

## Overview

In addition to its existing facility, Savillex has expanded its integration services with the opening of a new facility in Eden Prairie, MN, USA. With redundancy in manufacturing sites, Savillex is now able to offer a higher degree of supply chain integrity to its customers. The new state-of-the-art Eden Prairie facility features an applications lab and an ISO Class 7 cleanroom designed specifically for the assembly of single-use systems. Each system is custom designed and hand assembled to ensure the highest levels of quality. Savillex assembles systems for all areas of bioprocess manufacturing, and the new facility will have a special focus on systems for the highly demanding storage and transfer of BDS (bulk drug substance).



## Single Use Center of Excellence

The Eden Prairie facility, open in April 2020, is built for the assembly of single-use systems for the bioprocessing industry. It features an ISO Class 7 cleanroom with full wall plenum air returns and continuous monitoring of particles, temperature, humidity and differential pressure to ensure superior environmental control. The cleanroom is purposely designed for the assembly and packaging of single use systems.

A fully featured applications laboratory allows for the testing of new single-use products and process modeling for custom assemblies. Short run prototypes are built and tested in a wide variety of chemical and environmental exposures. The lab is capable of modelling extremely challenging processes for single-use systems like dry heat sterilization up to 250 °C and flash freezing down to liquid nitrogen temperatures (-196 °C).

## Full Customization

The facility employs an open architecture model, enabling the capability to perform high levels of single-use customization using components from almost any supplier, as well as custom parts manufactured in-house. Savillex design engineers can even customize containers - from the addition of ports and dip tubes, to the modification of overall container dimensions for specific applications. Savillex's manufacturing capability also includes injection molding, machining, over molding, fusion welding and in-house tool design and fabrication with expertise in a wide range of plastics including fluoropolymers and other challenging materials.



## Container Size Availability

Savillex Purillex® containers are made from PFA and FEP in sizes from 50 mL up to 2000 mL. Stability vials also available, ranging from 3 mL to 15 mL. All containers can be customized with addition of ports and dip tubes. Custom containers with dimensions designed to meet specific requirements can also be supplied.

## Regulatory Compliance

Savillex single-use assemblies comply with the following testing:

- USP <85> Endotoxins
- USP <87> Cytotoxicity
- USP <88> Biological Reactivity
- USP <661> Physicochemical
- USP <788> Particulates



All assemblies are visually inspected before and after packaging. Ready-to-use products are tested for bioburden prior to sterilization. All sterilization cycles used for ready-to-use products are validated to a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Additional tests are available upon request.

## Substantial Single-Use Experience

Savillex staff have decades of experience designing, validating and implementing single-use systems for critical bioprocess applications, including direct experience as end users in the bioprocess industry. Extensive real-world experience enables Savillex to develop single-use solutions across a wide range of applications. Savillex offers a complete technical consulting service, from design through to implementation.

## Global Reach-Local Presence

With local presence in North America and a network of trusted partners around the world, Savillex has manufacturing and supply capabilities to meet the most challenging requirements. Two US-based manufacturing facilities, direct supply infrastructure, plus US and EU based distributors ensure that products are delivered on time and to exact specifications. With integration capabilities at ISO Class 7 cleanrooms in two separate locations, supply chain integrity is assured. On-site audit visits are welcomed.