Biologic manufacturing capacity expansion with single-use technologies

Key variables to consider

cytiva

The following presentation is based on a simulation of a 2 × 2000 L mAb process. The simulation compares a single-use process train (SU) with a comparable stainless steel-based process train (SS), both modeled in a traditional, stick-built facility. Are you interested in a simulation of your biomanufacturing process? With our range of simulation tools, we can assist in this, whether it is for scale up/down, “de-bottlenecking”, process intensification, transition from stainless to single use, or general optimization.

Manufacturing setup simulation for 2 × 2000 L mAb process

Titer	**3 g/L**
Overall process yield	**70%**
Number of products per year	**4**
Facility utilization	**80%**
mAb output per year	**168 kg**

TITER

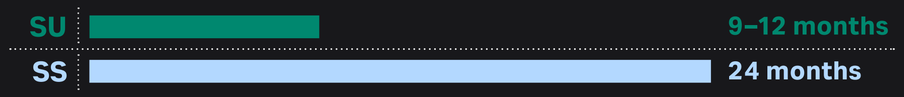
	2.0	3.0	4.0
2 × 500 L	28	42	56
2 × 1000 L	56	84	112
2 × 2000 L	112	**168**	224
4 × 2000 L	224	336	448

Assumptions: 70% recovery through purification of 20 batches per year, per reactor

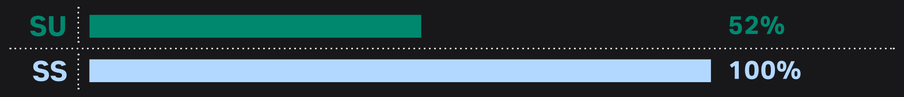
Time to market and capital expenditure

Single-use vs stainless steel technologies

Time to market



CAPEX



CAPEX = capital expenditure

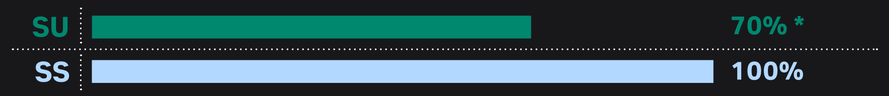
Stainless steel technologies
take longer to procure, source, qualify, and validate.
The initial cost is also higher.

Single-use technologies
provide faster time to market at lower capital expenditure.

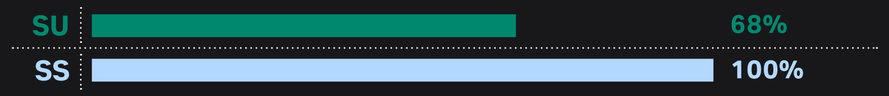
Operating expense

Single-use vs stainless steel technologies

OPEX



OPEX — labor



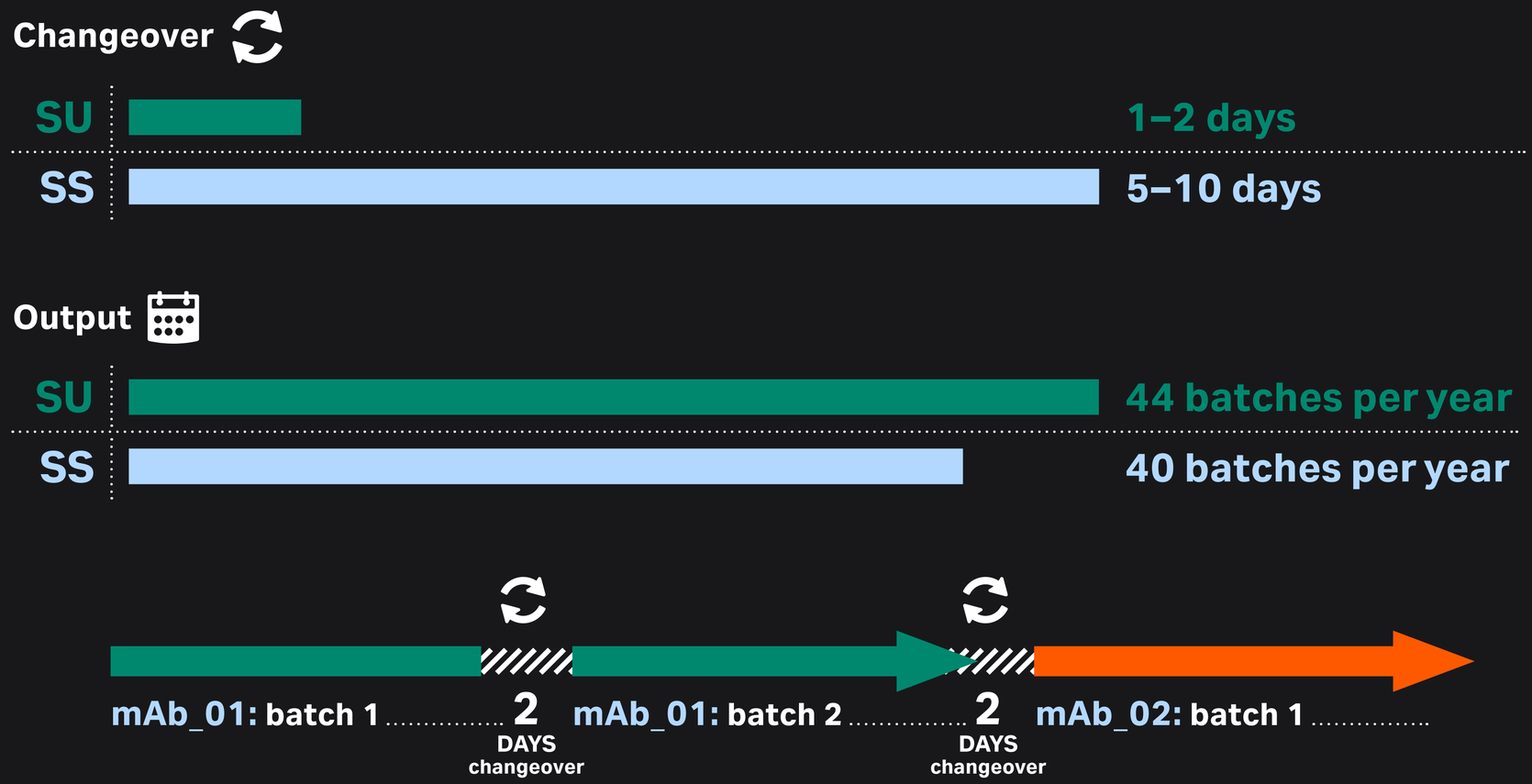
Single-use technologies allowed 32% reduction in labor, based on elimination of cleaning and sanitization in place (CIP, SIP), and related testing.

** Industry reports vary from 70% to 120%*

OPEX = operational expenditure

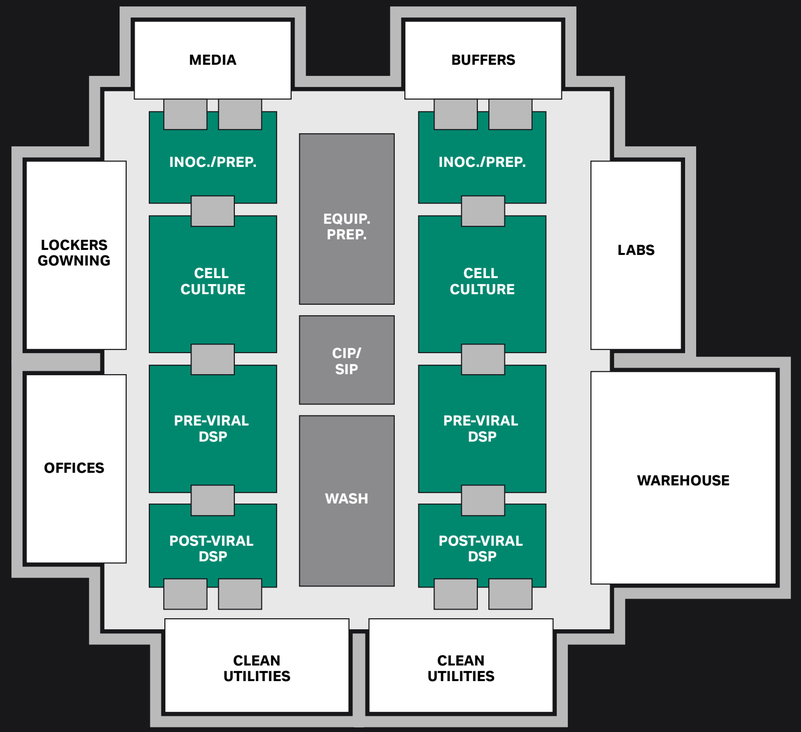
Changeover and output

Single-use vs stainless steel technologies

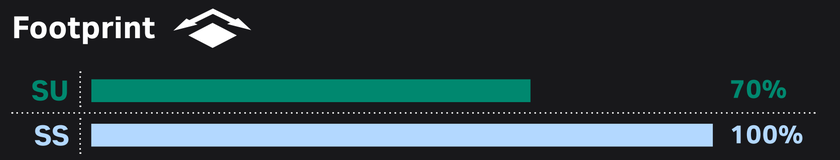


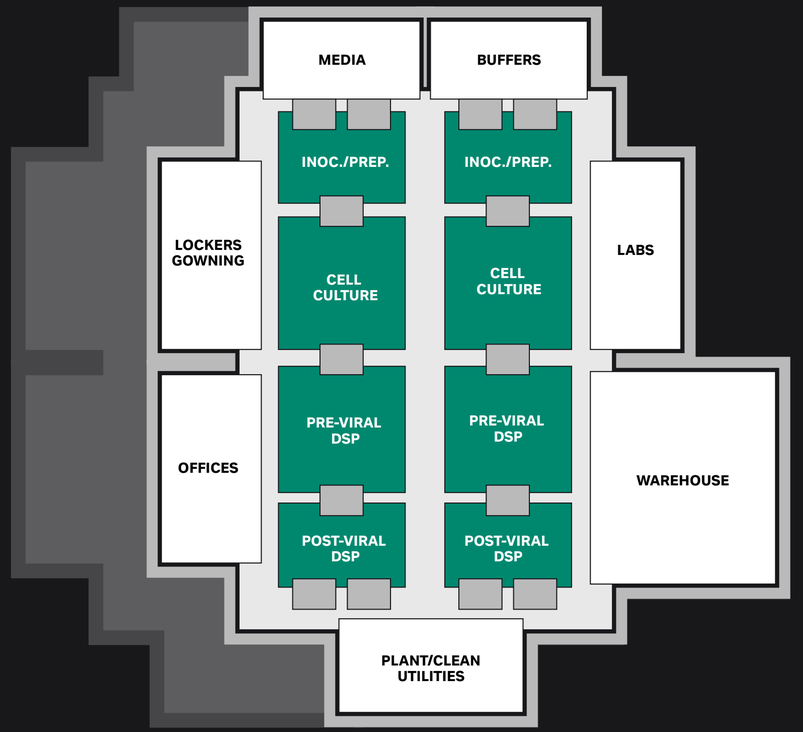
Footprint

Single-use vs stainless steel technologies



Stainless steel





Single-use

Single-use technologies enable smaller facility,
less cleanroom space — resulting in lower utilities and HVAC costs.

HVAC = central heating ventilation and air-conditioning DSP = downstream processing Equip. prep. = equipment preparation Inoc./prep. = inoculation/preparation

Cytiva's single-use technologies

Across the entire bioprocess workflow

Medium preparation:

Xcellerex™ XDUO 100 to 2500 L mixers, HyClone™ cell culture media

Buffer preparation:

Xcellerex XDUO 100 to 2500 L mixers, HyClone buffers and process liquids

Cell culture seed train

ReadyToProcess WAVE™ 25 system

Xcellerex XDR 200 L bioreactor

Xcellerex XDR 500 L bioreactor

Cell culture production

Xcellerex XDR 2000 L bioreactor

ReadyToProcess™ filter for CFF

Harvest operations

FlexFactory™ harvest

BioProcess™ NFF Pump System

Virus reduction

Xcellerex XDUO mixers

Purification operations

ÄKTA™ ready system

ReadyToProcess chromatography column

ReadyToProcess filter for CFF

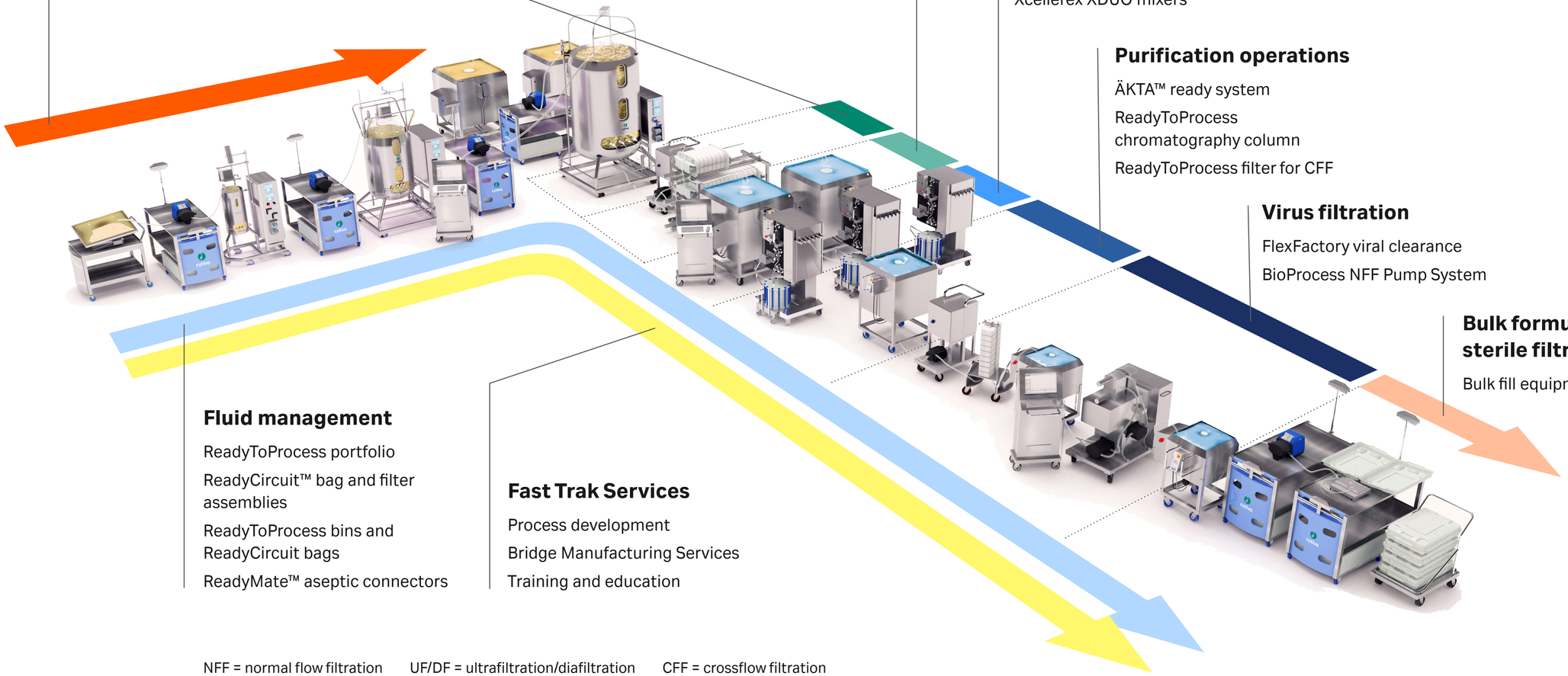
Virus filtration

FlexFactory viral clearance

BioProcess NFF Pump System

Bulk formulation and sterile filtration

Bulk fill equipment



Fluid management

ReadyToProcess portfolio

ReadyCircuit™ bag and filter assemblies

ReadyToProcess bins and ReadyCircuit bags

ReadyMate™ aseptic connectors

Fast Trak Services

Process development

Bridge Manufacturing Services

Training and education

NFF = normal flow filtration UF/DF = ultrafiltration/diafiltration CFF = crossflow filtration

cytiva.com/singleuse

For local office contact information, visit cytiva.com/contact

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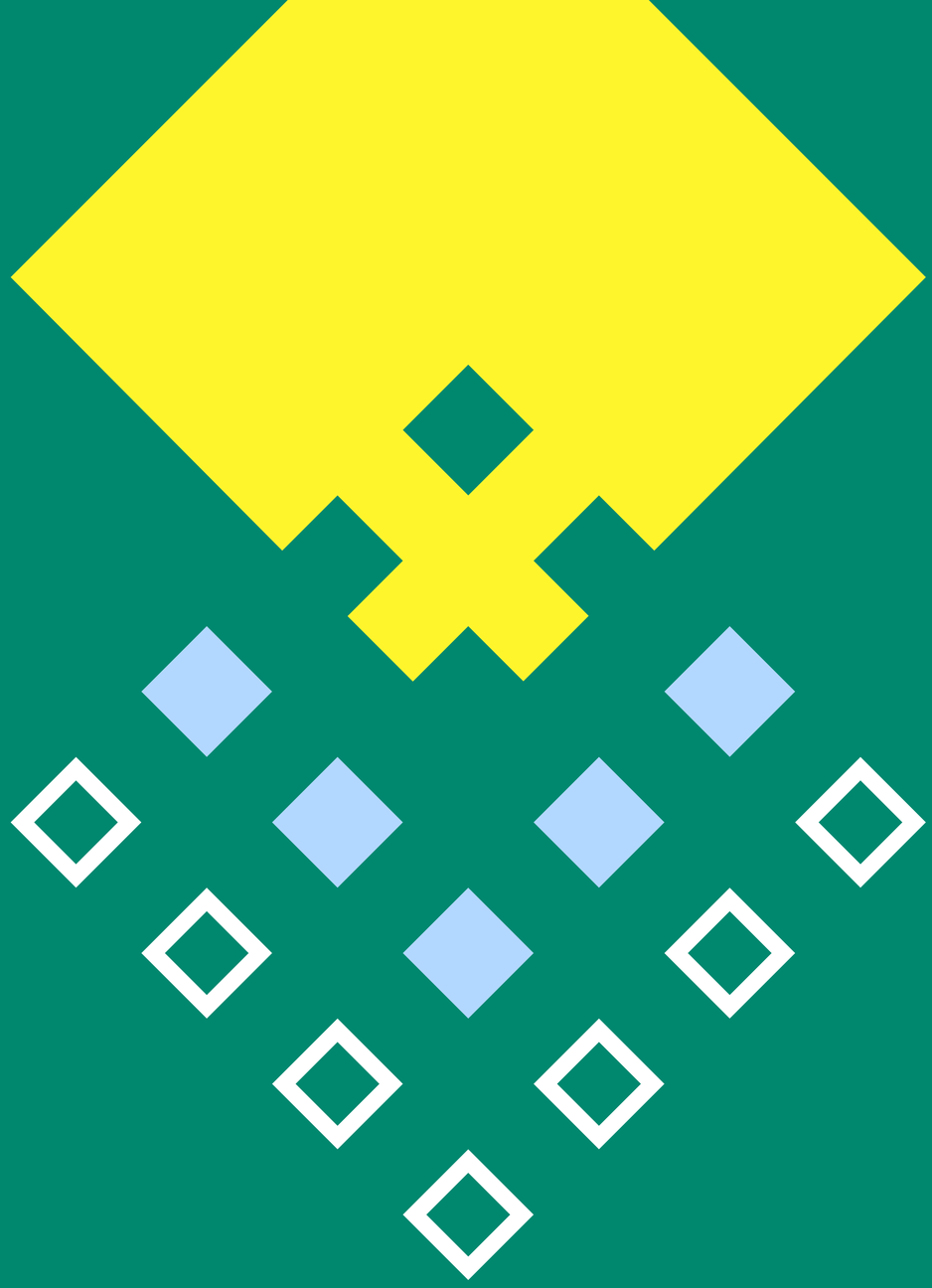

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