

CASE STUDY NO.3

Process Development – MSCs

PROJECT SPONSOR

Clinical phase company for MSCs based therapies

OBJECTIVES

To increase yields by scale-up (X10) and to design automated and controlled process in custom made bioreactor

TIME FRAME

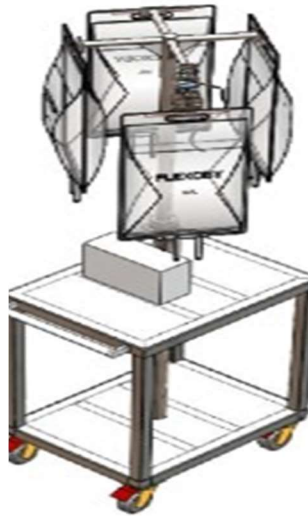
Step 1- up scaling in 2D- 4 months
 Step 2- building custom made bioreactor- 1 year

PROCESS DATA

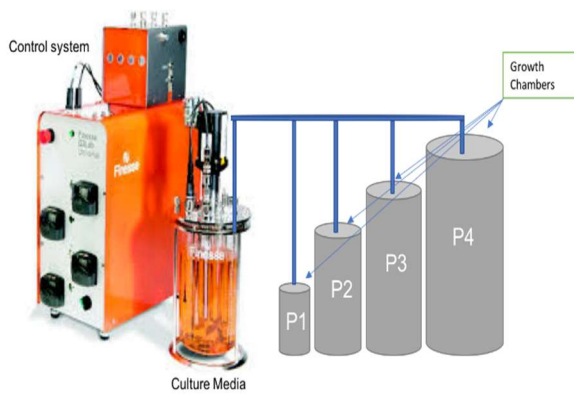
	Original process	Step 1	Step 2
<i>Culture vessels</i>	T75	Cell factory 10	Bioreactor
<i>No. of vessels at the last passage</i>	Up to 1000	16 X Cell factory 10	Seed train bioreactor
<i>Process time</i>	Several days	Several hours	Few hours
<i>Cell yield</i>	1.2 X 10 ⁹	5 X 10 ⁹	100 X 10 ⁹
<i>Increase fold</i>	-	4-5	20
<i>System</i>	Completely opened system	Minimal system openings, can be eliminated by using welder	Completely closed system

Step 1:

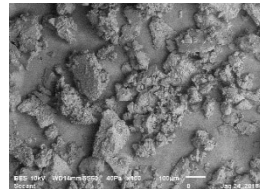
- Improving yields and quality
- Reducing process time and manual labor
- Cost effective



Step 2:



**SEM image (x100)
Flour particles**



**SEM image (x500)
Flour particles**

