



Process4Success – Process platforms for manufacturing of biological drugs and vaccines

Integrated Solutions, Sartorius Stedim Biotech

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Development of mAb yields



	1998	2003	2008	2013	2018
Titer [g/L]	0.1	1.0	3.0	10.0	> 15.0
Upstream Volume [L]	20,000	10,000	5,000	1,000 -2,000	500 – 1,000
Drug Substance [kg]	2.0	10.0	15.0	10.0 - 20.0	10.0 - 20.0

typical ranges of mAb required Clinical Phases:

Pre-clinic: 20 – 80 g **Phase I:** 0.5 – 2 kg **Phase II:** 1 – 12 kg **Phase III:** 2 – 20 kg

Applications of Single-use – Statements from the Industry

What application(s) would you consider suitable for Single-Use solutions?

	2010	2009
GMP Manufacturing	64.7 %	45.6 %
Pilot Plant Ops	82.3 %	17.3 %
R&D	76.4 %	13.0 %
Process Development	85.2 %	10.8 %

2nd Annual Survey of the Bioprocessing Market for Single-Use Solutions 2010, Aspen Brook Consulting, Inc.

Advantages of Single-use – Benefits stated by the Industry

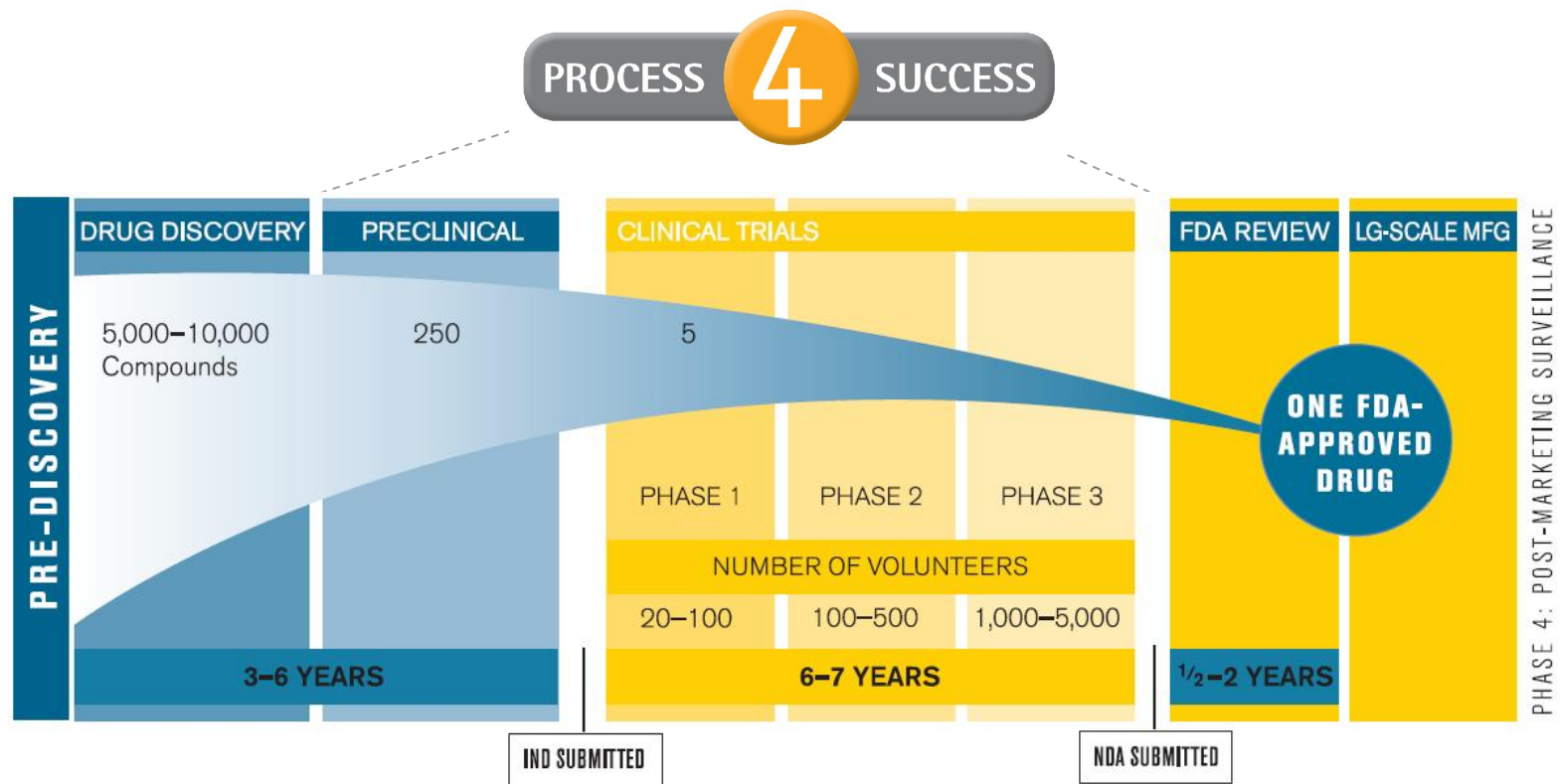
What do you consider the most important benefit of Single-Use solutions?

	2010	2009
Eliminate Cleaning	29.4 %	32.6 %
Increase Capacity	23.5 %	21.7 %
Reduce Costs	2.9 %	15.2 %
Improve Efficiency	17.6 %	8.6 %
Reduce Headcount	0.0 %	2.1 %

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Factory of the Future

Next generation manufacturing of biologic drugs and vaccines must be flexible, adaptable, scalable, economical



Picture:

PHARMACEUTICAL INDUSTRY **profile 2009**

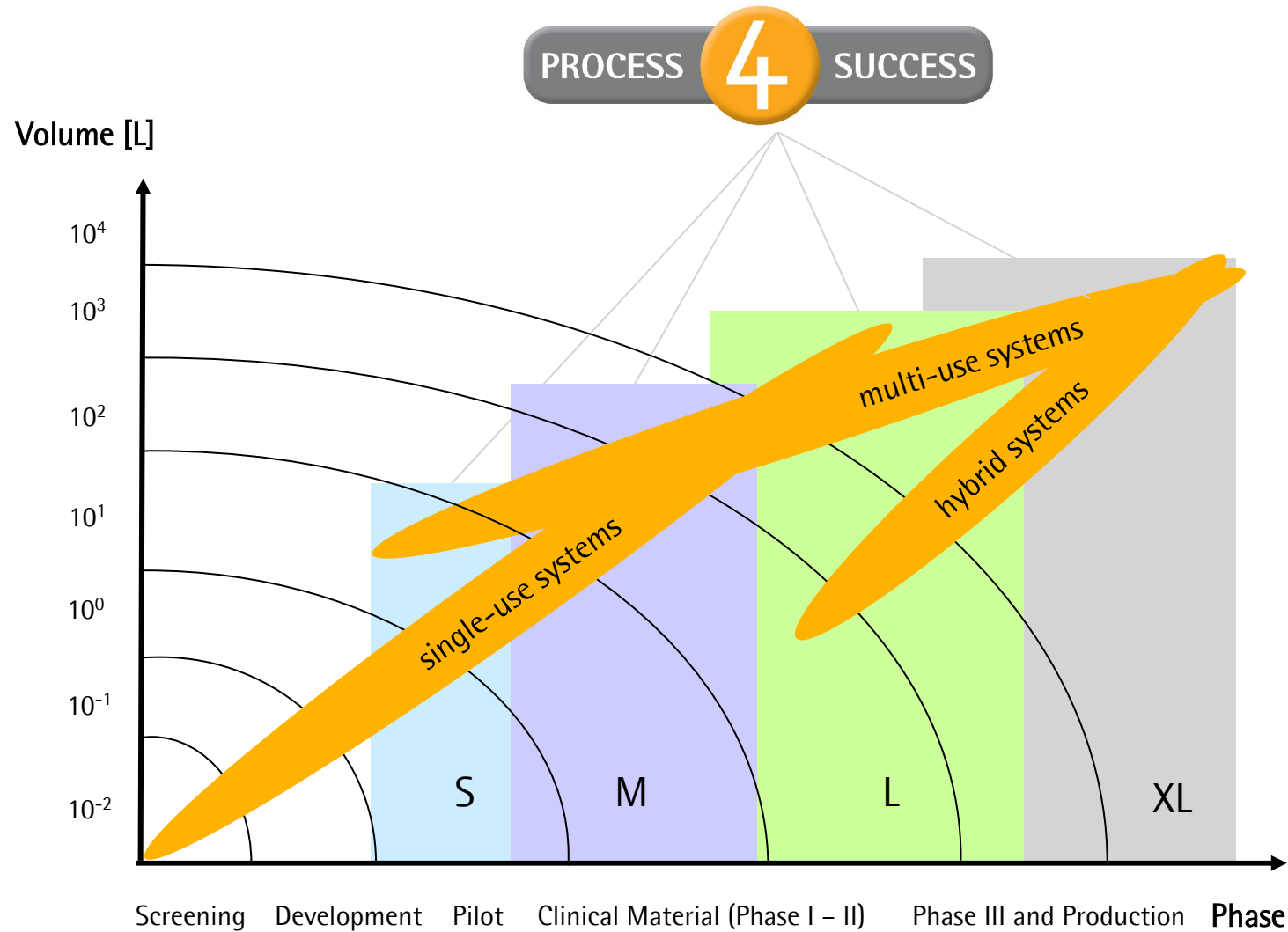
Available Process4Success platforms for mAb's

Batch Volume		50 L	200 L	500 L	1,000 L	3,000 L
Phase		Pre-Clinical / Phase I	Phase I / Phase II	Phase II / Production	Phase III / Production	Production
Product Titre		Standard Solutions (e.g. FlexAct)			Engineered Solutions	
future	> 10 g/L					
	5 g/L	✓	✓	✓		
today	3 g/L					✓
past	< 1 g/L					

Small
Mid
Large
Xtra-Large

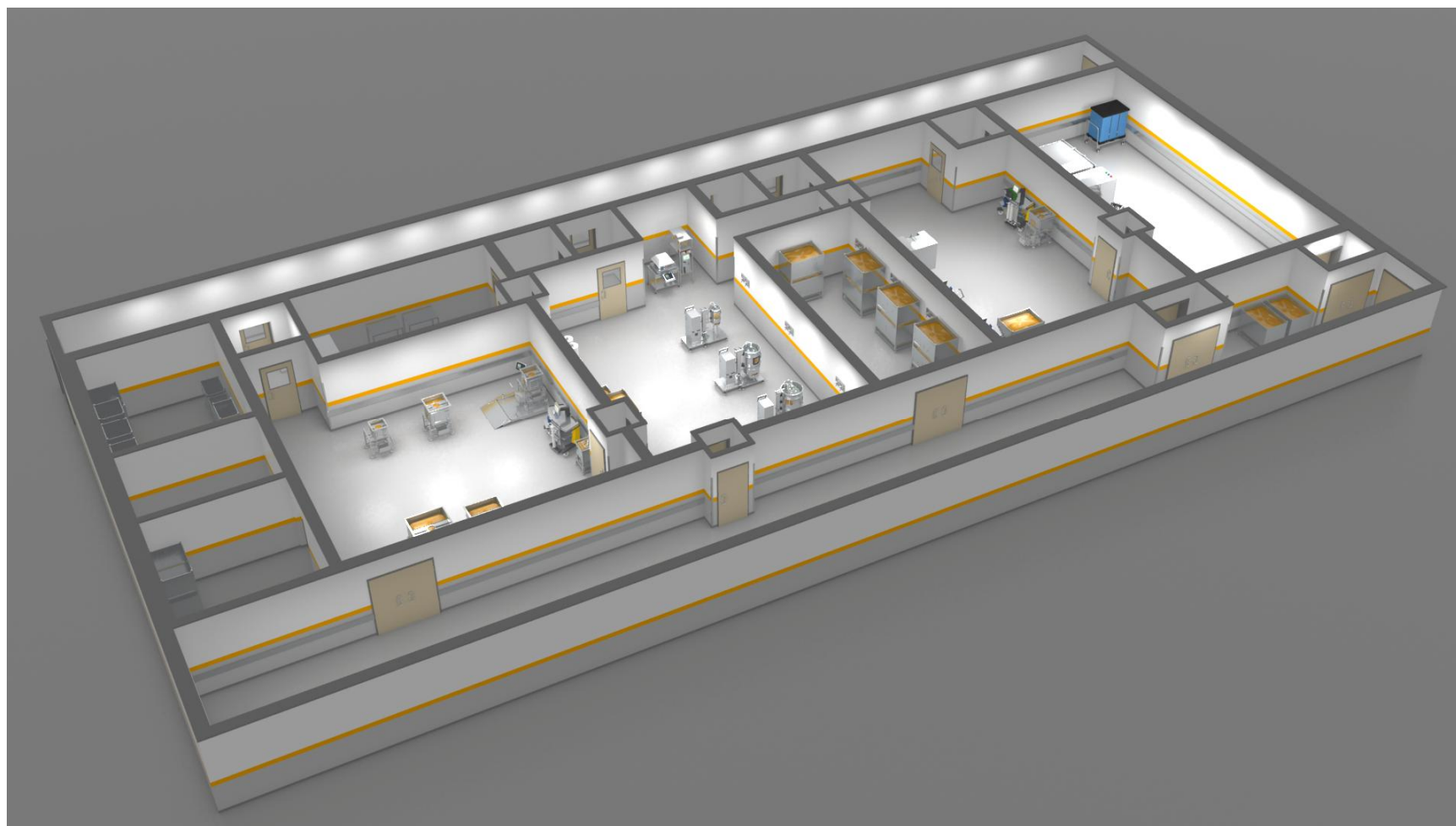
✓ := Process4Success available

Four Process Platforms in drug substance development



PROCESS **4** SUCCESS

mAb L – Virtual Tour



Major benefits of **PROCESS 4 SUCCESS**

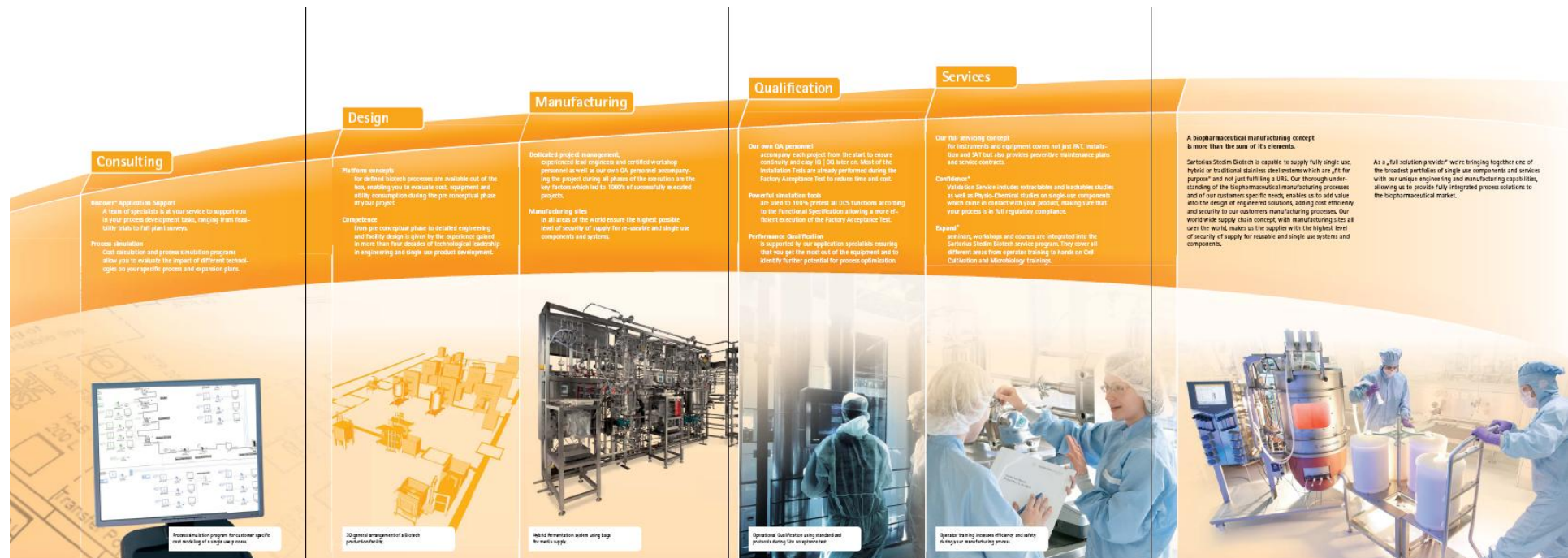


- Fast implementation
- Effective engineering workflow
- Flexibility in manufacturing
- Reliable performance
- Less investment costs



Integrated Solutions –

From URS to final Qualification



Process4Success – Expedite your Manufacturing Capacities!