

## Customer Experience - Regulatory



Andy Tsun, PhD,  
Co-Founder and VP of Discovery Biology, Biotheus Inc..

### Successfully filing an IND using Solentim's VIPS™ single cell cloning system

*"The VIPS™ system and software has helped our company to deliver a high-quality data-package that meets global regulatory standards. As a start-up we often wear multiple hats. The ease of use and reliability of the VIPS freed up valuable time and resources to help with platform development and to support the discovery team for other R&D activities."*

#### Introduction

Biotheus Inc. was granted an IND in March 2020 for its bispecific therapeutic asset, PM8001. Regulatory approval was attained with help from the Solentim VIPS™ system for single cell cloning and clonality reporting.

In this article, Dr Andy Tsun, Co-Founder and VP of Discovery Biology at Biotheus Inc, shares his company's experience using the VIPS, including how it helped accelerate their cell line development process and crucially satisfy the regulatory requirements.

#### CLD workflow - the need for speed

Due to the competitiveness of the therapeutic antibody space in China, it is of utmost importance to discover and develop their lead assets with high quality and speed.

"The VIPS system allowed us to shave off a few months from our development timeline and select highly stable single clones for manufacturing purposes. VIPS is an integrated system that fits into a typical CHO cell line engineering and development process, from generating cell pools or mini pools to single cell sorting and imaging to test for clonality" explained Dr Tsun.

"This optimizes the number of single clones that enter the ranking process and increases the efficiency of selecting clones that could meet our scale-up and manufacturing criteria.

"As a small biotech start-up with multiple discovery campaigns, we try to streamline and accelerate our pipeline development and push multiple lead candidates through to CHO pool generation and cell line selection. That's why we decided to purchase the VIPS system soon-after the founding of Biotheus to ensure that our cell line team could use their time efficiently.

"Compared with typical limited dilution processes, we increased our throughput by around three-fold by reducing the number of culture plates required during the cloning stage, which was facilitated by the robust single cell seeding functionality of the VIPS system.

"For our first project, the VIPS system helped to relieve pressure on our cell line development team whilst increasing throughput to deliver a high-quality data package.

"As a small team, this was very important due to the lack of manpower and resources at the early set-up phase of the company. Typically, we carried out imaging on days 0, 1, 2 or 3, 5, 8 or 9, and included this historical tracing information in our filing documentation. The cell line generation report (or clonality report) has satisfied our IND filing requirements for the Chinese NMPA" concluded Dr Tsun.

Biotheus also aim to use their IND filing documentation for ex-China filings with the EMA and US FDA.