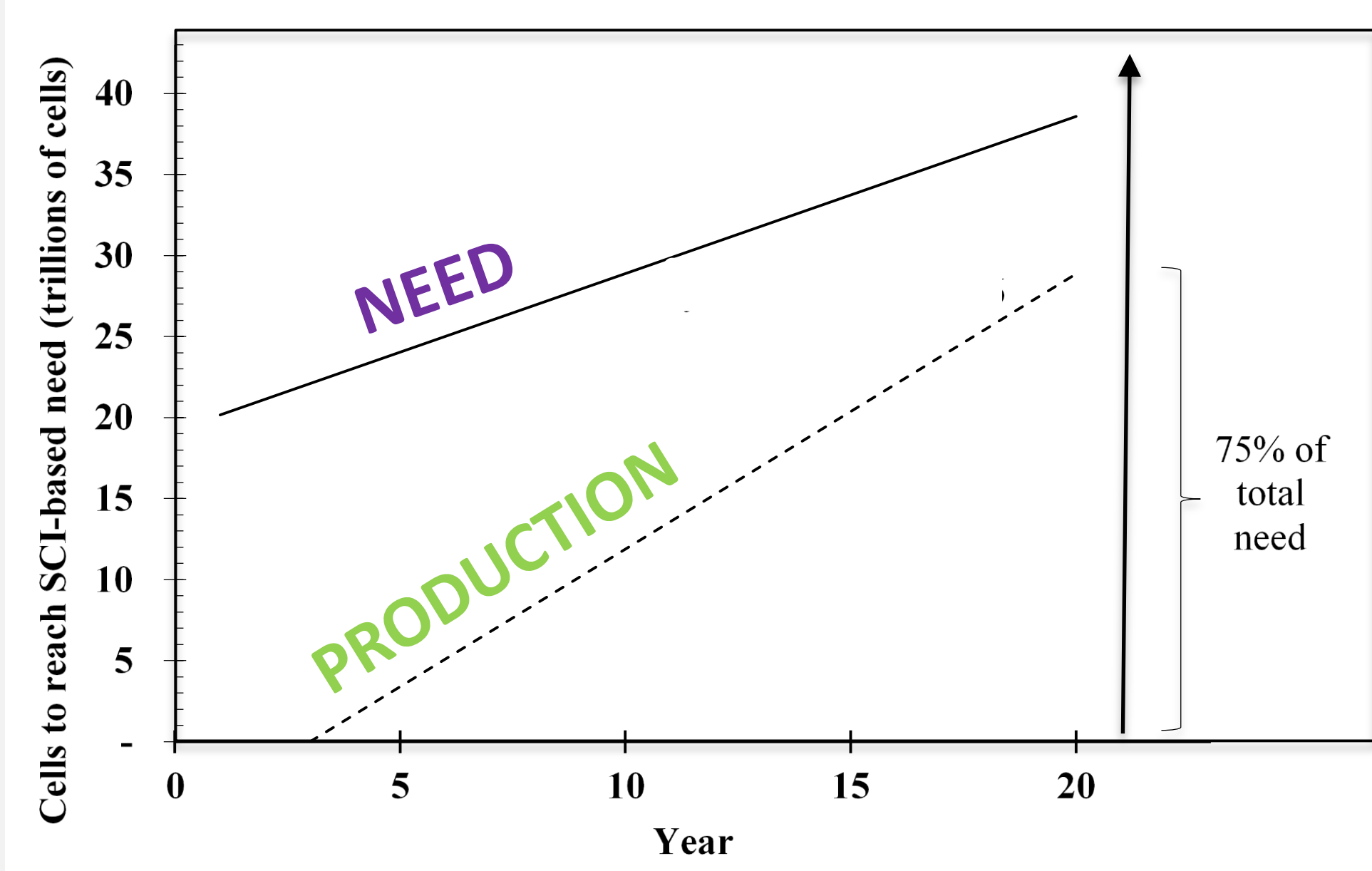
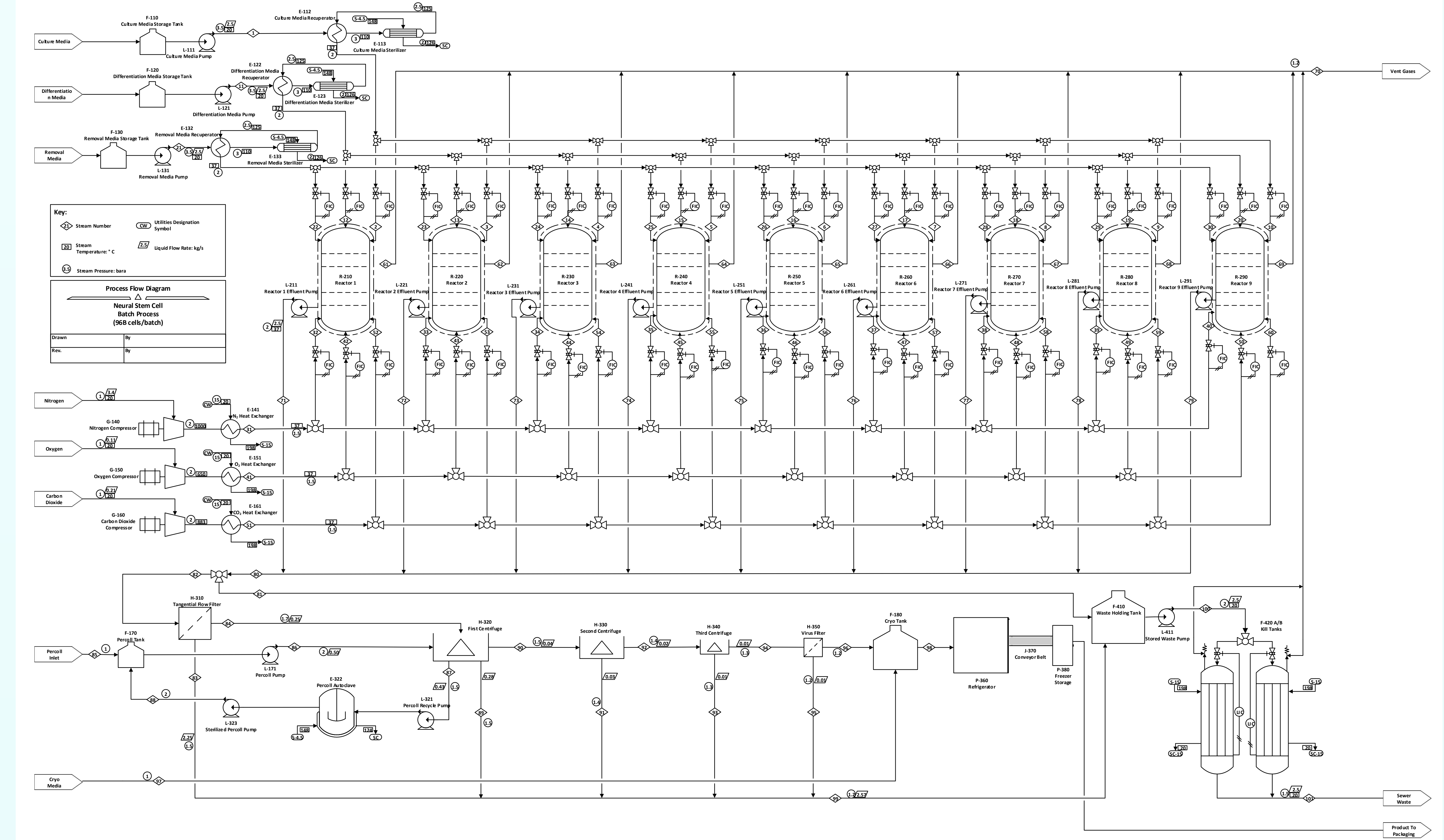
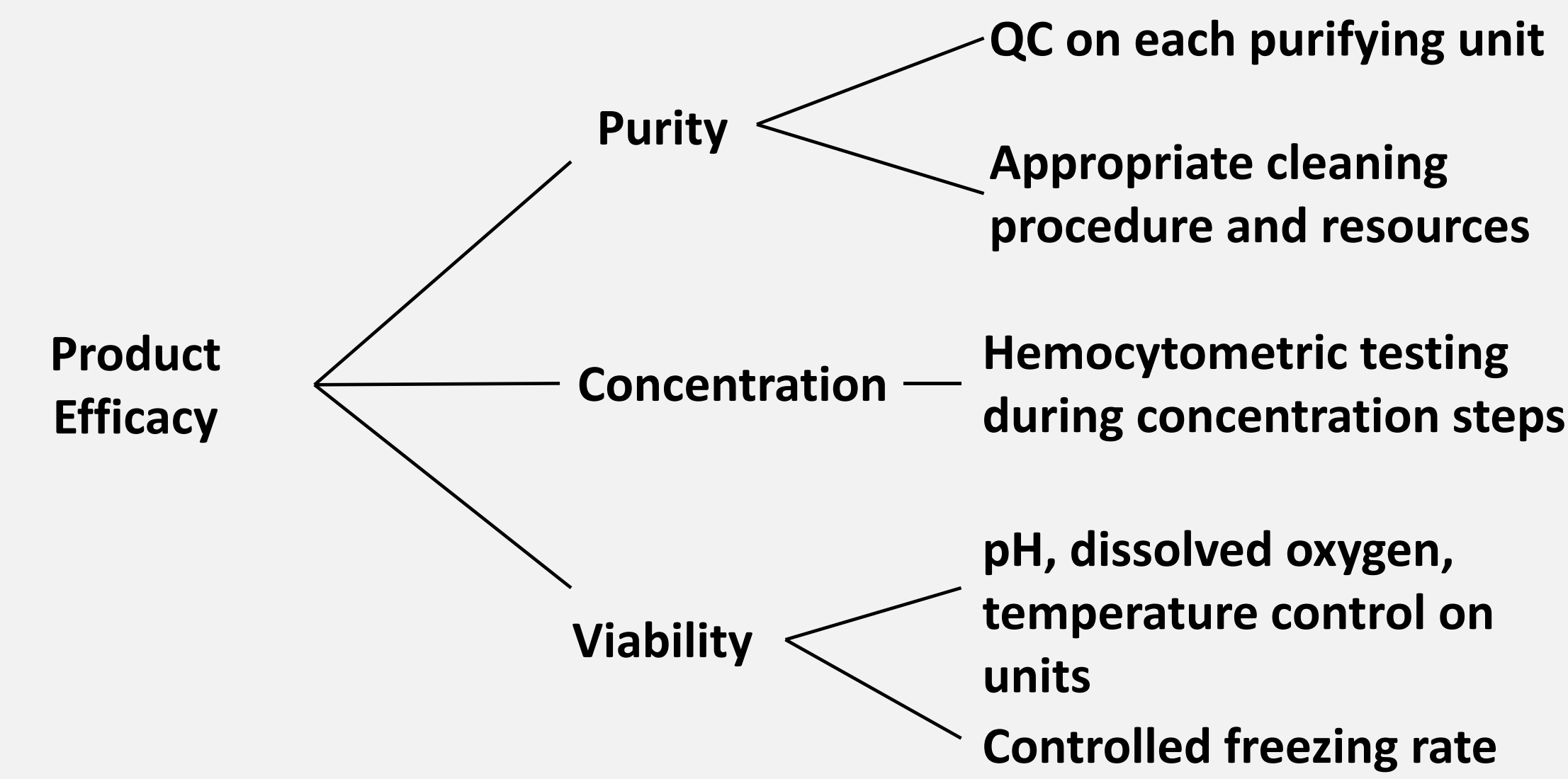


Clay Corporation strives to innovate the production of safe, pure and effective adult stem cells for the treatment of spinal cord injury (SCI).



Critical to Quality Variables

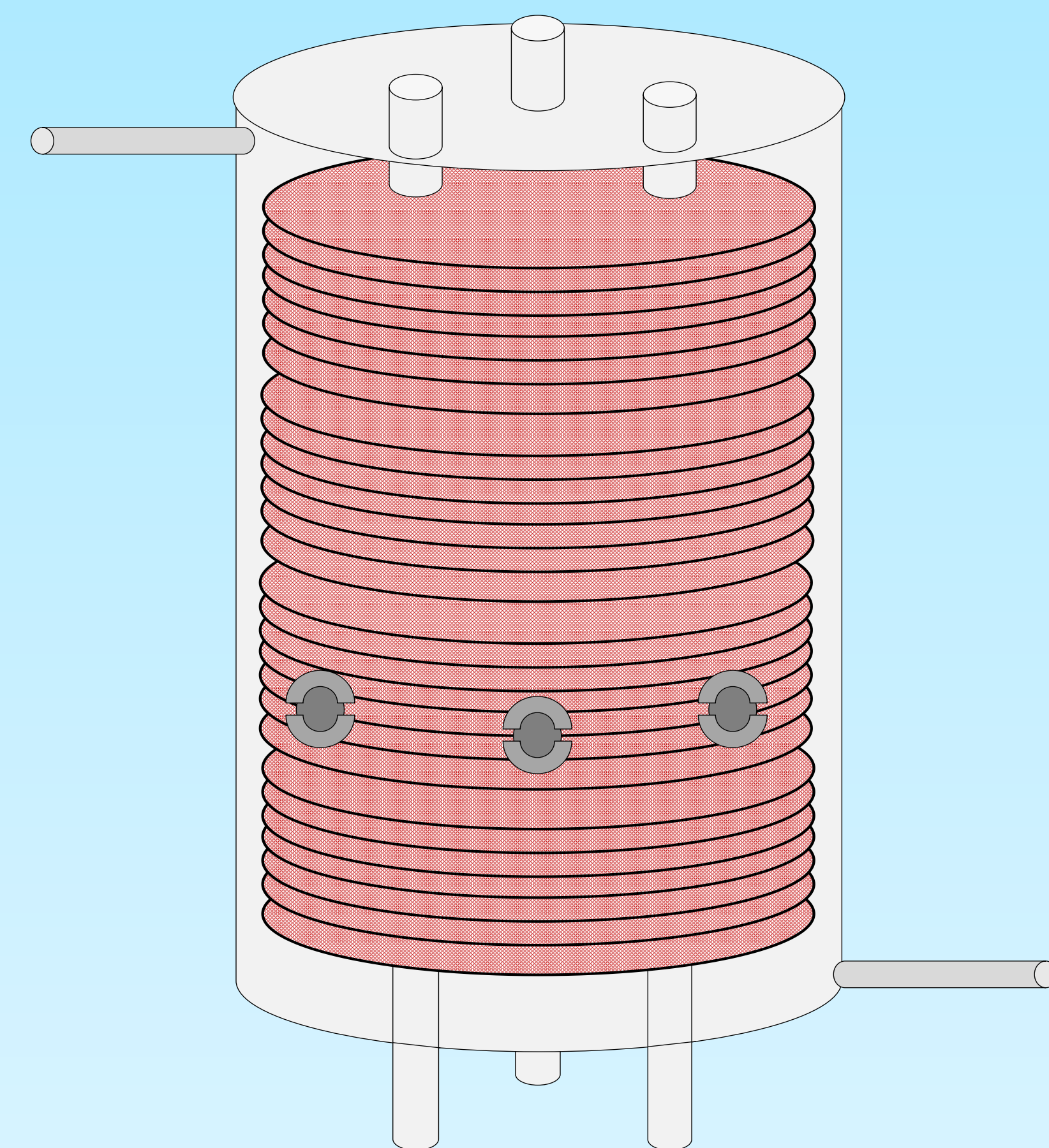


Mass Balance: kg/batch

Component	1	11	21	31	41	51	70	80	82	84	85	87	90	92	94	96	97	98	100
	Culture Media Feed	Differentiation Media Feed	Removal Media Feed	Nitrogen Feed	Oxygen Feed	Carbon Dioxide Feed	Overall Gas Outlet	Total Broth	TFF Feed	TFF Retentate	Percoll Inlet	Percoll Recycle	First Centrifuge Band	Second Centrifuge Band	Third Centrifuge Band	Virus-Free Cells	Cryo Media	Cells to Freeze	Waste
Culture Media	220,250							220,250											220,250
Differentiation Media		17,620.0						17,620											17,620
Removal Media			8,810.0																8,800
Oxygen					1,710,170		1,368,136												
Nitrogen				52,445,213			52,445,213												
Carbon Dioxide						2,850,283	3,192,317												
Removal Media with Stem Cells								8,800	8,800	880			44	2.2	0.11	0.11			
Organic Waste								10	10	10			2	4.4	0.22	0.21		0.11	
Percoll											264	1496	88	4.4	0.22	0.21		0.21	
Cryo Media																	3.3		263.79
Total	220,250	17,620	8,810	52,445,213	1,710,170	2,850,283	57,005,666	246,680	8,810	890	264	1,496	134	7	0.33	0.32	3.3	3.6	246,944

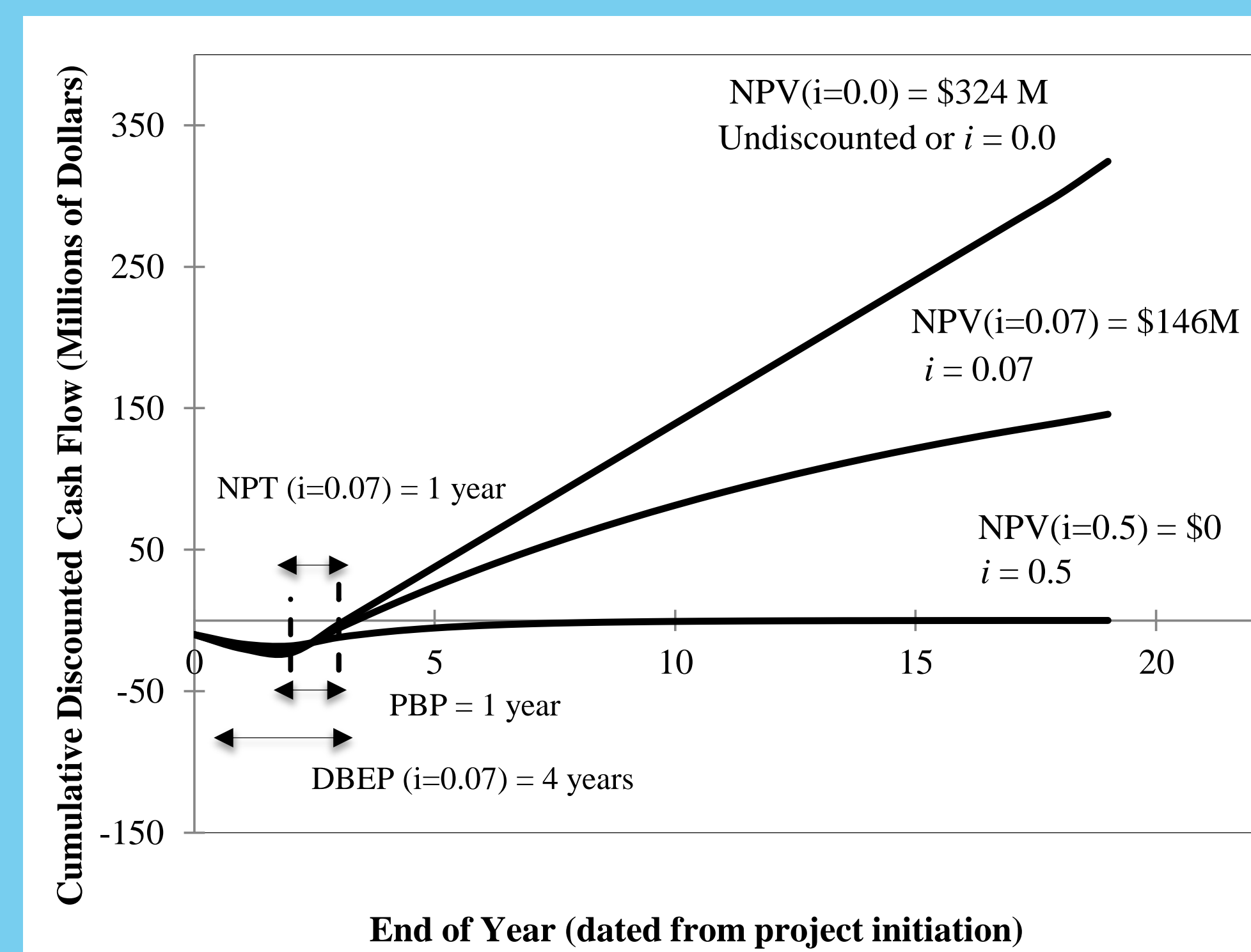
Clay Corporation's Custom Plate-Based Reactor

Modeled after the Xpansion 200[®] Bioreactor by ATMI Life Sciences



- Eliminates need for passaging
- Minimal shear-stress environment
- Excellent control over temperature, pH, and dissolved oxygen
- Decreased utility use compared to CSTRs

Economic Analysis



Profitability

Net Present Value_(i=7.4%) = **\$146 M**

Cost per treatment = **\$10,000**

Payback Period = **1 year**

Conclusions

Clay Corporation recommends proceeding with plant design.

- ✓ Feasible and safe process design (GMP)
- ✓ Critical to Quality Variables met
- ✓ Effective product for treatment of SCI
- ✓ Profitable after one year of production

Acknowledgments

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