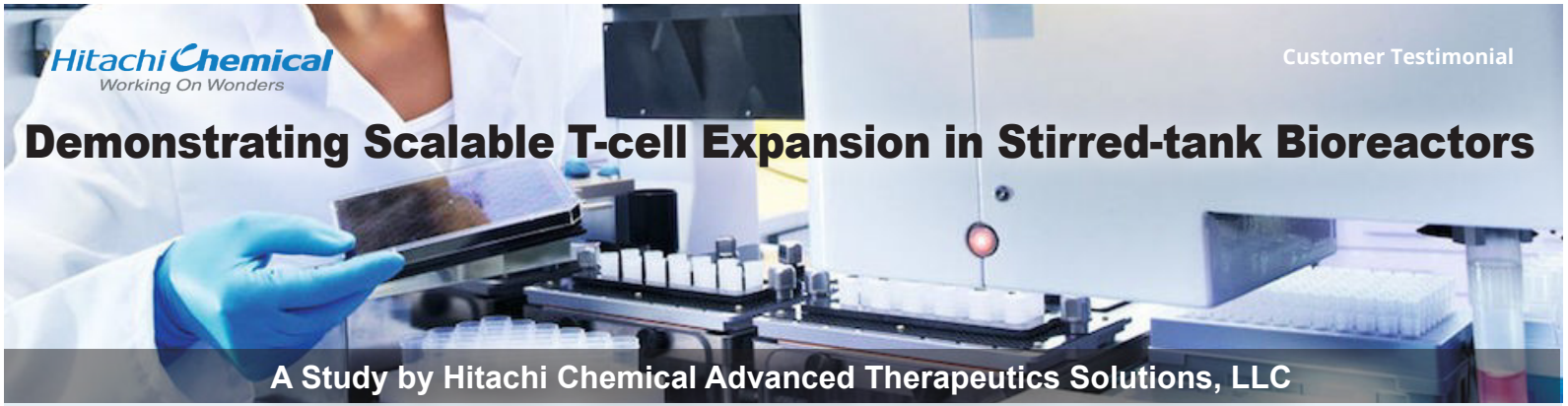

Hitachi Chemical
Working On Wonders

Customer Testimonial

Demonstrating Scalable T-cell Expansion in Stirred-tank Bioreactors

A Study by Hitachi Chemical Advanced Therapeutics Solutions, LLC

Introduction

'Working on Wonders' expresses a pioneering spirit to explore uncharted areas. Hitachi Chemical develops innovative solutions beyond the boundaries of chemistry, delivering 'wonders' that exceed the expectations of customers and society.

www.hitachi-chem.co.jp/english

User Commentary

"We are very happy with the NC-200™ and its ability to provide cell enumeration data quickly and accurately. The Via1-Cassette™ technology is wonderful."

Alex Klarer, Biomedical Engineer, Innovation and Engineering

Challenges

Emerging cell therapies indicate potential new pathways to treat life-threatening diseases. With recent US FDA approvals, T-cell therapies are the flagship technology in cell therapy and serve as powerful tools for treating a range of diseases in oncology and other areas. The expansion of immune cells during manufacturing for immunotherapies is crucial for these treatments to be effective. Patient cells must be expanded in culture until they reach a total cell number that is large enough to be an effective dosage. This paper examines the ability of immune cells, specifically T-cells, to grow in a microbioreactor compared to the current industry standard rocking culture method.

Two main advantages of bioreactor growth are the ability to grow larger quantities of cells in less space and to reduce the amount of media to be exchanged on a regular basis. The authors show that these microbioreactors deliver an overall growth rate comparable to that of standard culture methods. They also saw a four-fold increase in total cell number at the end of the culture period, while requiring less media by using perfusion in place of batch-fed media replacements.

The authors argue that this microbioreactor is a small-scale demonstration of the performance achievable by a full-size bioreactor. Large bioreactors would reduce costs related to cell culture reagents and potentially decrease the time it takes to expand the cells to the necessary quantity.

Samples from each culture were obtained on days 0, 2, 5, 7, 9 and 13. Vital cell count data was collected using Via1-Cassettes™ with the NC-200™ system. This monitoring of the growth of cells in culture is necessary to assure that the cells are dividing and not arrested due to stress or poor culture conditions. To this end, it is essential to be able to gather consistent and accurate cell counts. The counting of cells at the end of the culture period is most important because these cells are used as a drug to treat patients. Whenever a drug is administered to a patient the dosage must be precisely quantified. For cell therapy products, the total cell number is the dosage. Hence it is absolutely necessary to be able to get accurate and consistent cell counts for these immunotherapies.

Citation: Klarer, A., et al. 2018 "Demonstrating Scalable T-cell Expansion in Stirred-tank Bioreactors", BioProcess International

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21 CFR Part 11 Ready

21 CFR Part 11 is the US regulation for electronic signature and data storage. It requires biotech companies and other FDA-regulated industries to implement controls for systems and software involved in processing electronic data.

The ChemoMetec NC-200™ NucleoCounter is 21 CFR Part 11 Ready and a module is available as an optional extra, if required. Activation of the module locks the interface to prevent accidental or deliberate manipulation of the data.

The 21 CFR Part 11 license includes GMP-ready features such as logging in with user-group credentials which documents actions in a secured audit trail format making the NC-200™ suitable for regulated laboratory environments and the production and manufacture of cell-based products.