

Assessment of the scale-X™ bioreactor for the cultivation of Vero cells

Naobios has more than 15 years of experience developing manufacturing processes for viral-based products. The Vero cell line is one of the reference cell substrate for the production of viruses for various applications such as viral vaccines and oncolytic viruses. As an adherent cell line, Vero cells are cultivated in static containers (monolayer, multilayers tissue culture flasks).

When large quantities of cells are required, instead of scaling-out production using numerous static containers, scaling-up can be performed through different platforms like fixed-bed bioreactors or microcarriers based process in stirred-tank bioreactors.

Univercells Technologies has developed a new generation of fixed-bed bioreactor named scale-X™ bioreactor. To expand the services provided to its clients, Naobios has recently assessed the performances of Vero cells culture into the scale-X™ bioreactor provided by Univercells Technologies.

Few words about the scale-X™ bioreactor technology

Fixed-bed bioreactors can provide a scalable and intensified alternative for adherent-based virus production. The scale-X™ structured fixed-bed bioreactors are available in a variety of sizes from the scale-X™ hydro (2.4m² surface of culture), carbo (10-30m² surface of culture) and nitro (200-600m² surface of culture) models supporting product development, clinical and commercial manufacturing.

The fixed-bed of the scale-X™ bioreactor is structured. It alternates sheets of non-woven PET fabric and spacer netting wound in spiral.

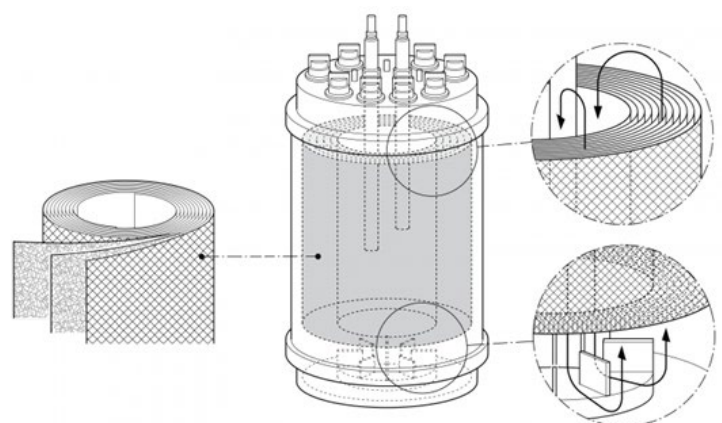


Figure 1 - Scale-X™ fixed-bed structure (source: Univercells Technologies)

Naobios assessed the performance of Vero cells growth into the scale-X™ hydro bioreactor, the homogeneity of cell growth into the fixed-bed and the robustness of the technology. Vero cells were cultivated in serum-free conditions in several bioreactors.

Cell growth performance was compared to historical data generated with Naobios' reference fixed-bed bioreactor. Cell growth homogeneity was assessed by dismantling several bioreactor vessels to quantify cell densities at different locations of the fixed bed (refer to Figure 5).

Results

Naobios successfully achieved the set-up of the scale-X™ bioreactor technology in its process development laboratory. The scale-X™ bioreactor technology demonstrated its capacity to support the growth of Vero cells in serum free conditions at a similar cell density level than the reference fixed-bed bioreactor used at Naobios (refer to Figure 2).

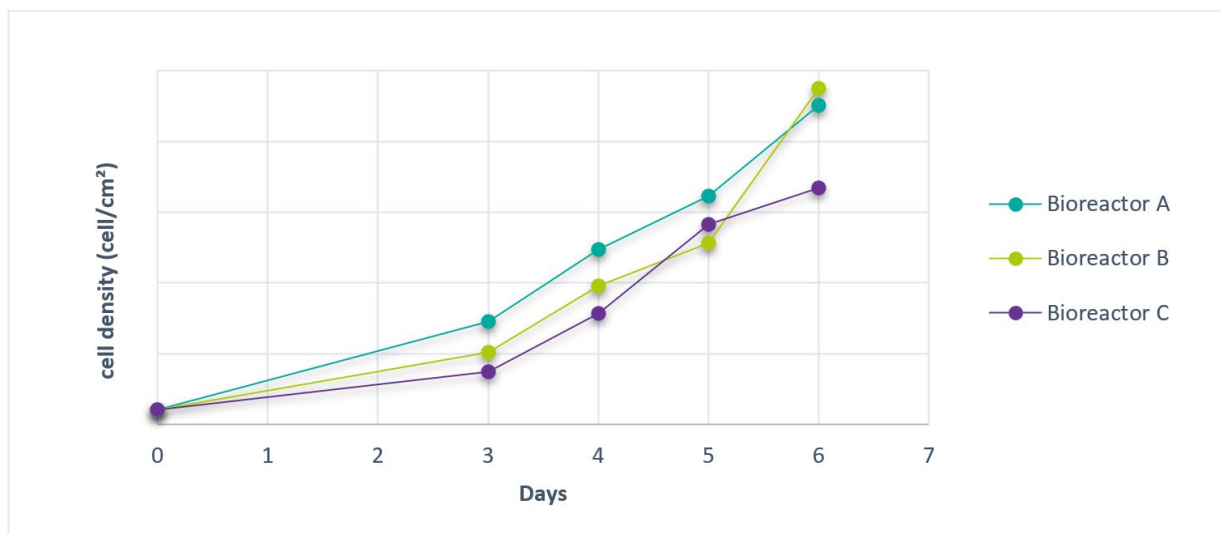


Figure 2 - Vero cell growth in scale-X™ hydro bioreactor

In addition, through the dismantling of the fixed-bed and the quantification of cell density at different heights on both layers, the homogeneity of cell growth within the whole 3D structure was demonstrated (refer to figure 3, 4 and 5).

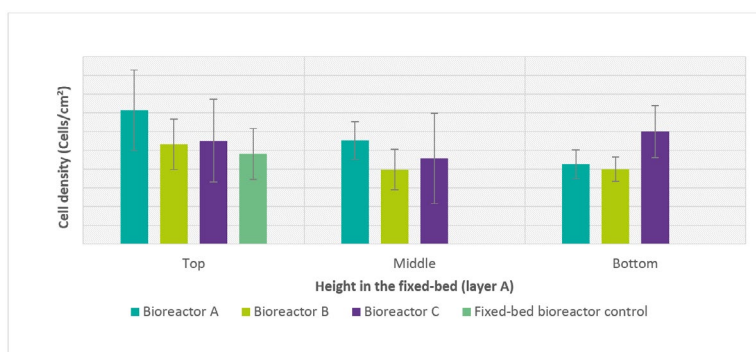


Figure 3 - Vero cell growth homogeneity into the scale-X™ hydro bioreactor (layer A)

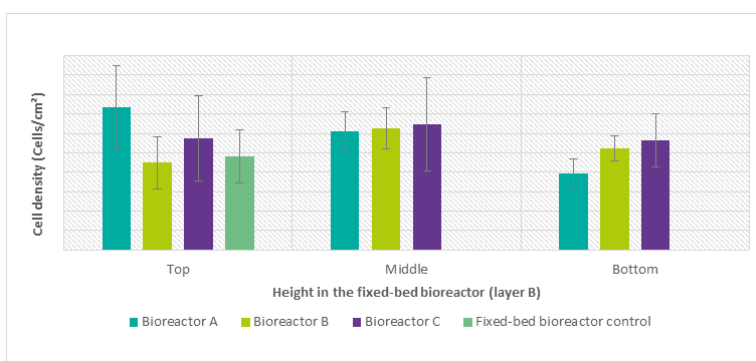


Figure 4 - Vero cell growth homogeneity into the scale-X™ hydro bioreactor (layer B)



Figure 5 - Dismantling the Scale-X™ fixed-bed structure

Conclusion

Naobios is thus considering the scale-X™ bioreactor as a suitable technology to be used for virus production using adherent cell lines. Custom feasibility studies and process development services using this technology are proposed to our clients to support their product development towards GMP manufacturing of clinical batches.

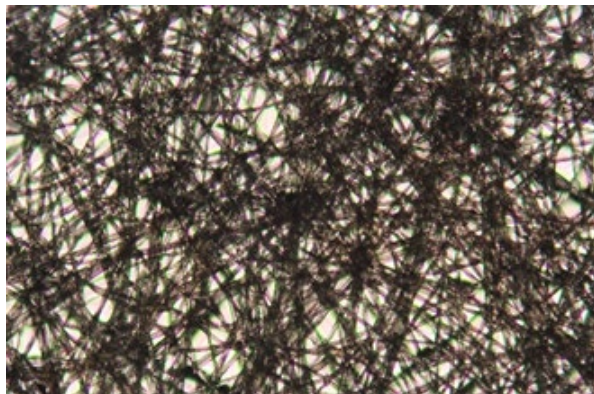


Figure 6 - Microscopic observation of Scale-X™ fiber - D1 post cell inoculation

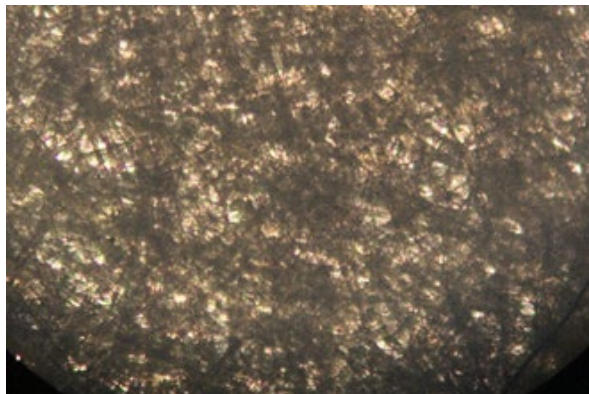


Figure 7 - Microscopic observation of Scale-X™ fiber - D4 post cell inoculation