Building a data-driven bioindustry

Website

Application note

BUILDING A DATA-DRIVEN BIOINDUSTRY
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Building a data-driven bioindustry

Accelerate Your Antibody Product To Market Based On QbD Strategy

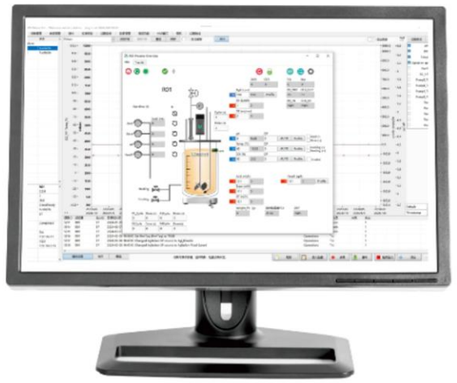
BUILDING A DATA-DRIVEN BIOINDUSTRY

ABOUT US

A pioneer in bioreactor innovations

TJX represents the international division of T&J Bioengineering and serves its global clientele through local partners. T&J Bioengineering is a Sequotia-backed startup that has emerged as a leading provider of high-throughput parallel bioreactor systems in China and a significant player on the global stage. T&J operates four facilities strategically located in Shanghai, Shenzhen, Singapore, and California. In Shanghai, the company's factories specialize in designing and manufacturing a range of systems, including single-use, glass, and stainless steel systems. Additionally, they produce GMP-compliant pressure vessels with capacities of up to 50,000 liters. Its R&D Center, situated in Shenzhen, often referred to as China's Silicon Valley, focuses on cutting-edge process analytical technologies. These include biosensors, software development, and automation solutions. With a dedicated team of over 200 full-time staff, T&J remains committed to advancing bioprocessing technologies and meeting the evolving needs of the industry worldwide.

Antibody Upstream Process Development and Production Solution



Data and Device Management System (D2MS)

STEP1
Screening of Cell Lines and Medium

ATOM HT
High-throughput microreactor system
20~50mL

+

Build-in DoE based on D2MS

STEP2
Process Development

CloudReady™
Small-scale parallel bioreactor 500mL-1.5L

+

QuickFlow HT
Auto Sampler

+

Endura SUB®
Single-use bioreactor for CloudReady 500mL-1.5L

STEP3
Seed Expansion

Opti-Cell mini
Benchtop Bioreactor
3L~15L

+

Endura SUB®
Single-use bioreactor
3L-15L

+

Endura SUB®
Single-use bioreactor
with 500L bag

STEP4
Antibody Production

Opti-Cell S/C/D
SIP Bioreactor System
50~5000L

+

Validation Document
for cGMP compliance

01

Accelerate your development from cell line screening

CHALLENGE

Hundreds of cell strains are initially screened, followed by the secondary screening of selected ones, typically using shake flask experiments. However, these strains may not be the optimal candidates due to differences from industrial fermenters.

SOLUTION

The ATOM HT automated High-throughput microreactor system boosts cell line and media development efficiency by more than 80%. Run up to hundreds of stirred vessels simultaneously, using built-in Design of Experiment (DoE) tools to screen for optimal cell lines and media combinations. Early selection under controlled conditions ensures the best candidates are chosen for scale-up to full production.

ATOM HT

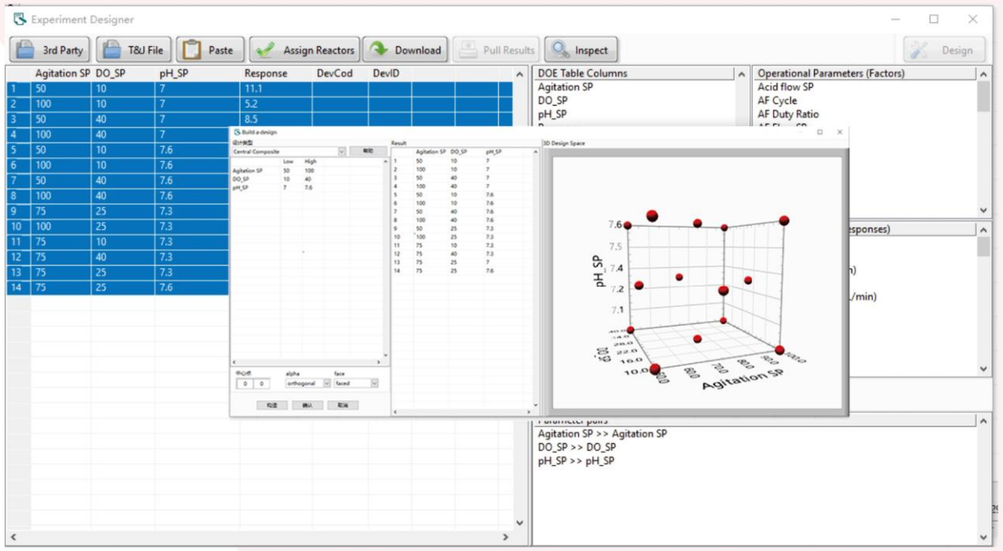
High-throughput microreactor system

Automated

High-throughput

Classic stirred vessel

Built-in, Full factorial DoE, Third-party software integration, Automated workflow by Experiment Designer



02

Build your small-scale process model based on QbD principle

CHALLENGE

It is usually necessary to evaluate different experimental conditions to identify those that support optimal growth, yield, and quality. However, conducting experiments sequentially is time-consuming, inefficient, and costly.

SOLUTION

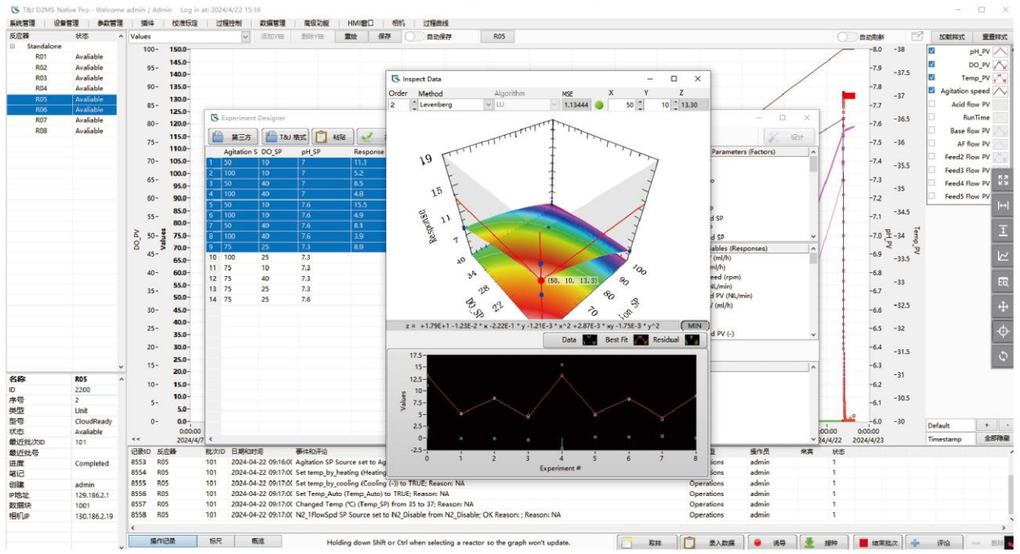
Systematically optimizing the design of actual parameters allows precise control of Critical Process Parameters (CPPs) via our CloudReady™ system, ensuring that Critical Quality Attributes (CQAs) stay within the design space. This leads to high-quality, consistently performing antibody products while ensuring the entire process is systematic, stable, and highly consistent.

CloudReady™

Small-scale parallel bioreactor 500mL-1.5L

- High-throughput
- Scalability
- Efficiency
- Infinite expansion

Response surface, Prediction, Analysis, Compare batches and trends



03

Advancements in PAT have enhanced real-time data acquisition and process monitoring

CHALLENGE

Biopharmaceutical production requires advanced analytical testing techniques due to the complexity of biologics like monoclonal antibodies and therapeutic proteins. Close monitoring during scale-up is essential, and sensitive testing with sophisticated data analysis is crucial for ensuring product quality.

SOLUTION

Integrating TJX or third-party PAT via D2MS boosts process efficiency and productivity by identifying issues early and reducing waste and costs. Monitoring CQAs closely enhances product quality and consistency, facilitating faster and more efficient technology transfer through improved process knowledge.

QuickFlow HT
Auto Sampler

- Auto sampling
- Low-temperature preservation
- Multiple sample volumes

Bioreactor system with integrated UPLC and Auto Sampler

- Automation
- Feedback control
- Real-time data collection

04

The single-use bioreactor reduces the time required from seed to production

CHALLENGE

Traditional bioreactors for seed cell preparation increase time and labor costs and also carry a higher risk of contamination.

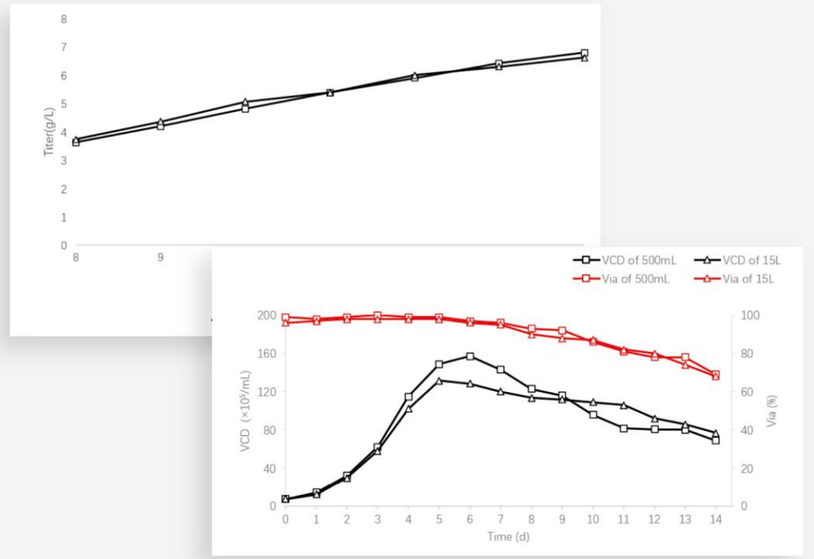
SOLUTION

By combining the design of traditional glass vessels with the benefits of modern single-use products, Endura SUB® significantly improves the efficiency of bioprocess development and seed production and reduces time costs.

Validation document, Compatibility with third-party, Support N-1 strategy

- Validation document
- Compatibility with third-party
- N-1 Support N-1 strategy

From Endura SUB® 500mL to 15L, Scalability, Consistency, Repeatability, cGMP compliance



05

Intelligent design and exceptional performance for your cGMP production

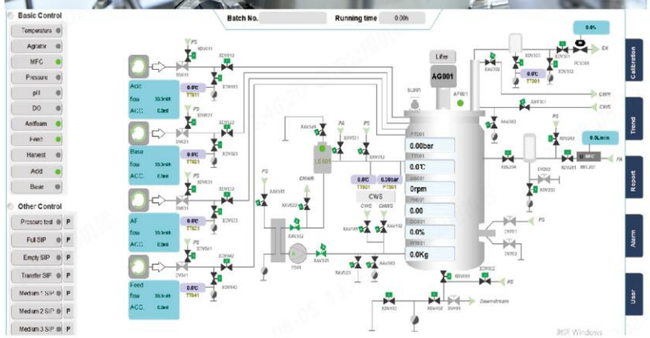
CHALLENGE

In the pharmaceutical industry, selecting between a stainless steel bioreactor and a single-use bioreactor is highly complex and requires careful consideration of factors such as cost, flexibility, time, and efficiency.

SOLUTION

Our Opti-Cell stainless steel bioreactor, with its highly automated cleaning, sterilization, and maintenance functions, offers flexibility comparable to single-use bioreactors. It also reduces costs by 30% compared to single-use systems and is better suited for the final production process.

Industrial standard PLC, Auto SIP/CIP, cGMP compliance



PLC — Industrial Standard PLC

Auto SIP/CIP

cGMP Compliance

cGMP guideline, Fully validatable, Quality guarantee