

## VACCINE PRODUCTION PLATFORM BASED ON HEK293 CELLS

Simple, reproducible, scalable.

High virus production in large scale stirred tank bioreactors with HEK293 cells in a synthetic medium.



# One platform for production of viruses and recombinant proteins –



## BENEFITS

Developed to maximize virus production with HEK293 cells. The platform consists of several modules which are integrated to each other and finetuned for maximal virus production in large scale stirred tank bioreactors.

**One platform for virus and protein production:**

One cell bank, one medium, one bioreactor setting for virus and protein production. No repetitive media development and process development necessary.

**Scalable:** Scalability is demonstrated from shake flask to stirred tank bioreactors.

**Simple:** Ideal from bench to manufacturing scale.

**Highest regulatory quality:** No risk for animal derived contaminants in culture media or cell bank.

**High reproducibility:** Minimal human interference into the process, thus highly reproducible.

## PRODUCT INFORMATION

HEK293 platform is developed for maximal virus and protein production in large scale bioreactors in an economical way due to high cell concentration obtained.

If basal medium is combined with the specific feed media, viable cell concentration up to  $3,5 \times 10^7$ /mL is achieved in stirred tank bioreactors.

Cell thaw and stock culture is implemented in shake flask. Cell expansion and virus production is performed in stirred tank bioreactors in batch or fed-batch process.

# HEK293 PLATFORM MODULES

## THE HEK293 CELL LINE

The cell line is obtained from Public Health of England and adapted to serum free suspension growth. Cell line is further adapted to resist high shear forces in large scale stirred tank bioreactors. Fully adapted suspension cells are frozen in serum free, animal component free media. Long term cell bank stability is proven over years in performance testing. Cell bank history and development report are part of cell bank delivery package for high regulatory acceptance.

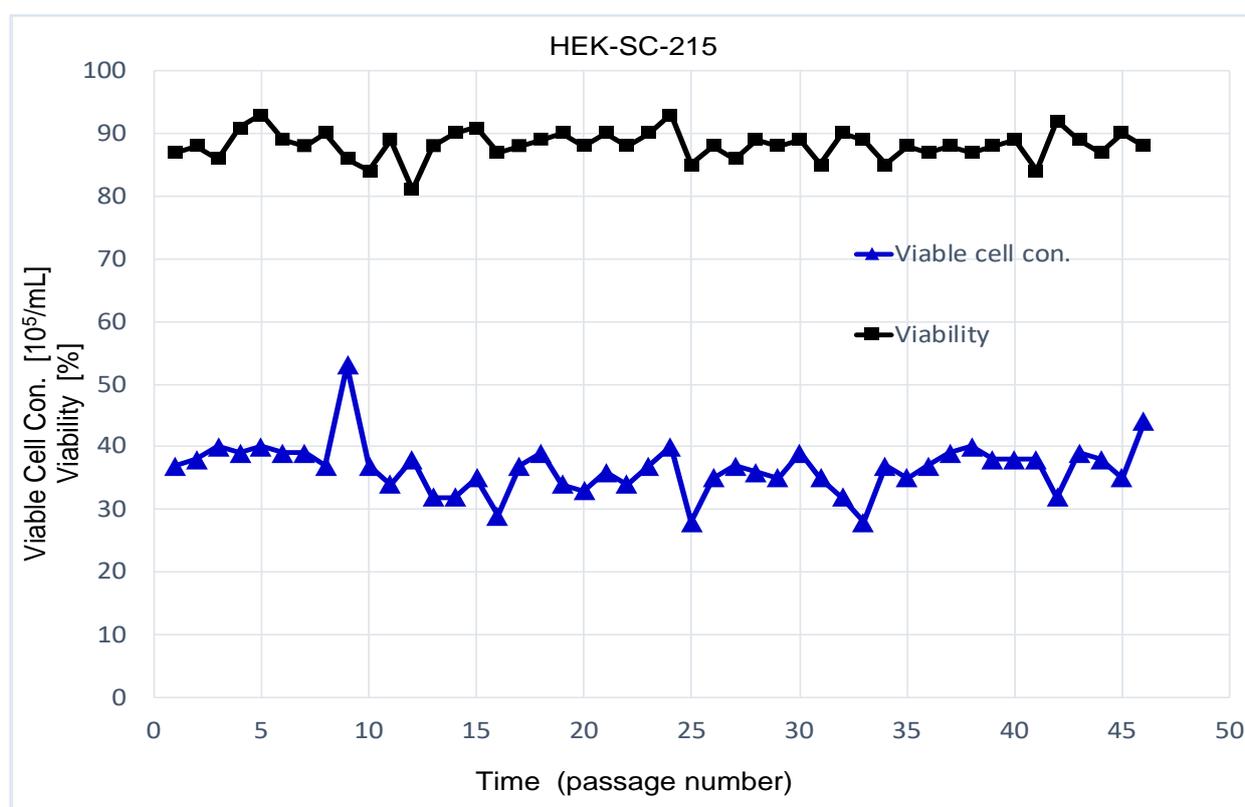


Figure 1: HEK293 suspension cells are cultured in stock culture in shake flasks in ORCHID S stock culture medium for 46 passages (138 days). Shake flasks were inoculated with a cell concentration of  $5 \times 10^5$ /mL and cultures were splitted every third day.



## ORCHID - HEK293 CULTURE MEDIA AND FEEDS

ORCHID P medium is free of serum, animal components and hydrolysates. The medium is developed for maximal virus and recombinant protein production in suspension HEK293 cells. If combined with ORCHID FEEDs the media support a viable cell concentration up to  $3,5 \times 10^7$ /mL. Suspension HEK293 cells have been carried for more than 3 years in ORCHID medium with no loss of viability.

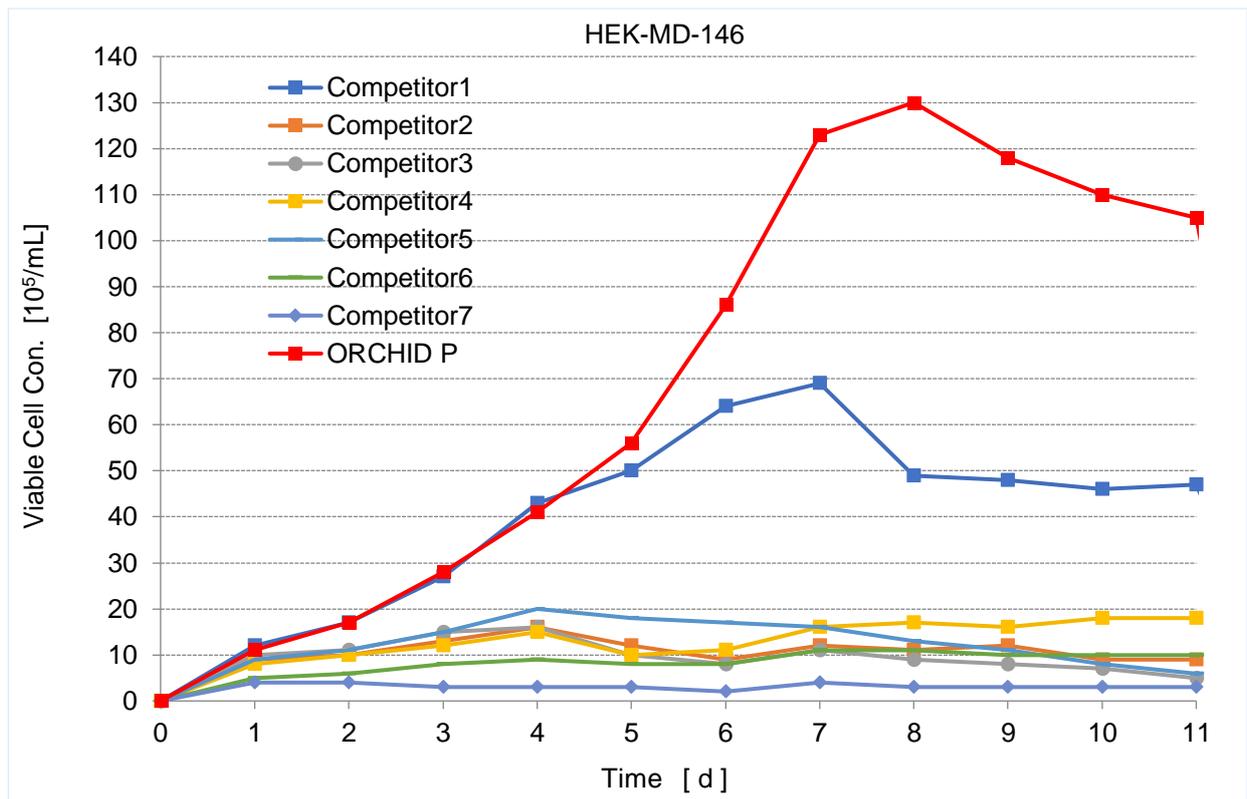


Figure 2: Growth performance of suspension cells in commercially available media. Cells are adapted to corresponding media for 4 passages before testing the growth performance. Experiment is performed in batch in shake flask.

## HEK293 BIOREACTOR PROCESS

A whole process is developed starting with cell thaw, stock culture, culture expansion and bioreactor steps. All process steps are reproduced up to 10 times to demonstrate the robustness. The bioreactor process can run in batch or fed-batch modus depending on what is planned to produce. The process is designed for large scale. Detailed process description and support in process transfer are parts of the package.



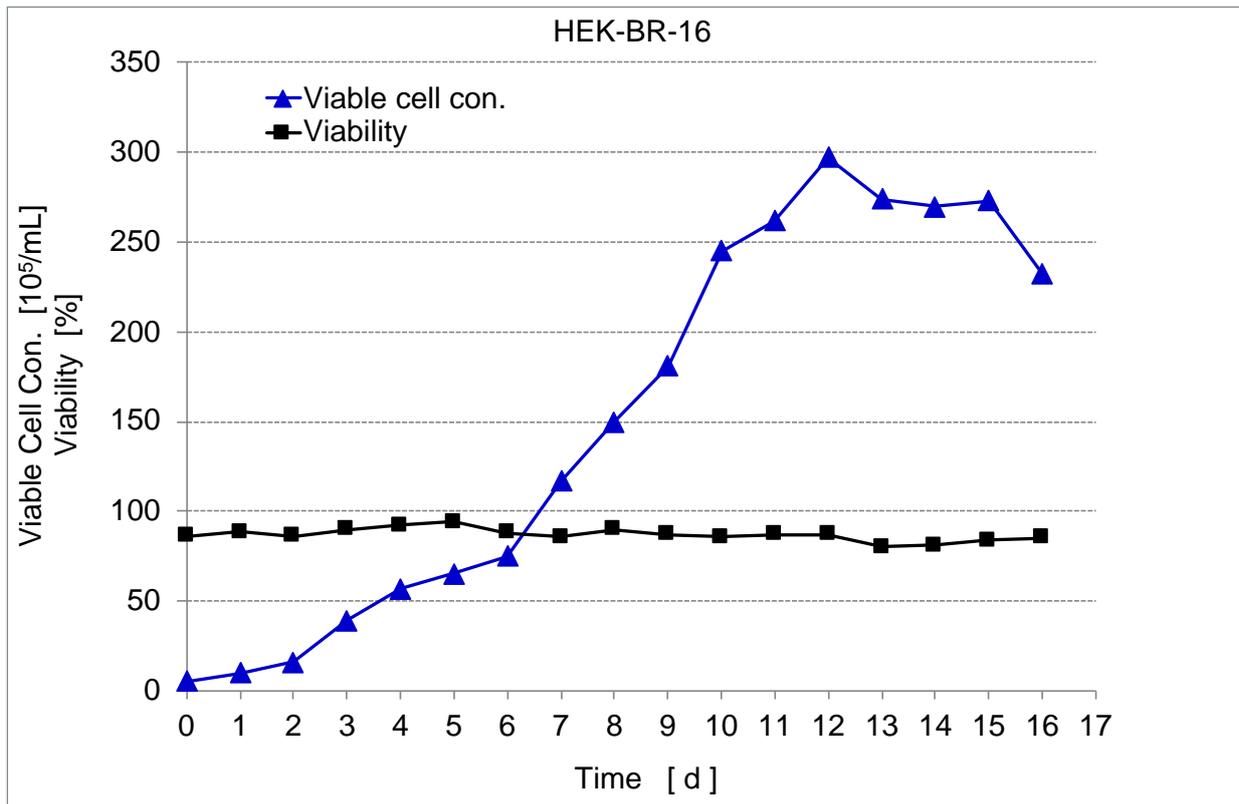


Figure 3: HEK293 suspension cells cultured in 4 L stirred tank bioreactor in fed-batch process. Cells are cultured in ORCHID P basal medium and fed with ORCHID FEEDs.

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