Single-use technology and sustainability: quantifying the environmental impact

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1 November 2016

Imagination at work

Agenda

Biopharmaceutical industry—business drivers

Single-use technologies can enable today's outcomes

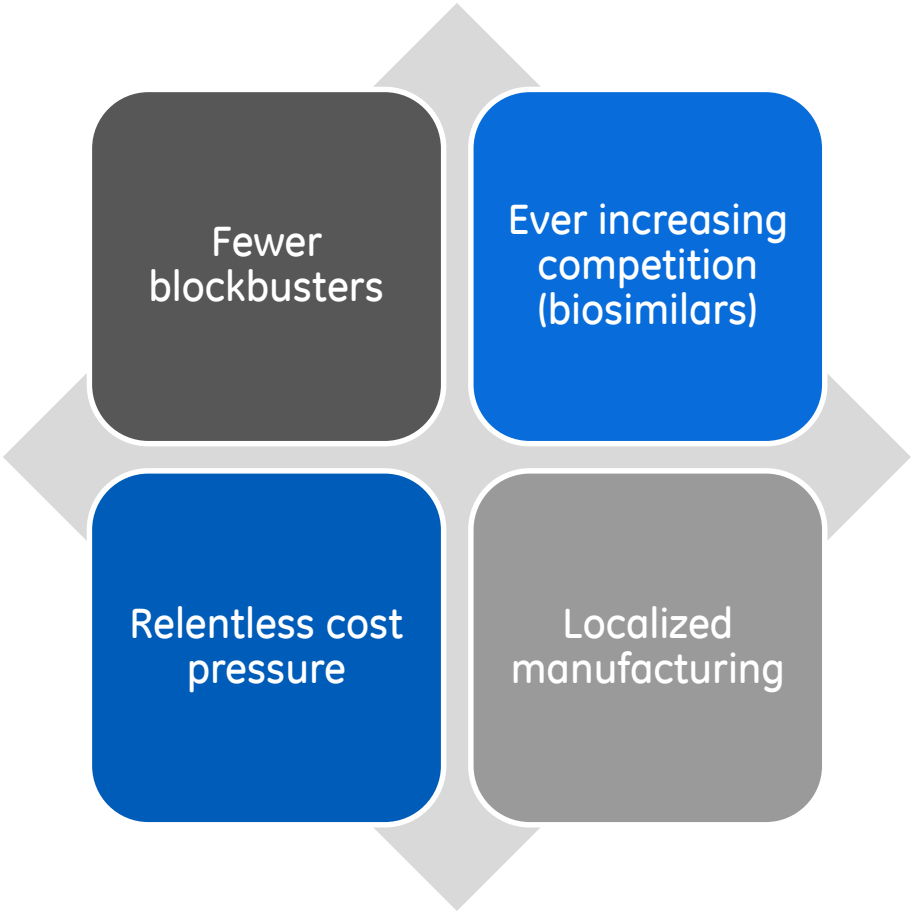
Relationship of single-use technology and sustainability

GE's new life cycle assessment study

Insights to guide your single-use journey

Questions

Drug development and manufacturing is a highly complex and competitive industry



Desired outcomes

Higher productivity, titer/yield

Higher plant utilization

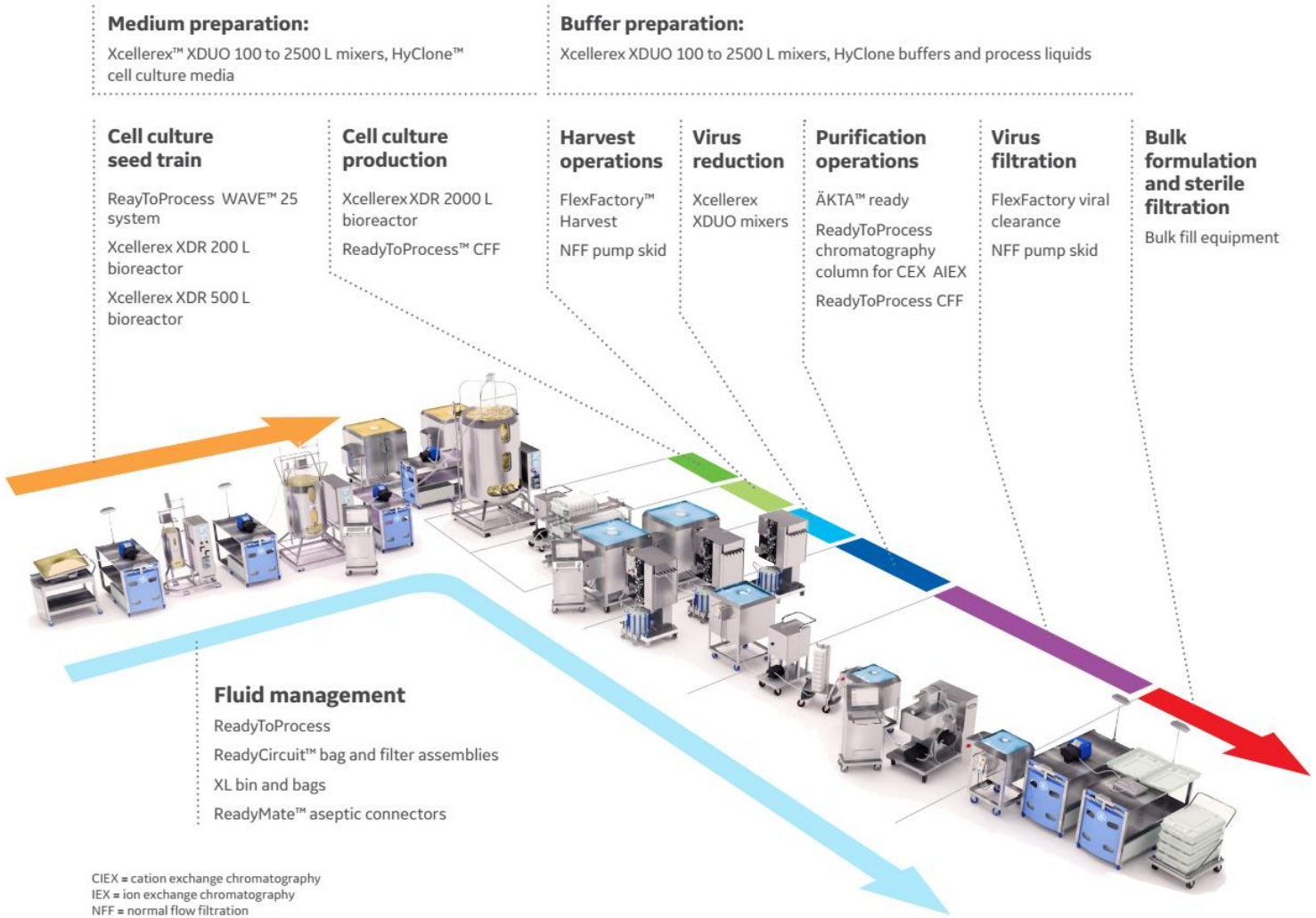
Multi-product, flexible manufacturing

Less variability, failures, and waste

Higher efficiency

Higher manufacturing quality standards

Single-use technologies enabling today's outcomes



CIEX = cation exchange chromatography
IEX = ion exchange chromatography
NFF = normal flow filtration
UF/DF = ultrafiltration/diafiltration
CFF = crossflow filters

Benefits of single-use technology

Sustainability

Flexibility

Cleaning

Process economy

Relationship of single-use and sustainability

Image courtesy of division of Industrial Biotechnology, KTH/Biotechnology

Ecosystem quality

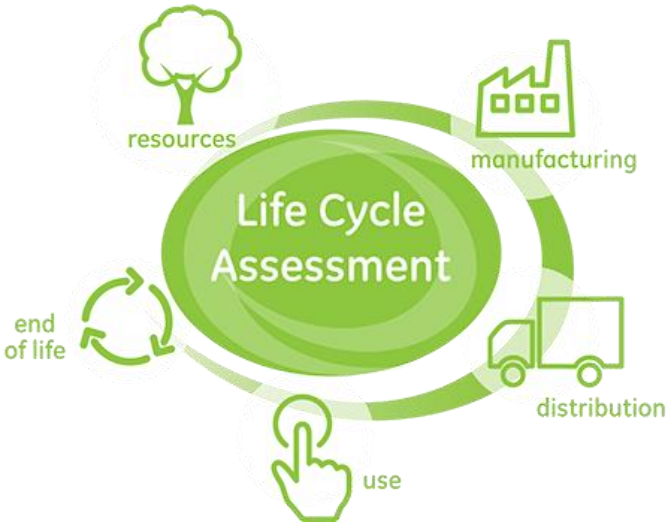
Natural resources

Human health

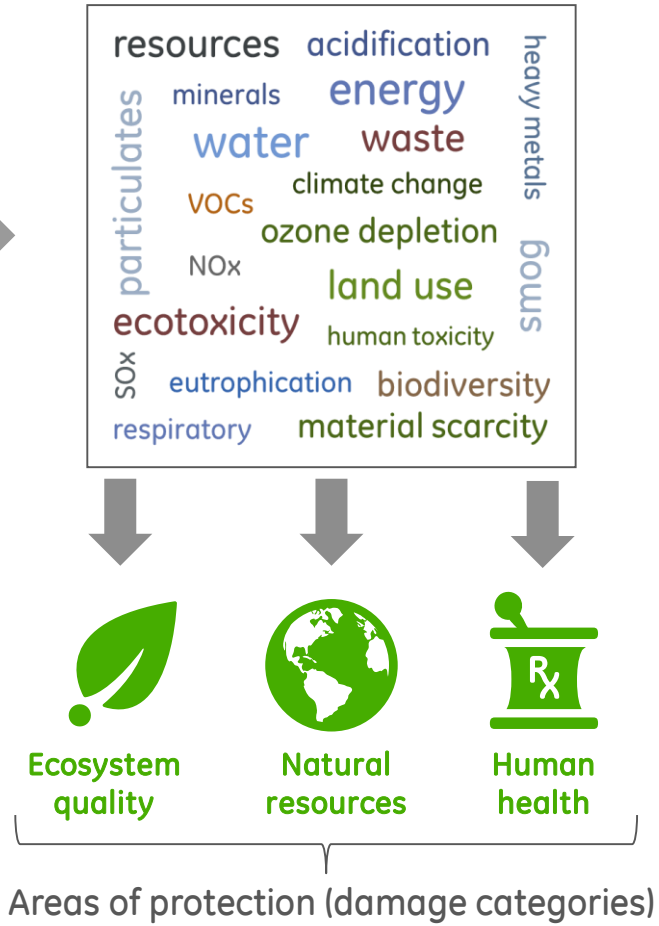
GE Healthcare FlexFactory™ biomanufacturing operations in Marlborough, MA, USA

- Industry shift towards single-use technology
- Understand environmental trade-offs associated with technology shift
- How can single-use technology help achieve sustainability goals?

Assess overall environmental impact throughout a product or service's life cycle



More than just carbon footprint



Understanding the net environmental impact of a product/service across its value chain, how and where to make improvements

- Support decisions
- Evaluate alternatives
- Prioritize opportunities for improvement
- Mitigate environmental issues

2010 to 2012 LCA results

WAVE Bioreactor™ system + ReadyToProcess™ full process train for mAb production

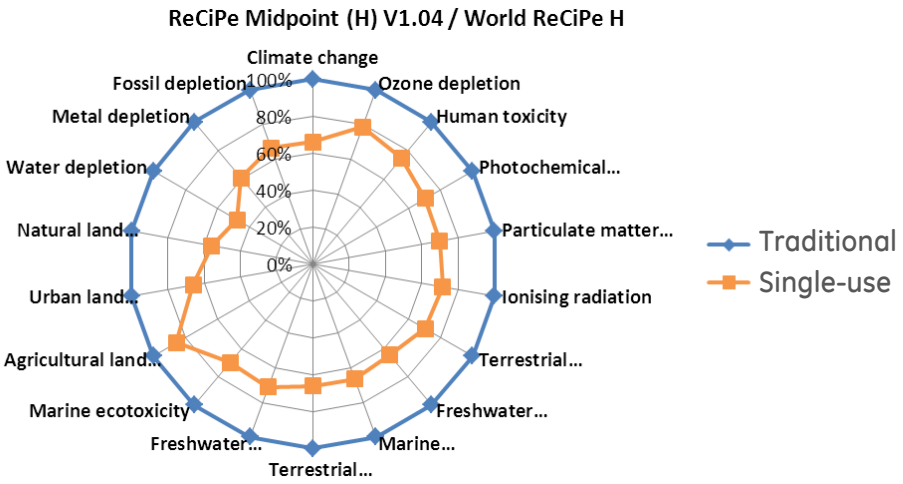
Purpose/driver of LCA

- To compare the potential environmental impacts of multi-use vs single-use process technology

Results/lessons learned

- Single-use technology exhibits lower environmental impact across the full life cycle
  - reduction of water for injection (WFI), process water, steam
  - less requirement for cleaning and sanitization in place (CIP, SIP)
- End-of-life impacts negligible compared to use phase and supply chain

Full process train, 2000 L scale

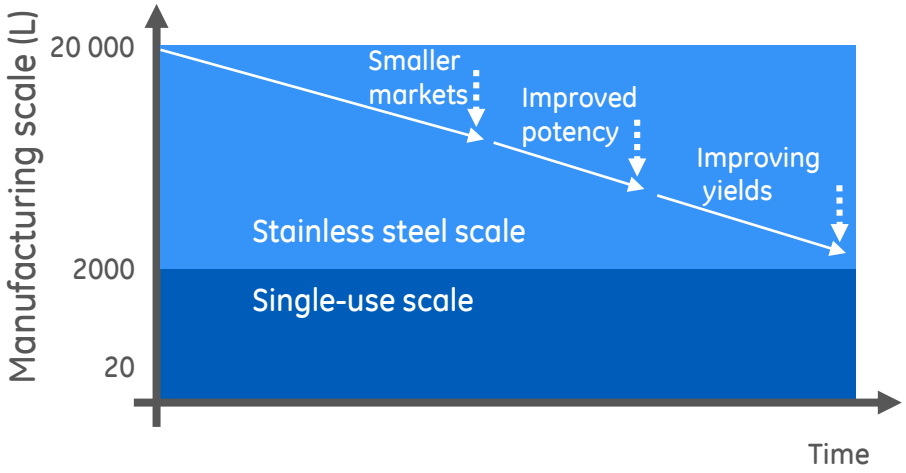


Result was unexpected, counterintuitive, and only accessible through detailed LCA

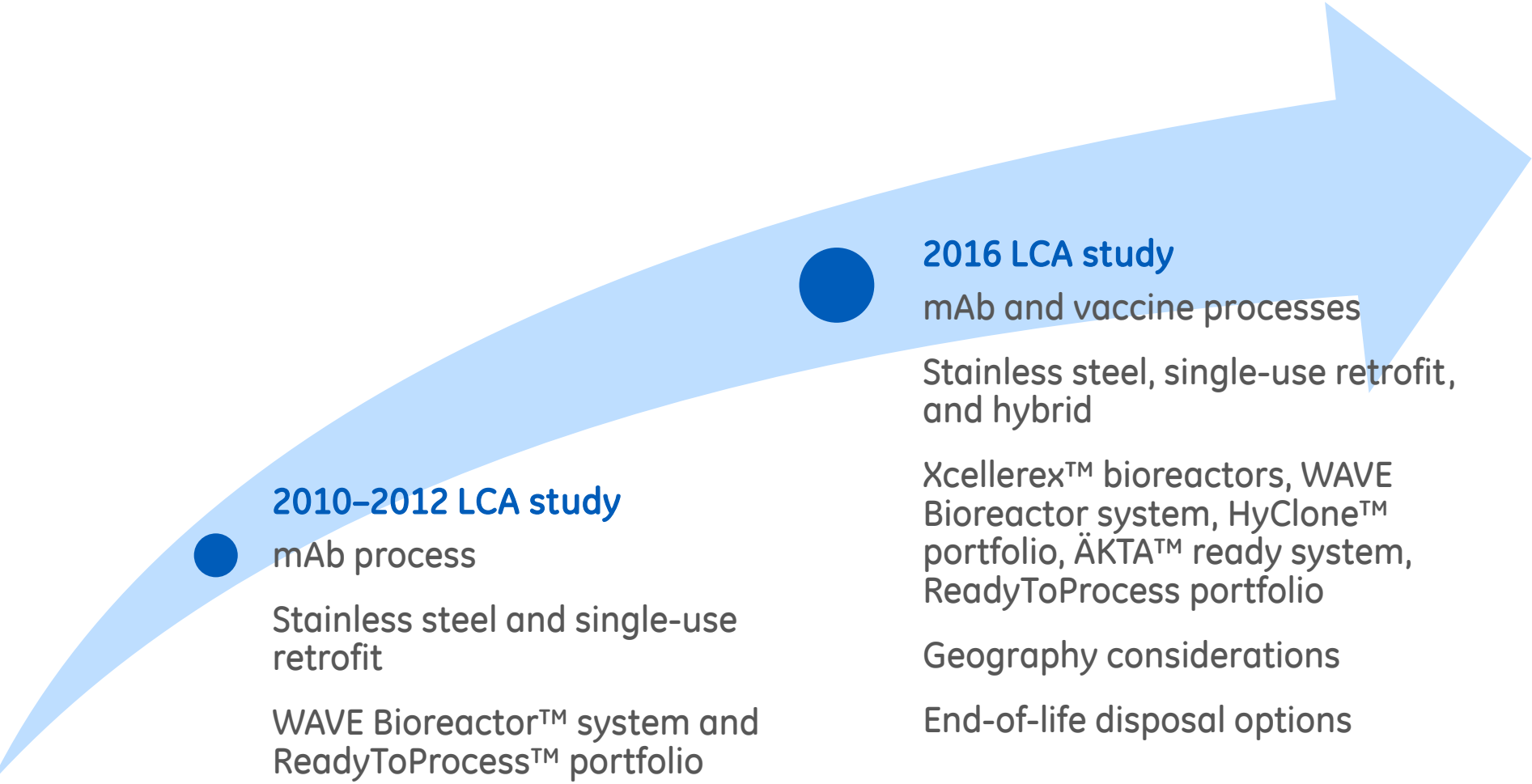
Pietrzykowksi M. *et al*, An Environmental Life Cycle Assessment Comparison of Single-Use and Conventional Process Technology for the Production of Monoclonal Antibodies, *J. Clean. Prod.* **41**, 150-162 (2013).

Bioprocess evolution requires new insights

- Expansion of single-use capability into new geographies
- Trend towards increased use of facilities with optimized floor plans
- Incorporate broader range of single-use technologies
- Support customer interest and requests for new LCA results



LCA study being updated and expanded



2010–2012 LCA study

mAb process

Stainless steel and single-use retrofit

WAVE Bioreactor™ system and ReadyToProcess™ portfolio

2016 LCA study

mAb and vaccine processes

Stainless steel, single-use retrofit, and hybrid

Xcellerex™ bioreactors, WAVE Bioreactor system, HyClone™ portfolio, ÄKTA™ ready system, ReadyToProcess portfolio

Geography considerations

End-of-life disposal options

LCA study scope, phase I

Image courtesy of division of Industrial Biotechnology, KTH/Biotechnology

Stainless steel/ single-use hybrid

Like the GE Healthcare FlexFactory™ biomanufacturing operations in Marlborough, MA, USA

mAb

200 L
500 L
2000 L
2 × 2000 L
4 × 2000 L

200 L
500 L
2000 L
2 × 2000 L
4 × 2000 L

200 L
500 L
2000 L
2 × 2000 L
4 × 2000 L

6 g/L titer | 10-batch campaign

Participants: Ecoassessment Center of Excellence at GE, GE Healthcare, Quantis, BioPharm Services, Ltd.

LCA study scope, phase II

Image courtesy of division of Industrial Biotechnology, KTH/Biotechnology

Stainless steel/ single-use hybrid

Like the GE Healthcare FlexFactory™ biomanufacturing operations in Marlborough, MA, USA

mAb	Stainless steel/ single-use hybrid	Single-use facilities (retrofit)
200 L	200 L	200 L
500 L	500 L	500 L
2000 L	2000 L	2000 L
2 × 2000 L	2 × 2000 L	2 × 2000 L
4 × 2000 L	4 × 2000 L	4 × 2000 L

Vaccine		
50 L	LCA model can explore environmental improvement opportunities in stainless steel, single-use, or hybrid	50 L
200 L		200 L
500 L		500 L

LCA study scope, phase II

Traditional stainless steel facilities

Image courtesy of division of Industrial Biotechnology, KTH/Biotechnology

Stainless steel/ single-use hybrid

Single-use facilities (retrofit)

Like the GE Healthcare FlexFactory™ biomanufacturing operations in Marlborough, MA, USA

	200 L	200 L	200 L
	500 L	500 L	500 L
	2000 L	2000 L	2000 L

Third party critical review to be performed

Vaccine	50 L	LCA model can explore environmental improvement opportunities in stainless steel, single-use, or hybrid	50 L
	200 L		200 L
	500 L		500 L

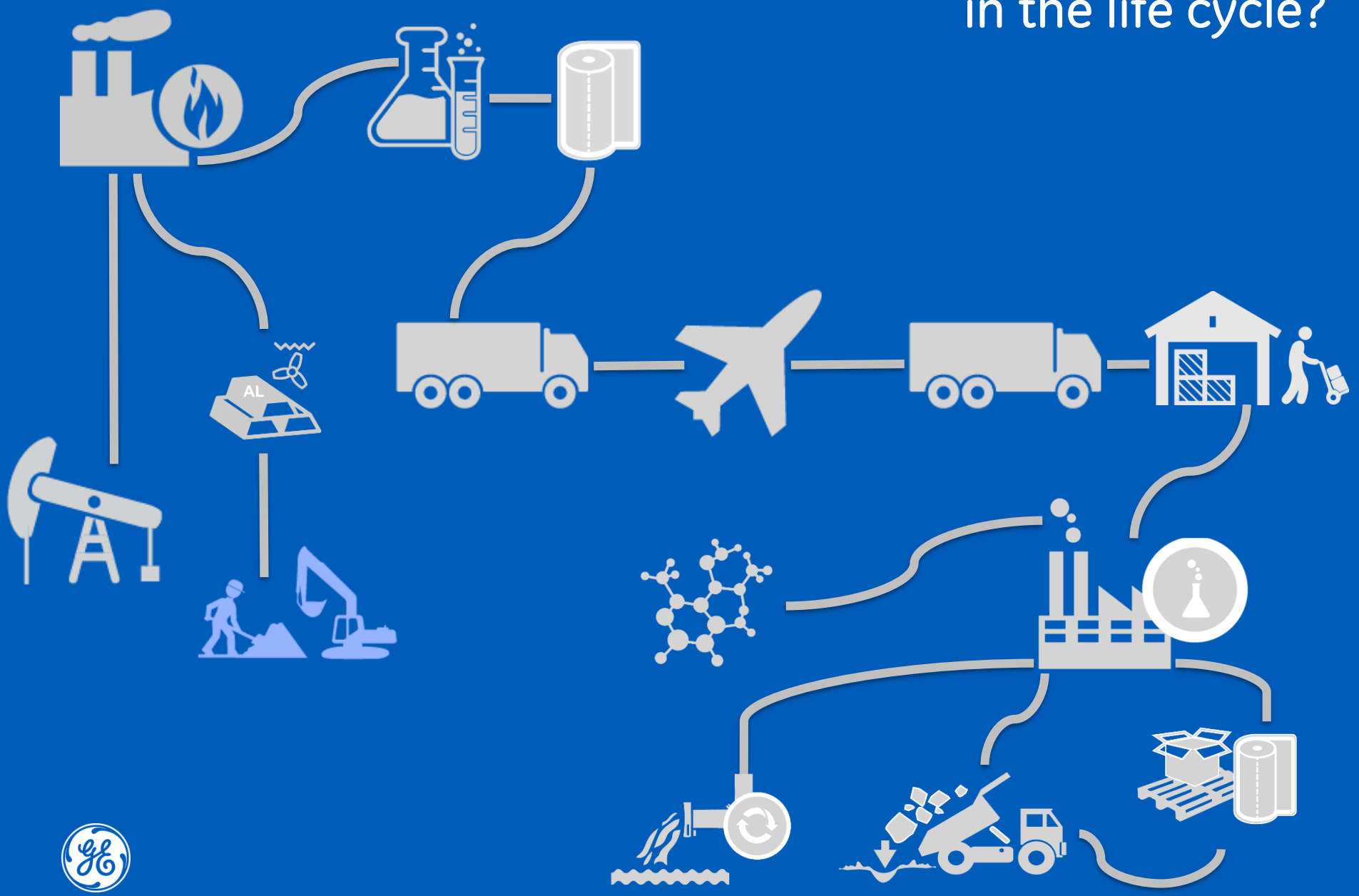
Hybrid process configuration

Process	% Single-Use
Traditional	0%
Hybrid	62%
SU retrofit	100%

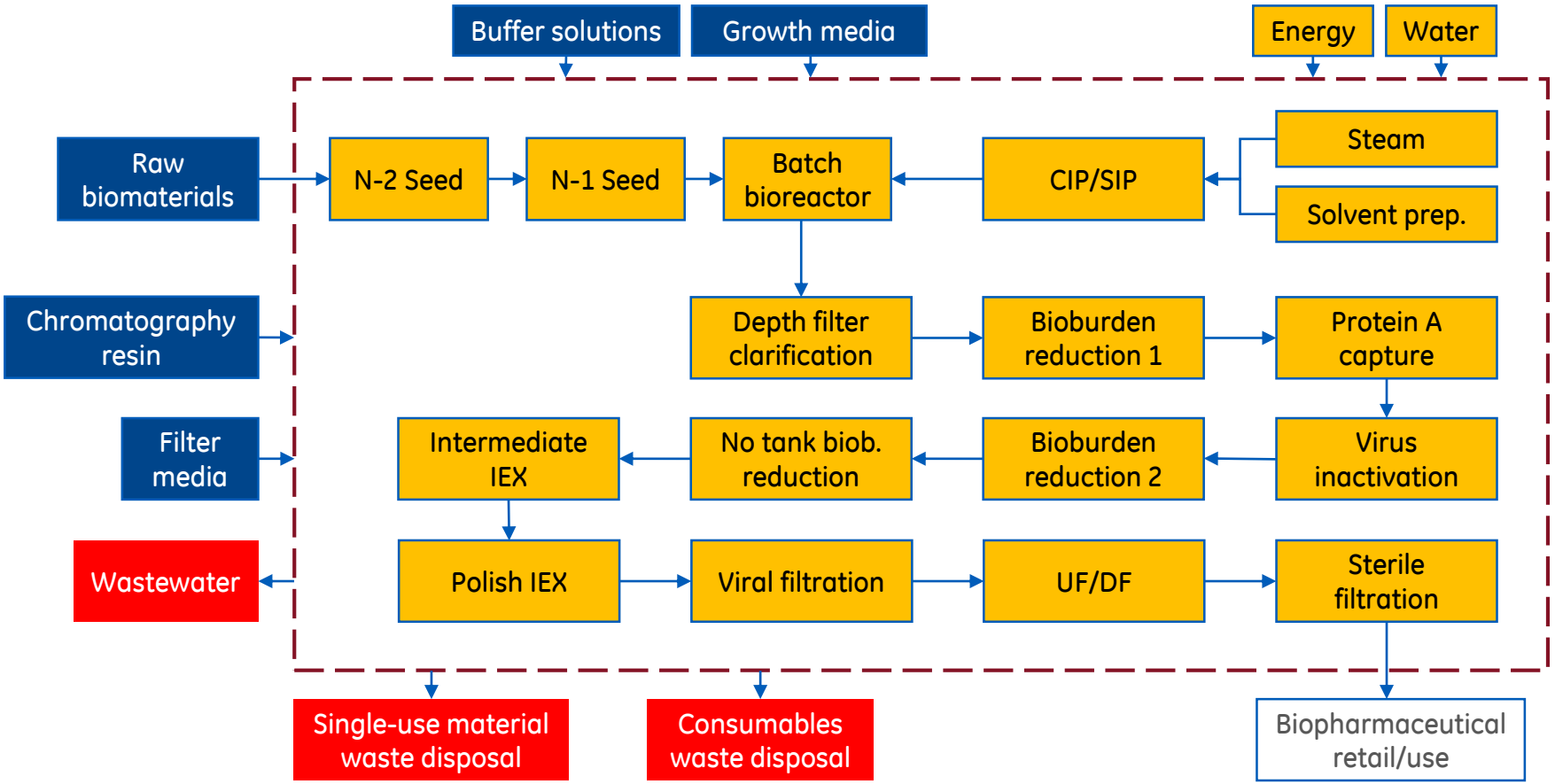
Unit Op Number	Unit Op Name	Equipment used for comparison					
		SU Retrofit		Hybrid SU-Trad			
		Nominal Technology	#SU	Nominal Technology	#SU	#Trad	%SU
1	N-2 Seed	WAVE	7.0	WAVE	6.5	0.0	100%
2	N-1 Seed	Xcellerex XDR	11.0	Xcellerex XDR	6.5	1.0	87%
3	Production	Xcellerex XDR	14.0	ss bioreactor	4.0	7.0	36%
4	Clarification	SU Harvest filter skid and holder, SU Depth filter & SU Polishing filter	11.6	ss filter housing + depth filtration	3.0	4.0	43%
5	Bioburden reduction I	ss filter housing + biob. filter	16.6	ss filter housing + biob. filter	12.0	1.0	92%
6	Protein A	AKTA system + AxiChom 450 column MabSelect SuRe resin	20.0	ss column + protein A resin	6.5	9.0	42%
7	Virus Inactivation	Xcellerex XDUO	16.2	ss mixing vessel	10.4	2.0	84%
8	Bioburden reduction II	Filter Capsules - Bioburden Filter	11.6	Filter Capsules - Bioburden Filter	9.0	1.0	90%
9	Sterile filtration II	Filter capsule/sterile filtration	11.6	ss filter housing + sterile filter	9.0	1.0	90%
10	IEX Bind & Elute	AKTA system + pre-packed column Capto S ImpAct resin	18.0	ss column + IEX resin	6.5	12.0	35%
11	AIEX Flow Through	Millipore Pro Magnus Viral filter skid and holder + Viresolve Pro	18.0	ss column + AIEX resin	4.4	6.0	42%
12	Viral Filtration	Millipore Pro Magnus Viral filter skid and holder + Viresolve Pro	15.9	ss filter housing + viral filter	3.0	4.4	41%
13	UF/DF	TFF SS system (UniFlux) + UF filter (Pellicon Casettes)	15.0	TFF ss system + UF filter	3.0	1.4	68%
14	Sterile filtration II	Peristaltic pump +Filter capsule/sterile filtration	1.3	ss filter housing + sterile filter	1.2	3.2	27%
				Total	85.0	53.0	62%

North American East Coast, 2 × 2000 L processing scale

What is included in the life cycle?

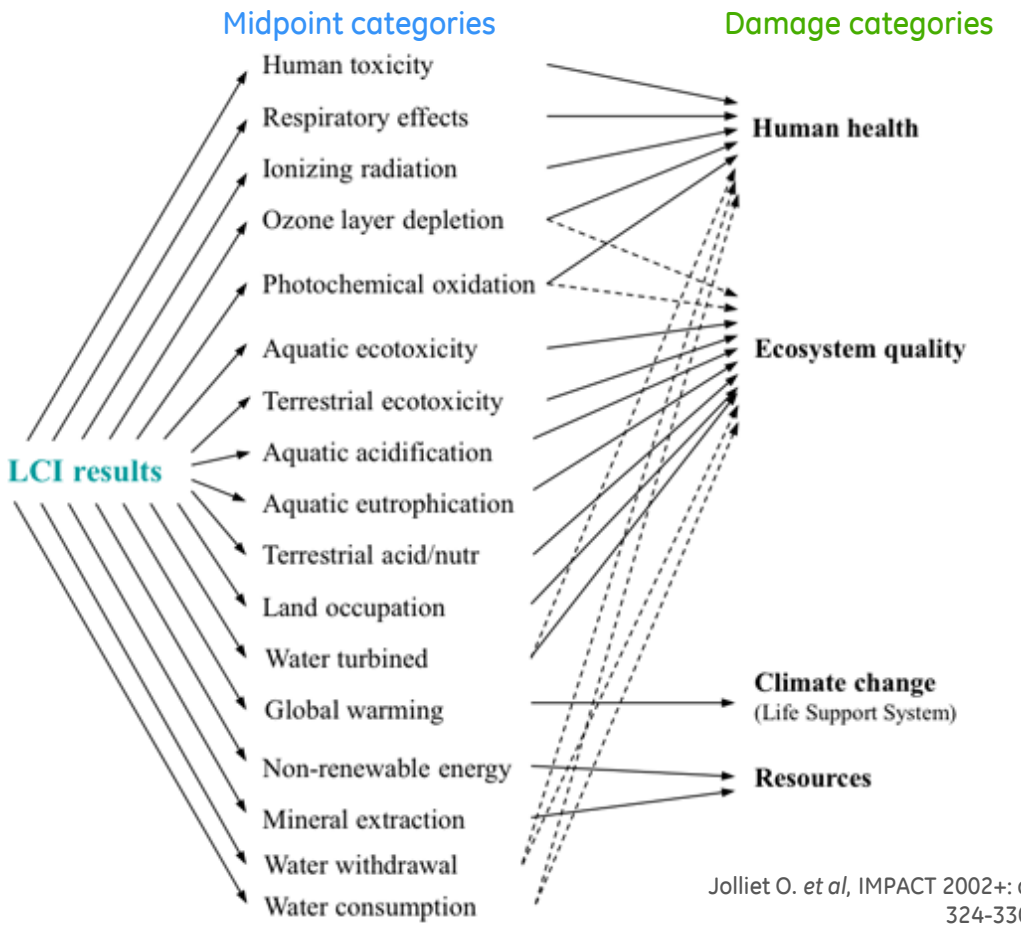


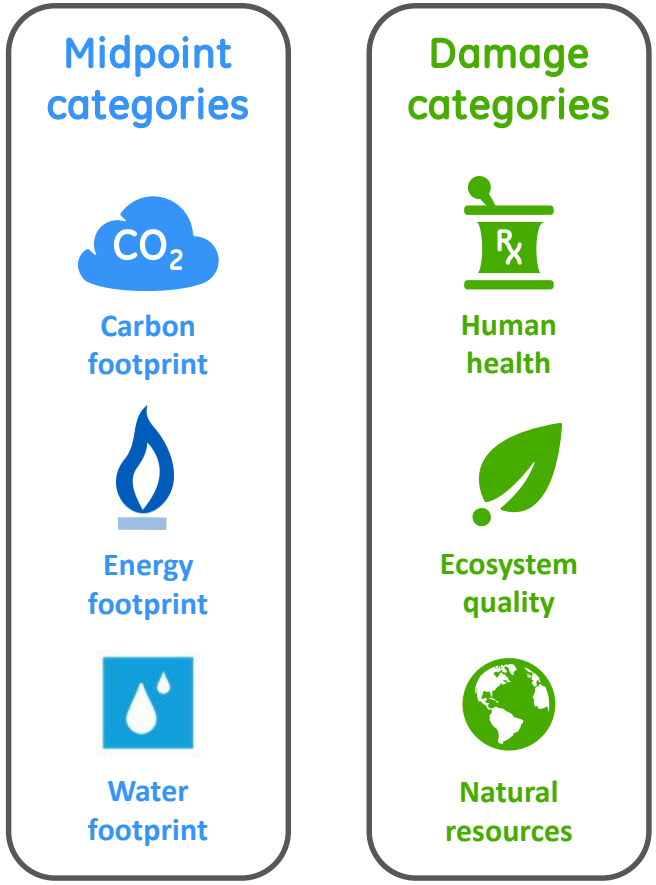
mAb bioprocessing configurations studied



biob. = bioburden, CIP/SIP = cleaning/sanitization in place, IEX = ion exchange chromatography, prep. = preparation, UF/DF = ultrafiltration/diafiltration
Note: General unit operations shown; configuration can change due to scale, product choice, technologies used, etc.

Environmental impact assessment

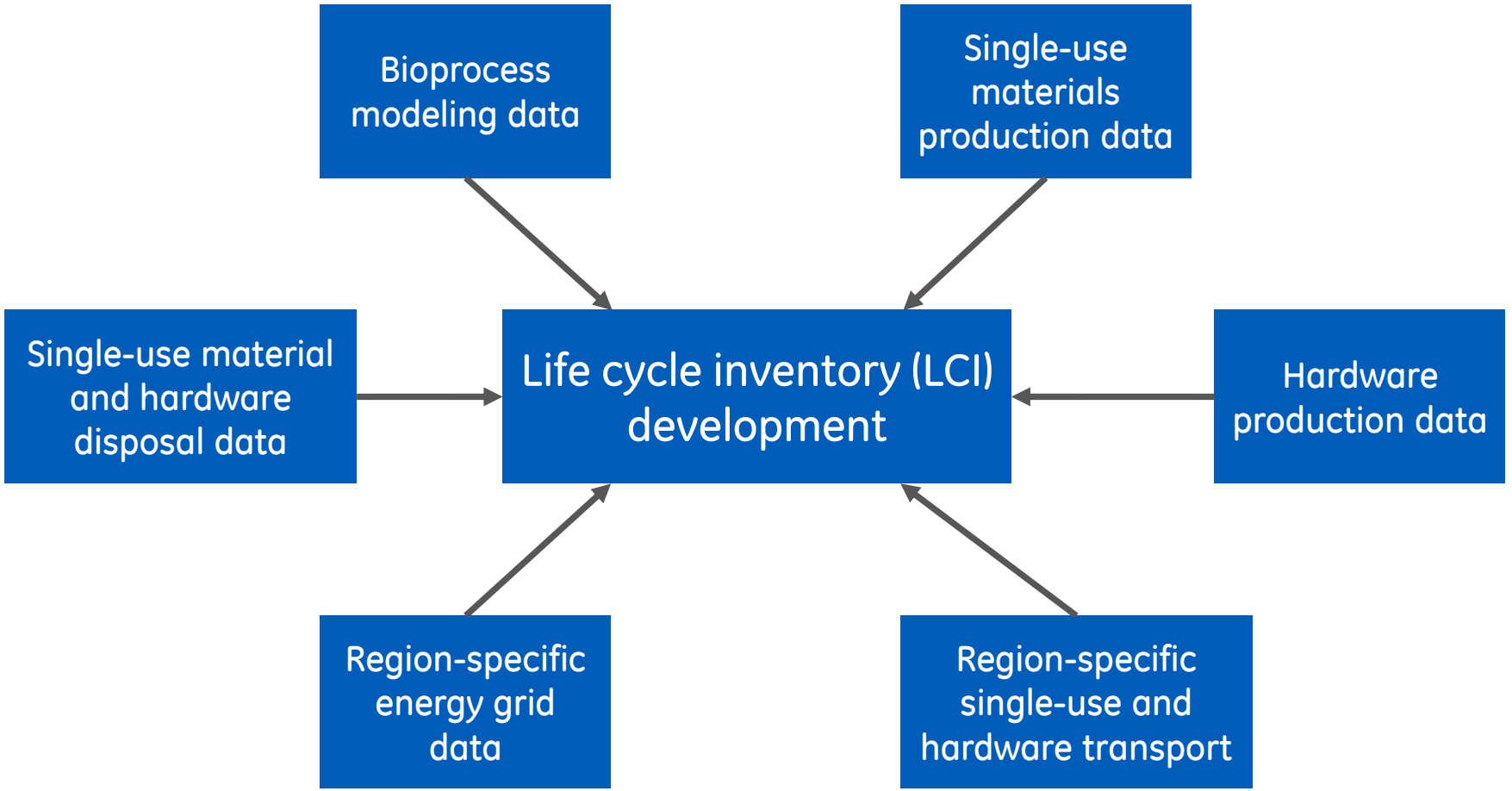




Jolliet O. *et al*, IMPACT 2002+: a new life cycle impact assessment methodology, *Int. J. Life Cycle Assess* **8(6)**, 324-330 (2003) as adapted by Quantis in version Q2.22 of IMPACT 2002+: User Guide

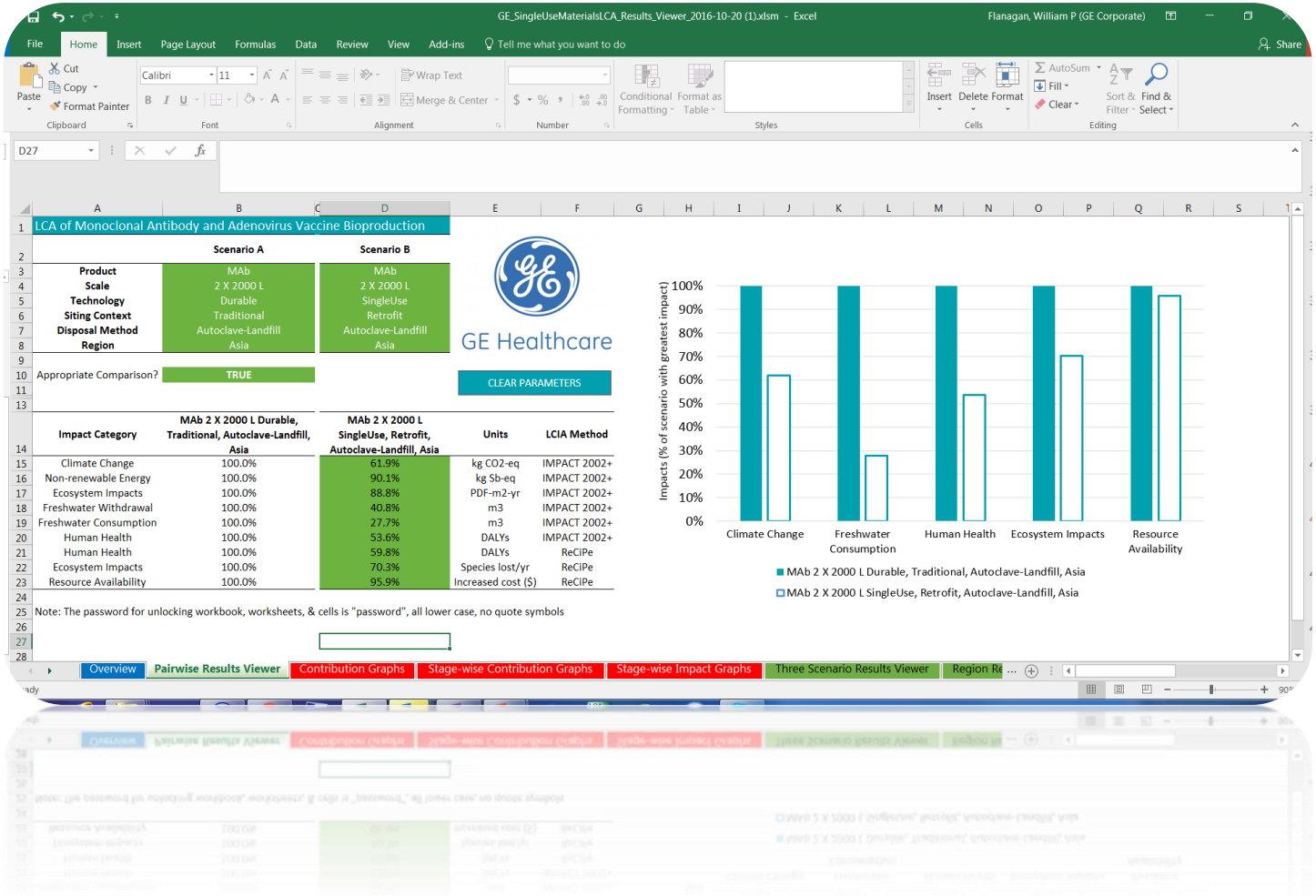
LCI = life cycle inventory

Bioprocess modeling and data collection



Case studies

Single-use LCA results viewer



Looking at the LCA results from three different bioprocess perspectives

US-based, medium-sized biotechnology company expanding capacity

Large multi-national biopharmaceutical company expanding global capacity

Large multi-national biopharmaceutical company upgrading existing stainless steel process

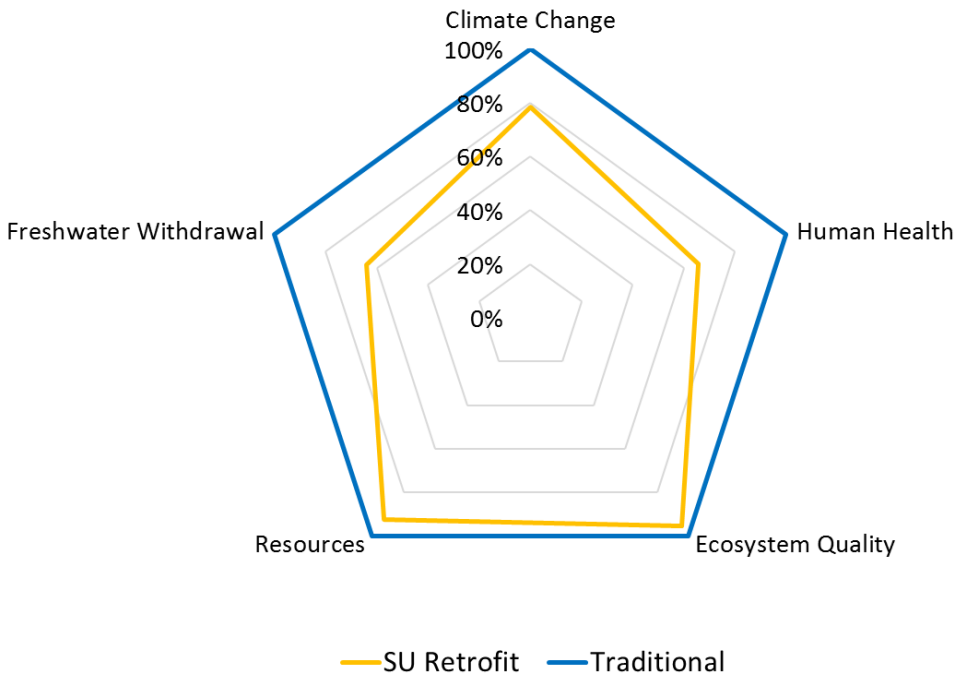
Does the increased use of plastics mean my environmental impact will increase?

US-based, medium-sized biotechnology company expanding capacity

Up to 55% reduction in life cycle impact across the five environmental impact categories

Single-use technologies provide a nearly 55% reduction in total impact for some environmental impact categories, some reduction in all, compared with traditional technologies

North American East Coast,
2 × 2000 L processing scale



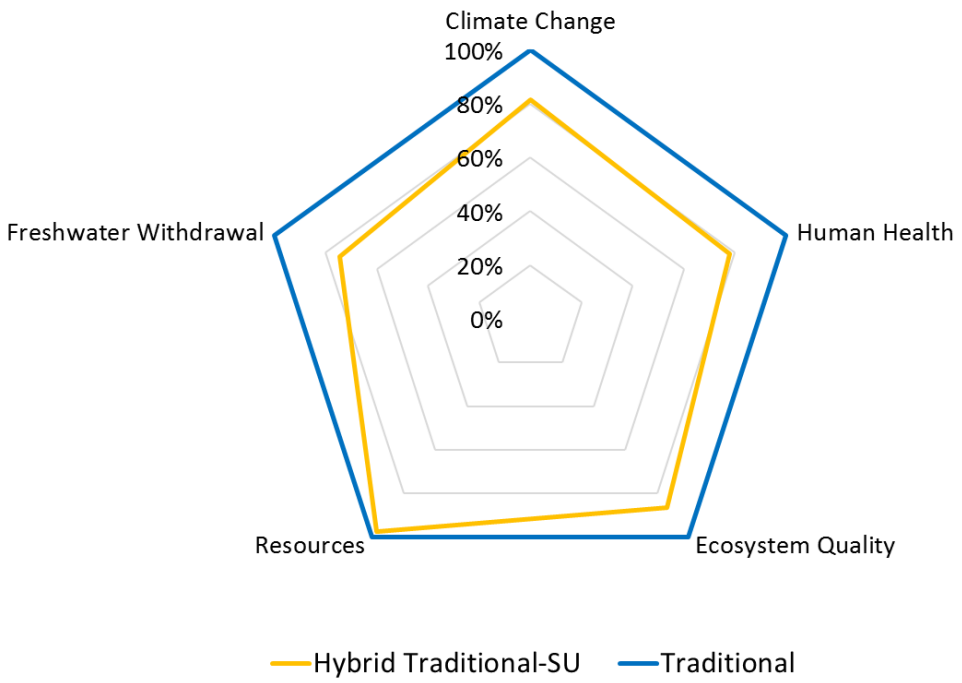
SU Retrofit = single-use facility (retrofit modeling), Traditional = traditional stainless steel facility

Preliminary results

Hybrid traditional-SU process configuration captures proportional environmental benefit

A hybrid traditional-SU process chain captures proportional benefit, with greater improvements for conversion of upstream unit processes

North American East Coast,
2 × 2000 L processing scale



Hybrid Traditional-SU = a hybrid process configuration (retrofit), Traditional = traditional stainless steel facility

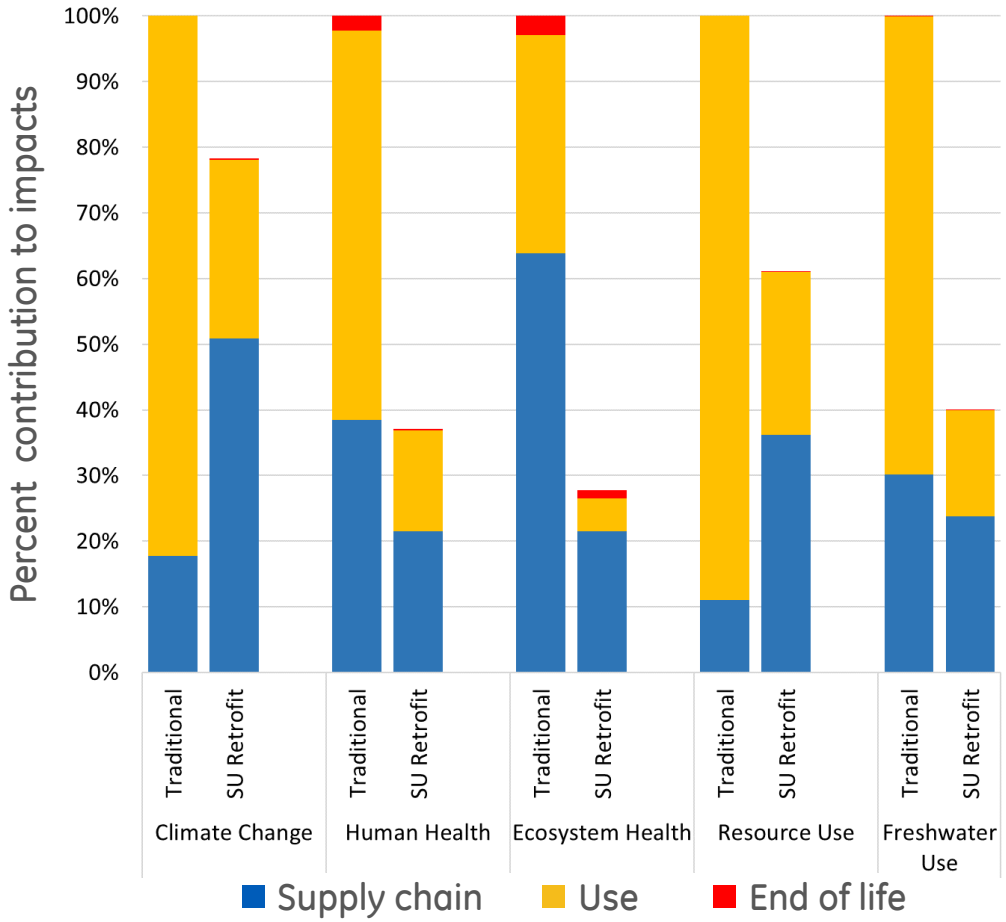
Preliminary results

Differences in impact during a product's lifecycle

The single-use process scenario has a larger share of impact in the supply chain, while greatly reducing the impact in use

End of Life impacts small relative to other life cycle stages

North American East Coast,
2 × 2000 L processing scale



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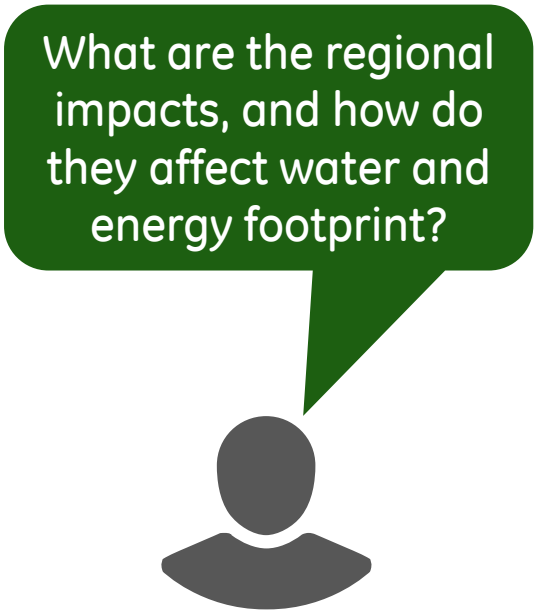
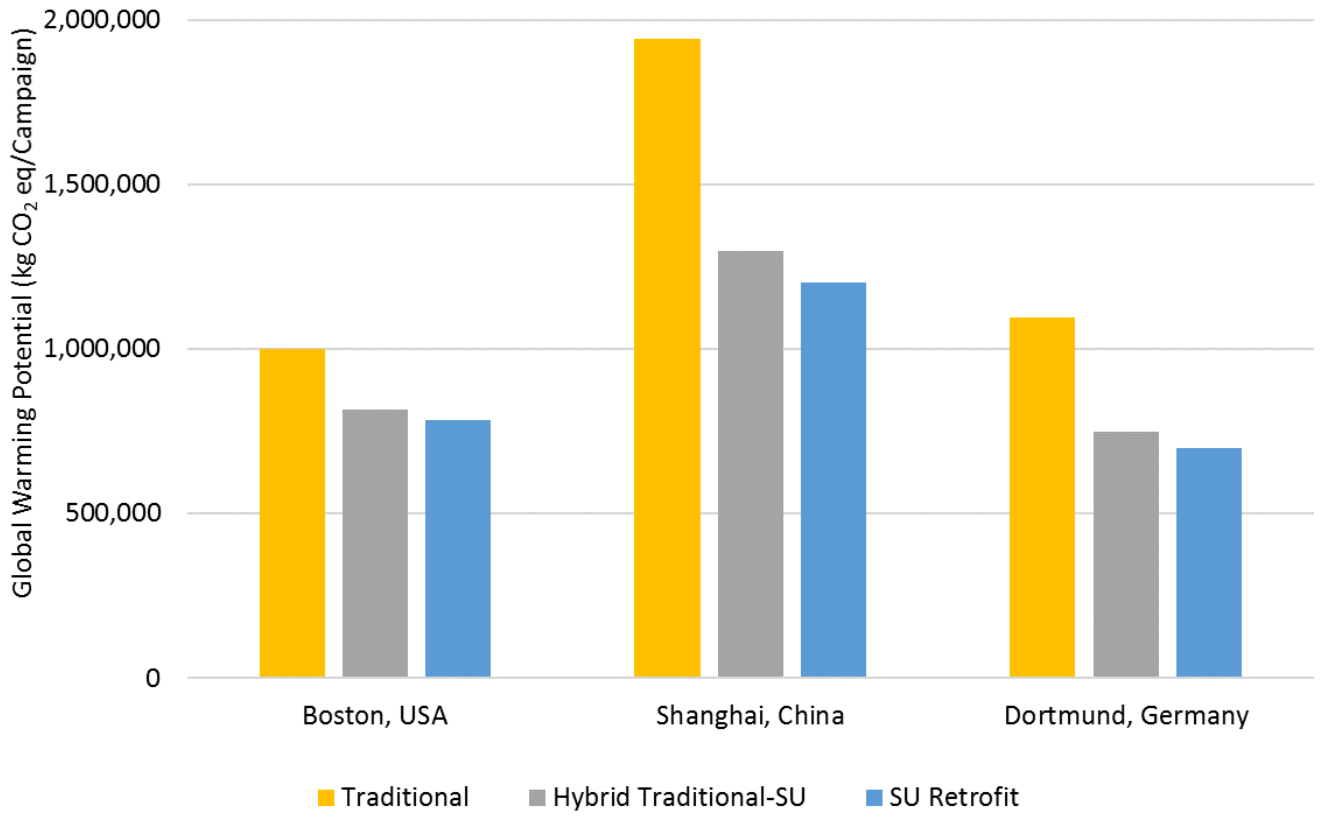


Large multi-national biopharmaceutical company expanding global capacity

The carbon footprint savings vary among the three locations examined



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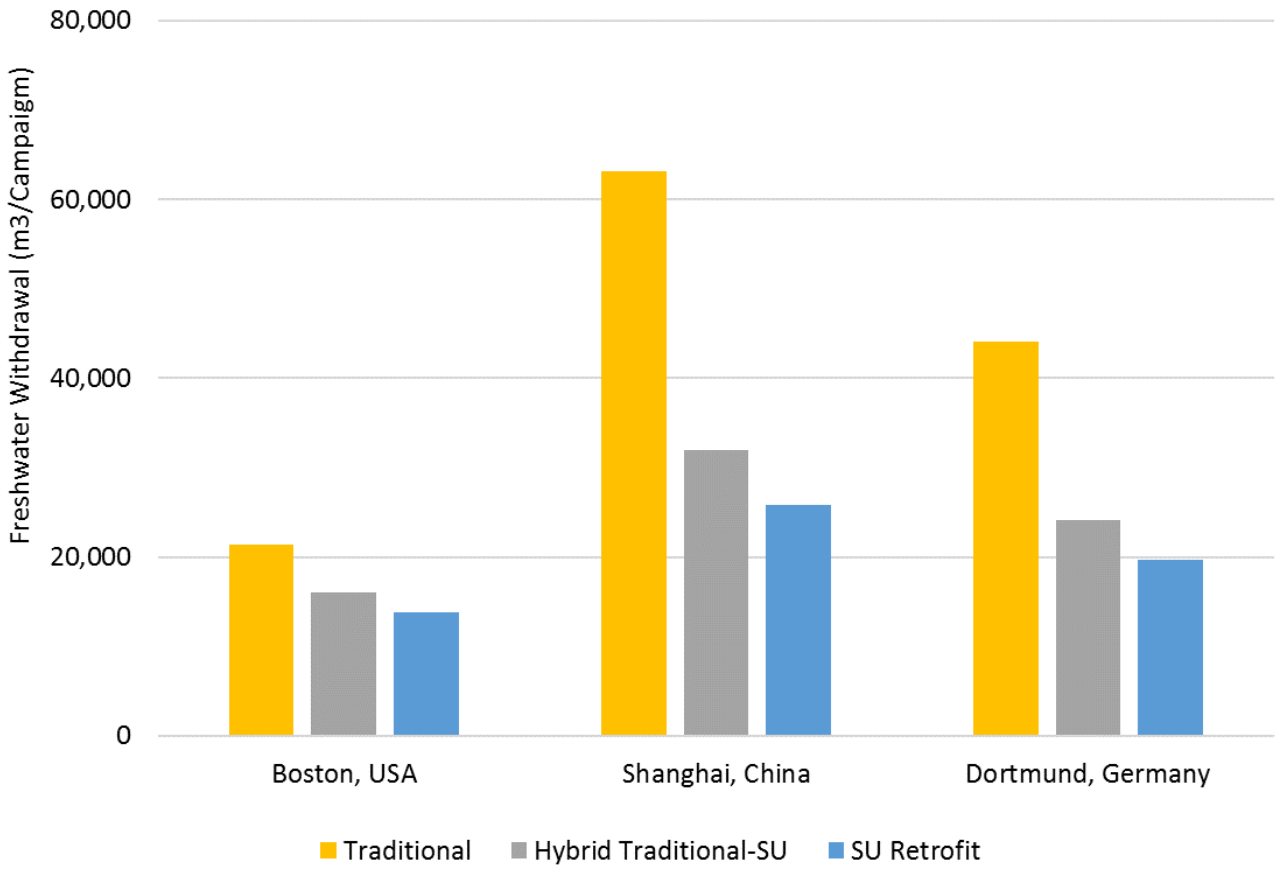
Preliminary results

The water use savings vary among the three locations examined



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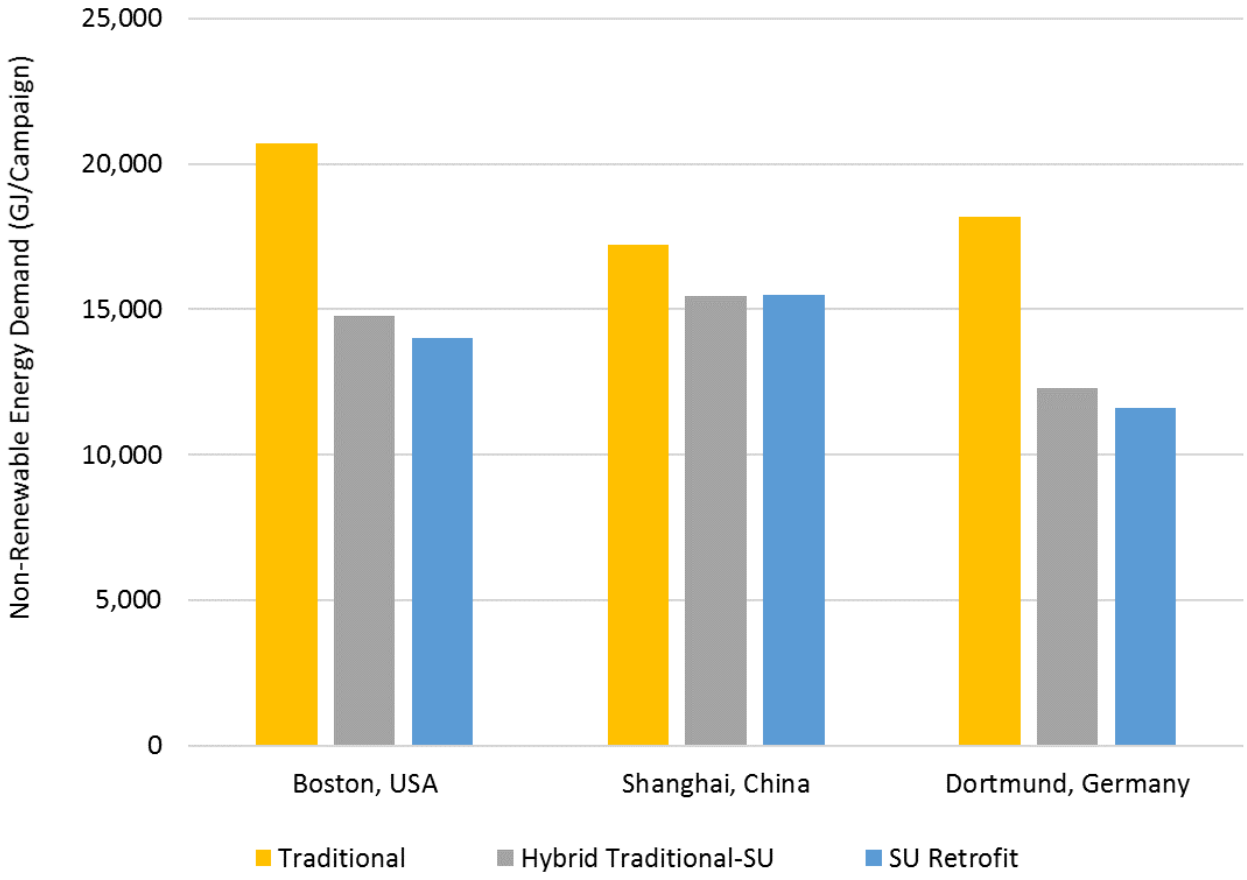
Preliminary results

The energy use savings vary among the three locations examined



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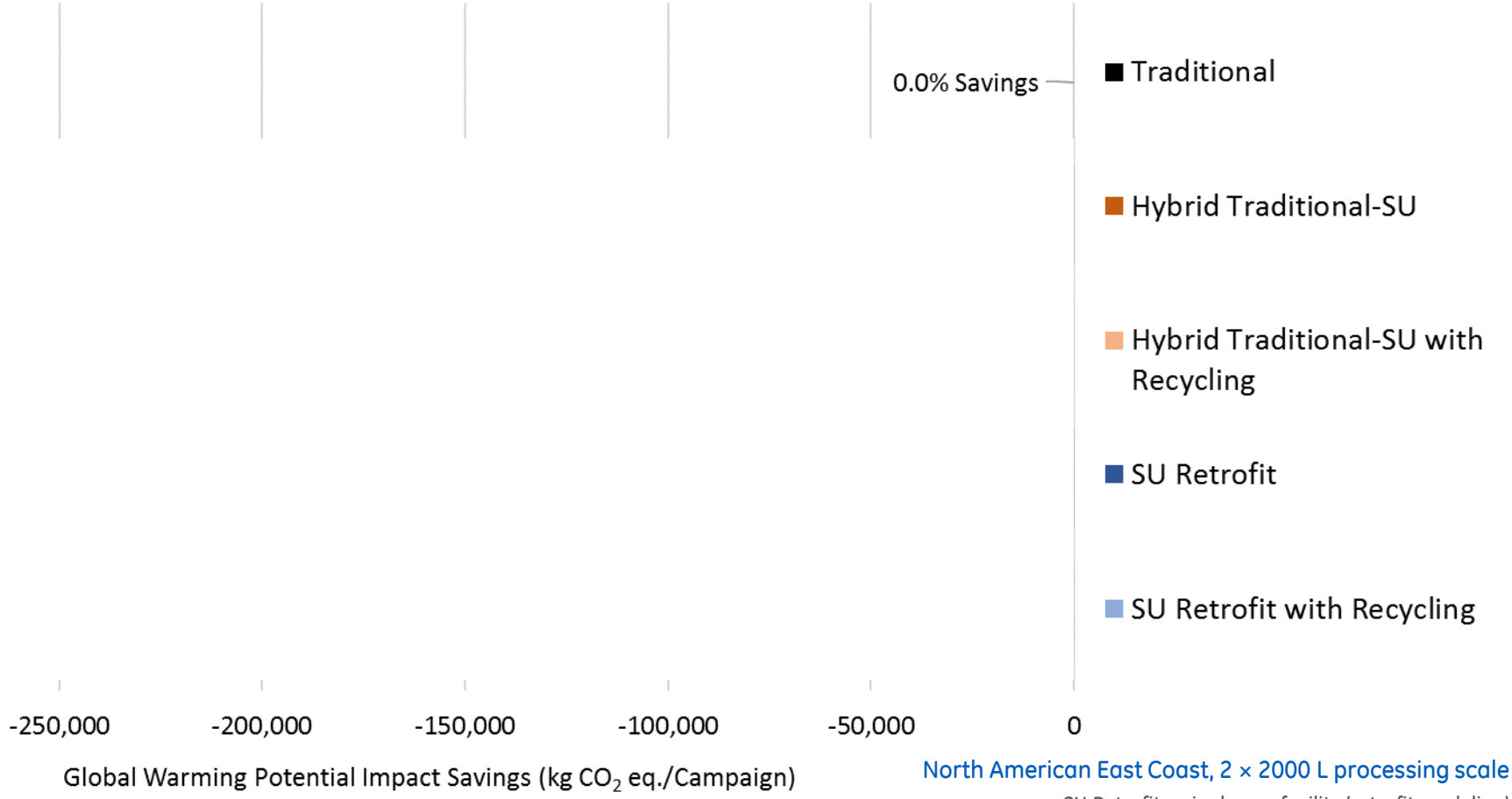
Preliminary results

How will expanding capacity change my carbon footprint?

Large multi-national biopharmaceutical company upgrading existing stainless steel process

Achieving carbon footprint reduction goals



North American East Coast, 2 × 2000 L processing scale

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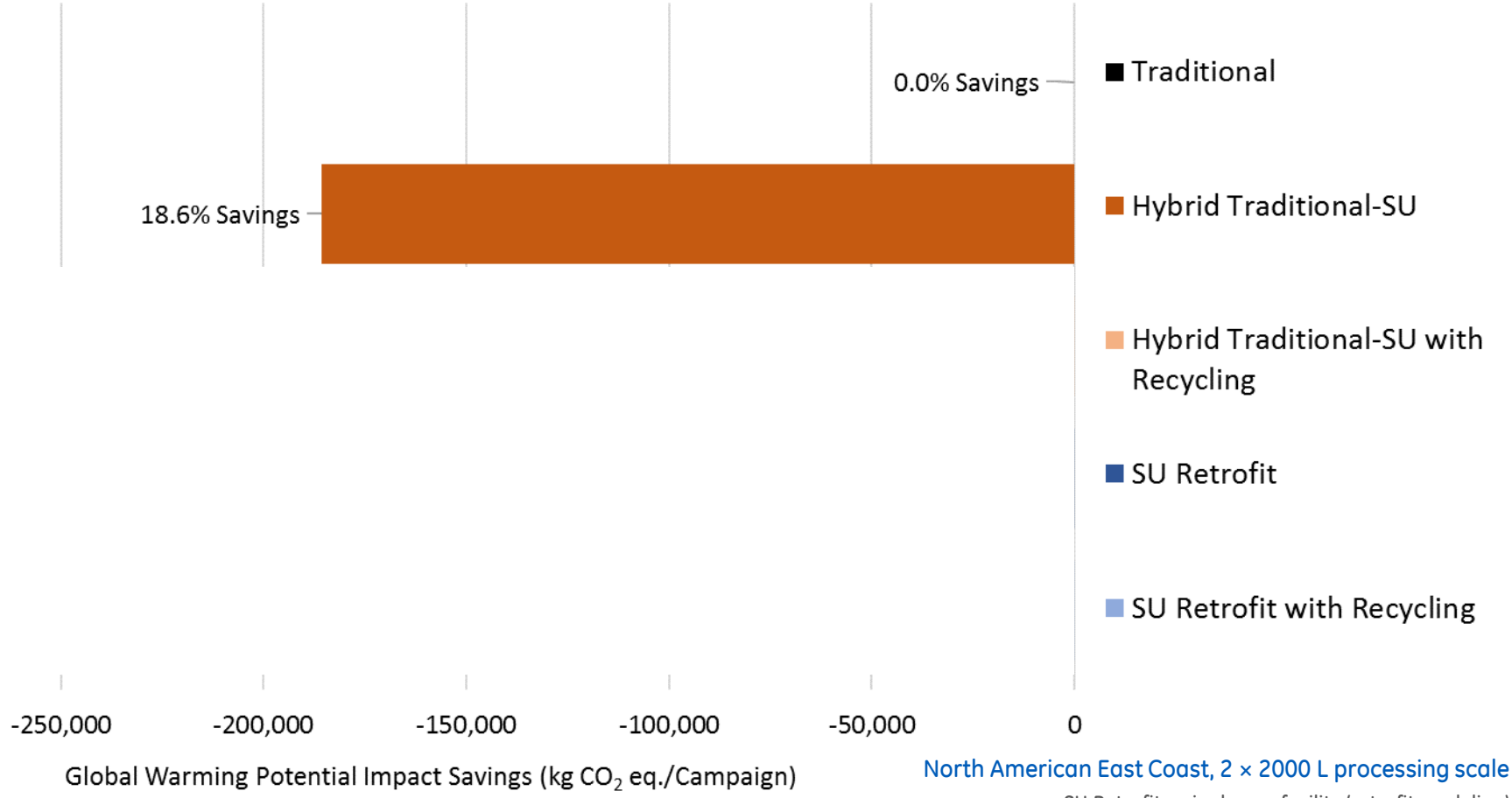
Preliminary results

Achieving carbon footprint reduction goals



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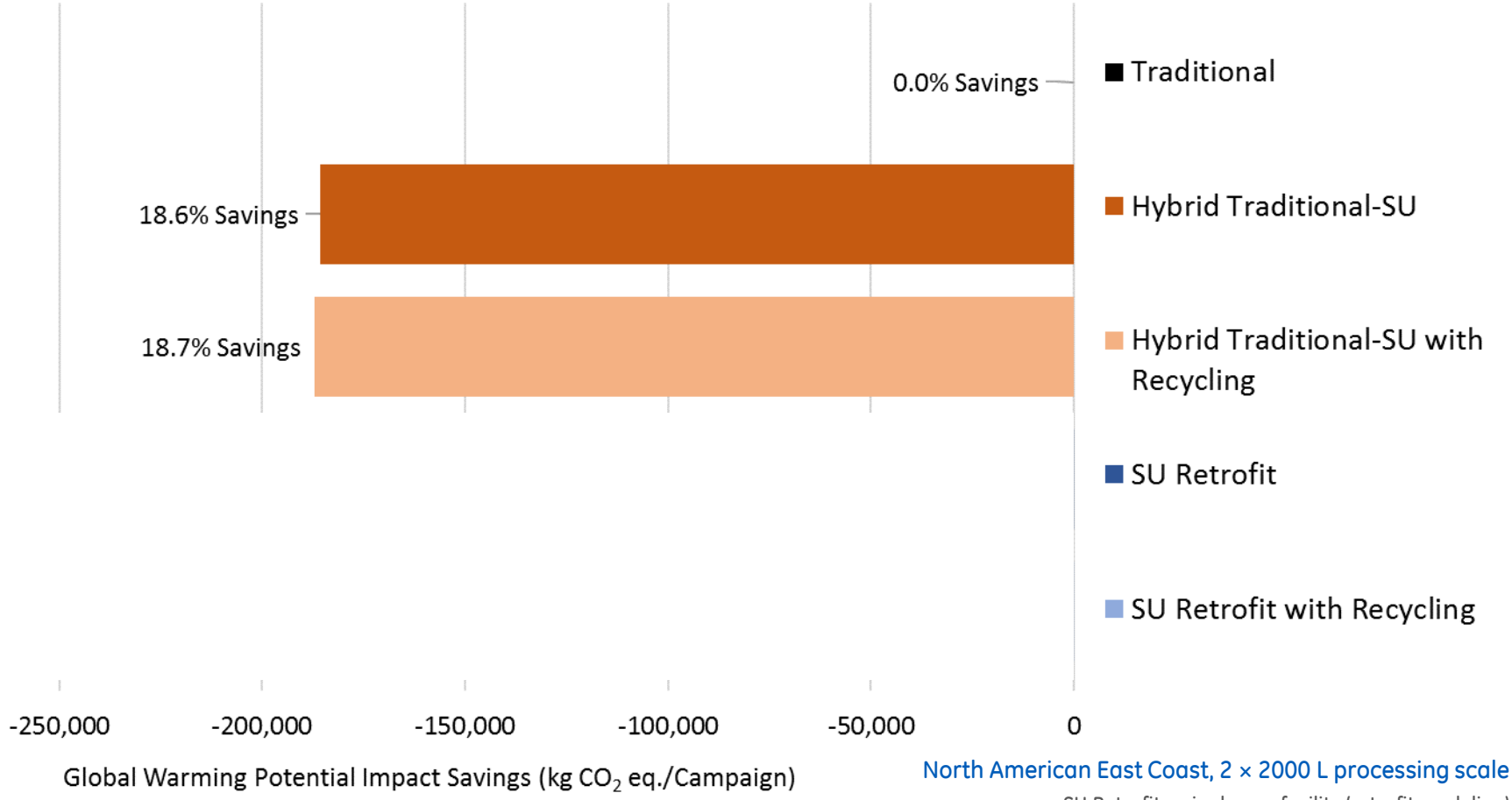

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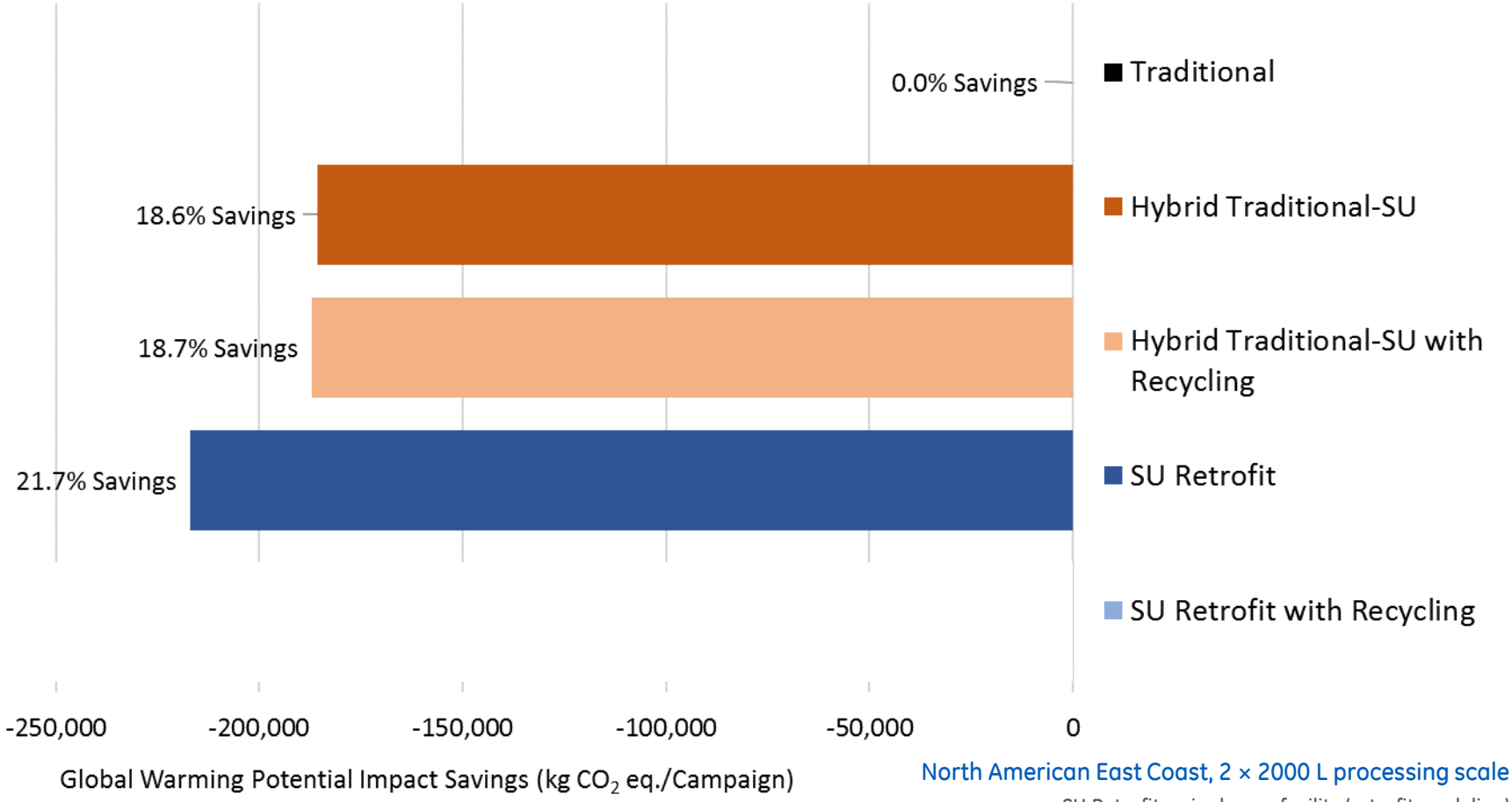

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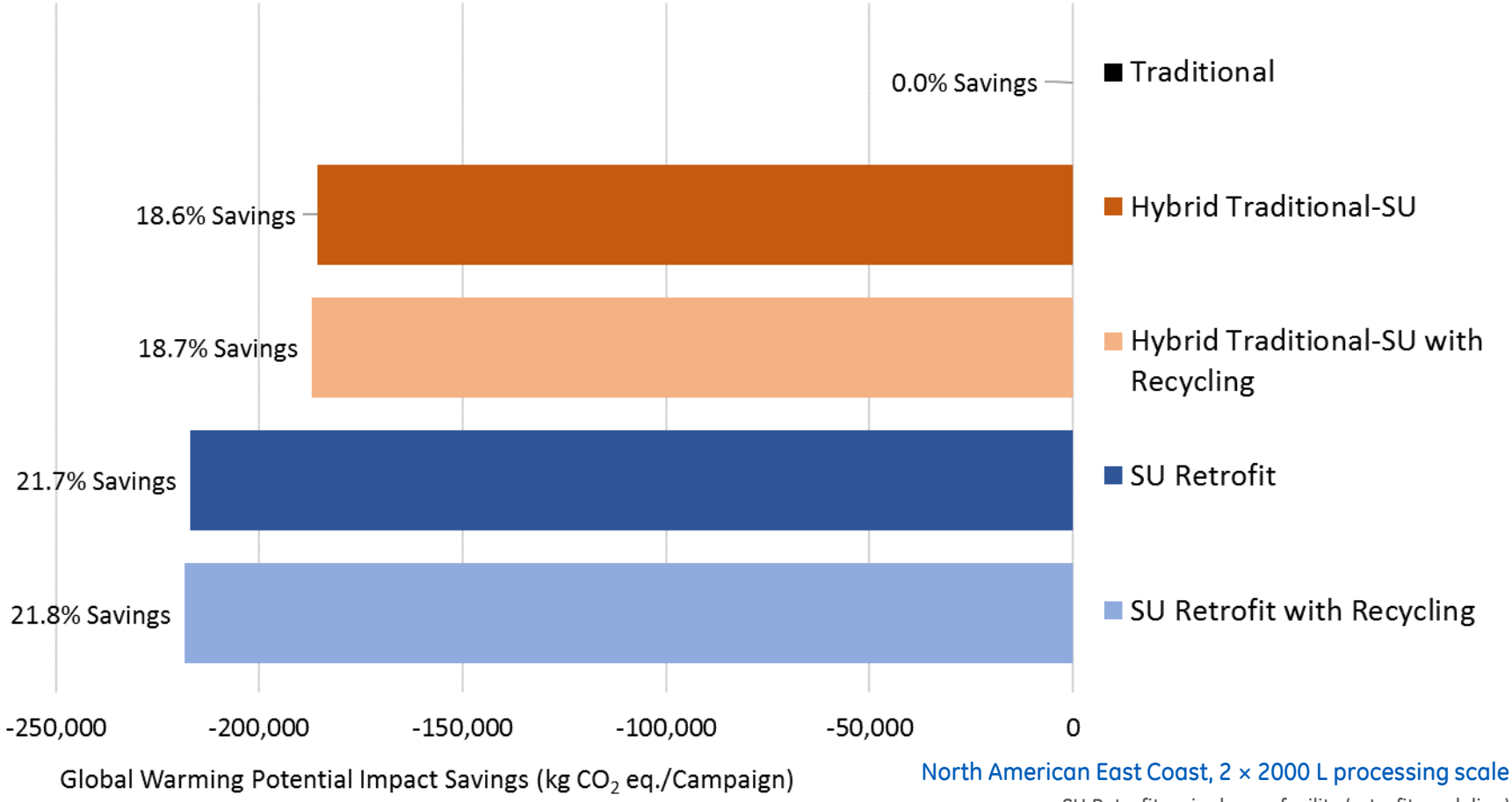

North American East Coast, 2 × 2000 L processing scale

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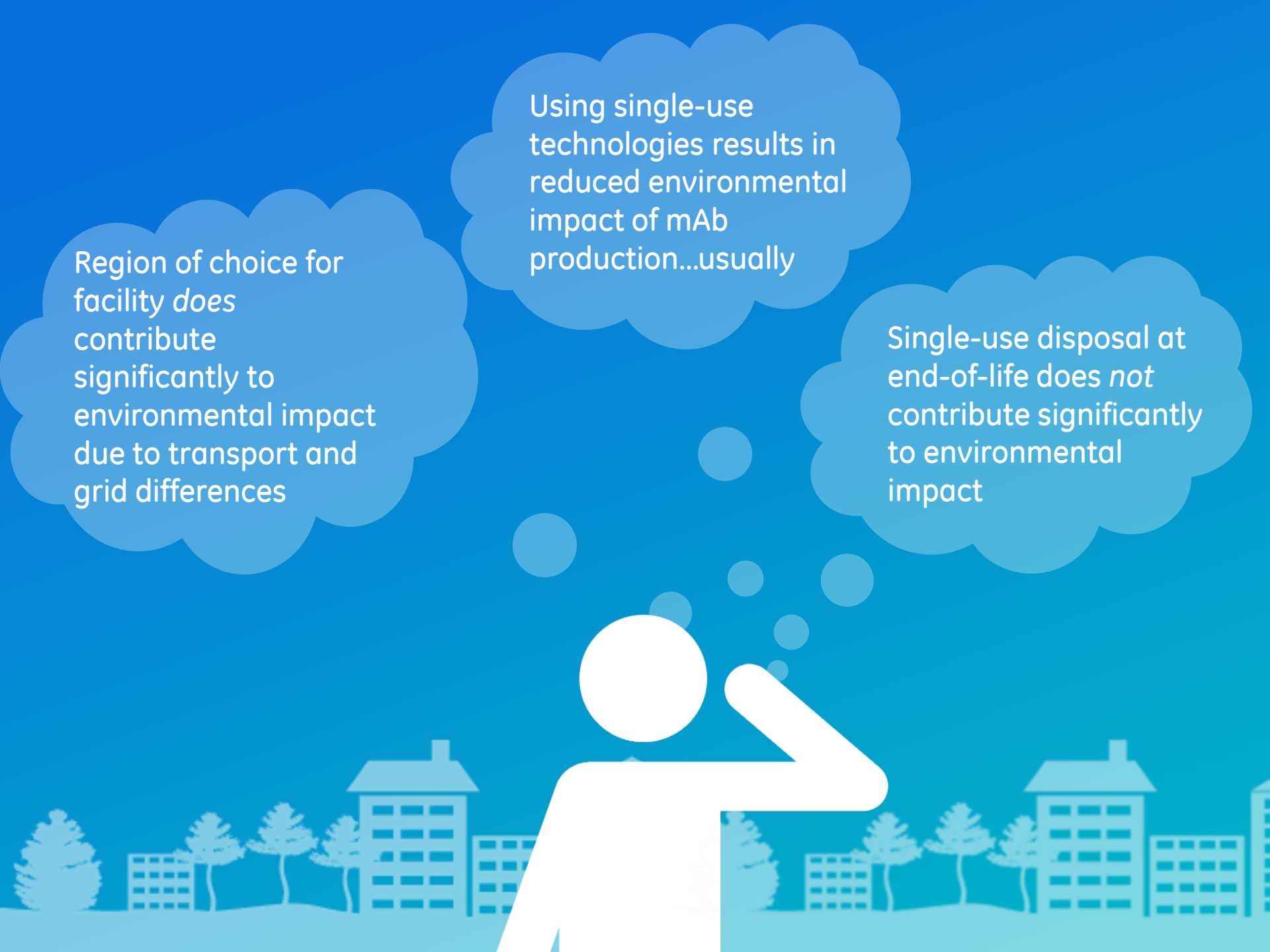
Traditional = traditional stainless steel facility

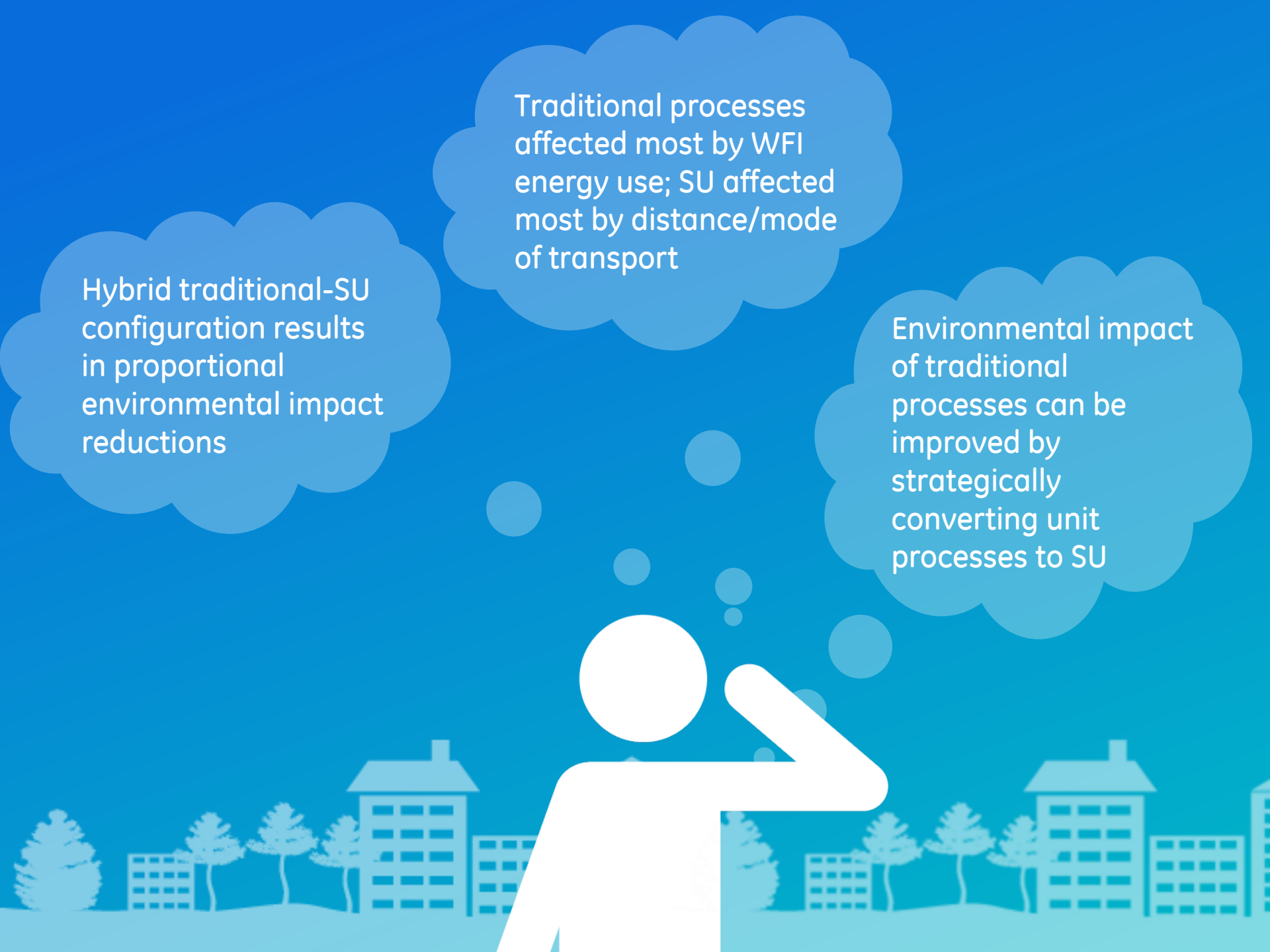
Preliminary results

Using single-use technologies results in reduced environmental impact of mAb production…usually

Region of choice for facility *does* contribute significantly to environmental impact due to transport and grid differences

Single-use disposal at end-of-life does *not* contribute significantly to environmental impact




Traditional processes affected most by WFI energy use; SU affected most by distance/mode of transport
Hybrid traditional-SU configuration results in proportional environmental impact reductions
Environmental impact of traditional processes can be improved by strategically converting unit processes to SU

What is your scenario?

This is an ongoing, collaborative study addressing customer sustainability questions

What are your key questions relative to single-use and sustainability?

Contact us!

Acknowledgements

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