

Media Development & cGMP Manufacture Platform

To meet the needs of industrial customers, QuaCell has increased its R&D investment in products and services, and also continuously improved its media production and manufacturing capacity. Through the comprehensive upgrading of production equipment, the full layout of 3000kg/ batch production capacity, and the optimization of production efficiency in the future, it has laid a solid foundation for the delivery of high-standard industrial orders.



Product Advantages

- **One-stop service:**
formula development + 30L cell culture process
+ formula cooperation + commissioned OEM
- **Information security:**
A complete and strict formula confidentiality process ensures data security and traceability
- **Supply stability:**
Dual base layout + Global raw material supply system
- **Rich practical experience:**
Have served over 50 clients, with experience in overseas project services

Manufacturing Scale

0.5KG

Media Production scale

3000KG

Maximum Single-batch
production scale

2

Production base

2

Invention patents

20+

Global stability of the
supply chain

250+

Standing media raw
materials

The process

Requirement
validation

Encryption
process

Formulation
evaluation

Pilot
production

Large-scale
production

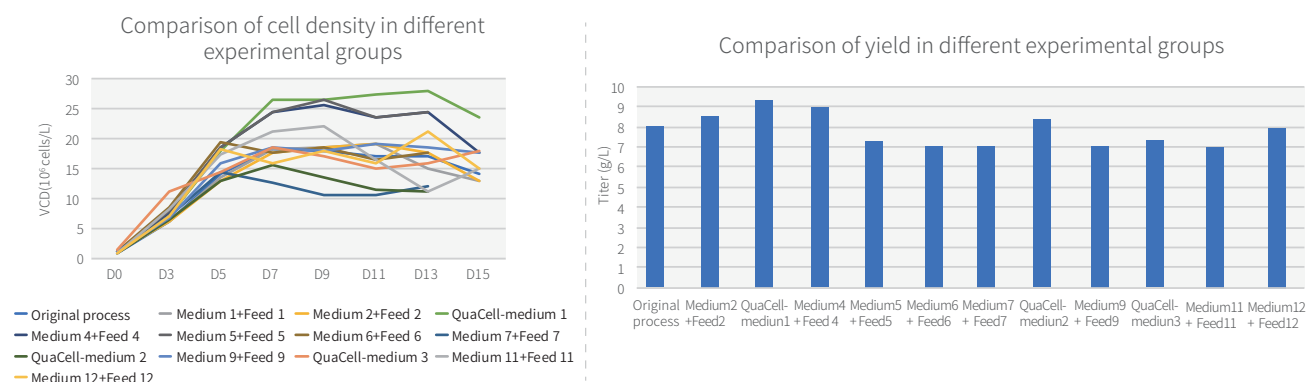
Quality
release

Delivery

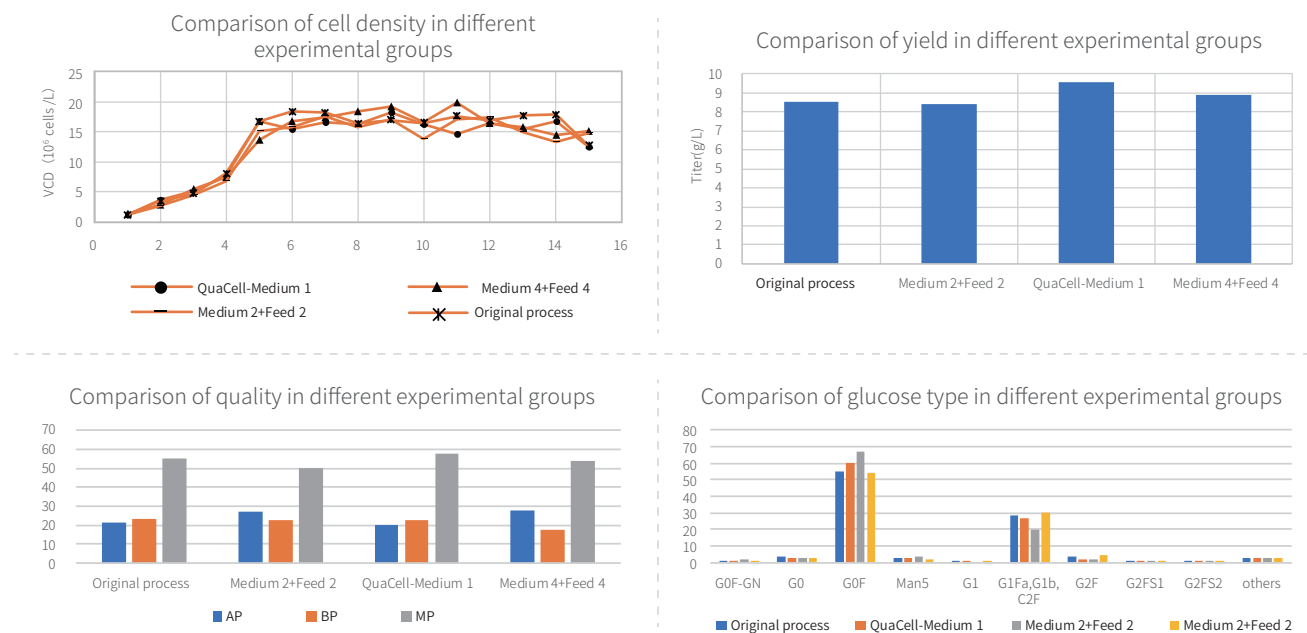
Data Presentation

It is a phase I clinical project, the cells are ECACC-CHO-K1, and the product is a monoclonal antibody. The main focus is to ensure that the quality is close to the original process, and the secondary goal is to increase yield. Moreover, the project's advancement period is tight, and it is required to be delivered quickly.

In the first round of shake flask testing, the yield was selected, and 12 medium combinations from different manufacturers were tested. There were 3 test combinations for QuaCell. Medium 1+feed 1, medium 2+feed 2 and QuaCell- medium 1 had higher yields and entered the second round of scale-up testing.



The second round of scale-up tests (1L): Data such as cell density, viability, yield, glucose type, and acid-base peak were monitored. The results showed that the yield of QuaCell- Medium 1 was significantly increased, and the quality data was close to the original process. Finally, QuaCell-Medium 1 was selected to continue the project. QuaCell completed the delivery of 6000L of culture media and feed within 1.5 months, meeting the core requirements of the project for "cost reduction, quality assurance, increased yield, and short delivery time".



Quality System

- ◆ **Strict supplier evaluation and raw material management system**

Assessment and audit of core raw material suppliers

- ◆ **Refer to GMP standard production management**

Dry powder production is strictly managed according to the GMP standard.

- ◆ **Obtained ISO9001 quality system certification**

Certificate issued by SGS, an internationally renowned certification body.

- ◆ **Logistics Chain Enterprise Resource Management (ERP)**

ERP traceability records throughout the entire process from raw material procurement to finished product delivery.

