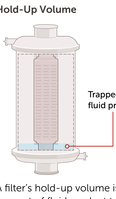
Through chemical processing and synthesis of membranes, pore morphology can be adjusted. Asymmetric pore structures allow gradual pore-plugging to occur and enhance a filter's capacity to filter a fluid stream, maximizing throughput.

Membrane Layering



Filters with multiple layers can isolate a drug molecule, such as a mAb, by removing other biological debris and contaminants. Pre-filter layers can remove larger particle loads, maximize throughput capacity, increase retention efficiency, and extend a downstream filter's life span.

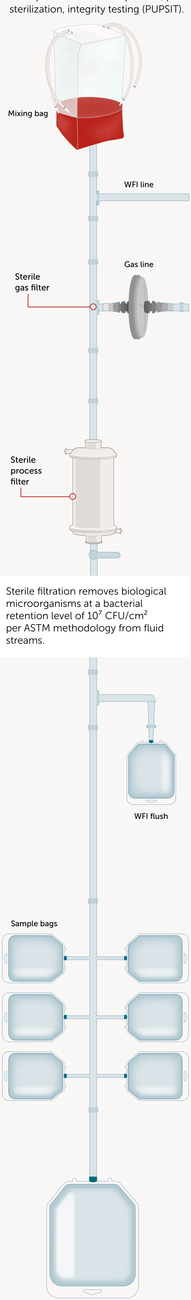
Hold-Up Volume



A filter's hold-up volume is the amount of fluid product trapped within the filter and not recoverable. Optimizing the filter capsule design reduces dead volume.

SINGLE-USE INTEGRATION WITH FILTRATION

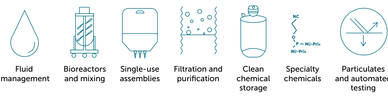
This is an example of a single-use assembly system setup for bulk filling and optimized to enable pre-use, post sterilization, integrity testing (PUPSIT).



Sterile filtration removes biological microorganisms at a bacterial retention level of 10^7 CFU/cm^2 per ASTM methodology from fluid streams.

CONSIDERING THE FULL PROCESS SPECTRUM

Sterile filtration solutions from Entegris can be adapted to a wide variety of bioprocessing steps, and they fit perfectly into workflows that use single-use Aramus™ bags. Entegris' engineered solutions and quality-by-design product help ensure product yield and safety in life sciences applications.



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