

CellQualia™

INTELLIGENT CELL PROCESSING SYSTEM



Joint development with the Foundation for Biomedical Research and Innovation (FBRI) at Kobe

Bringing Manual Cell Culture to Automated Manufacturing, to deliver a higher level of quality control.

In regular cell manufacturing, the quality of raw materials (cells) varies and status of culture changes from moment to moment with conditions and time. The idea of Quality by Design (QbD) is to analyze such fluctuations, find out the relationship with the quality of the final product, and then set allowable range of fluctuations for successful manufacturing.



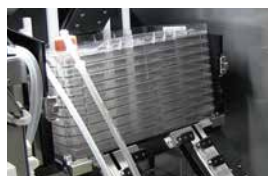
Intelligent Cell Processing System is equipped with Process Analytical Technology (PAT) to monitor culture status in real time, and stabilizes process by automation; these enable us to manufacture cell products based on QbD concept.

Features

- ◆ Fully closed system to secure the asepsis of processes as a whole.
- ◆ Designed to use standard multi-layer flasks; scale-up would be feasible with the protocol established with culture dishes or flasks.
- ◆ Can monitor cellular image and medium components in real time.
- ◆ Auto-sampling port is available for off-line analysis of biomarkers, such as cellular metabolites.



Fully-closed liquid feed system



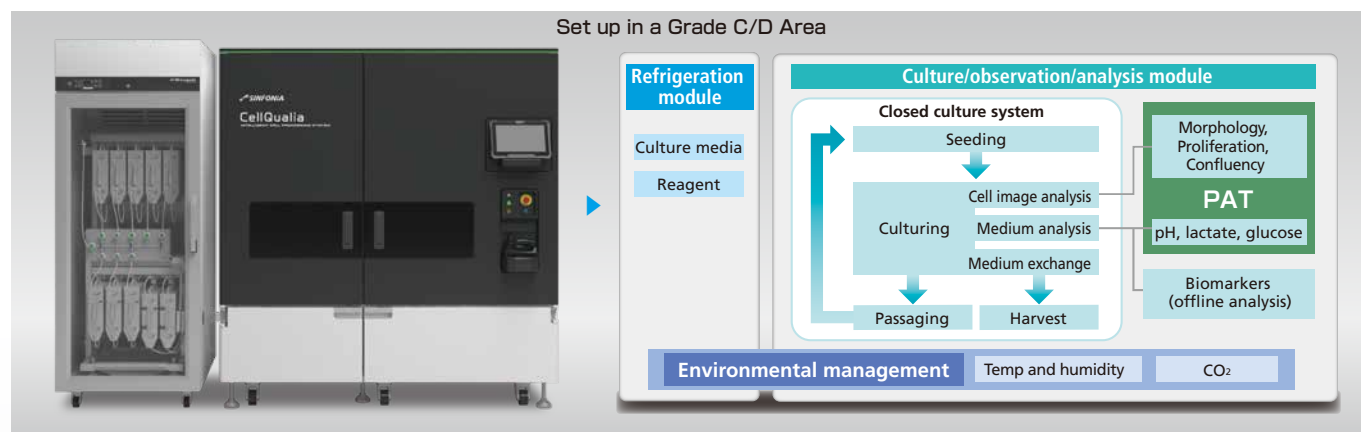
Multi-layered culture vessel



Aseptic connector

- ◆ Can save manpower, eliminate human error, and reduce dependency to skilled staff; all of them will contribute to cost reduction.
- ◆ The data obtained by the system which compatible to CSV (Computerized System Validation) will contribute to establish quality management system; it will consistently cover the process from receipt of starting material to product shipping with upper management system.

System Configuration



CellQualia™ official Site



<https://www.cellqualia.com>
Watch Us On YouTube



► Ver. QbD
► Ver. System overview & How to manufacture cell

CellQualia™ official Account

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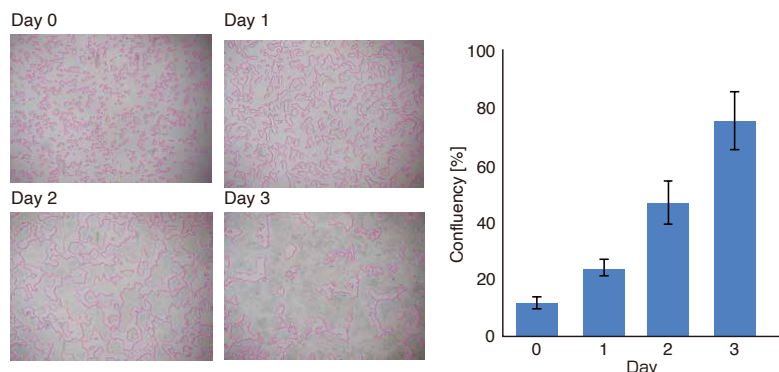
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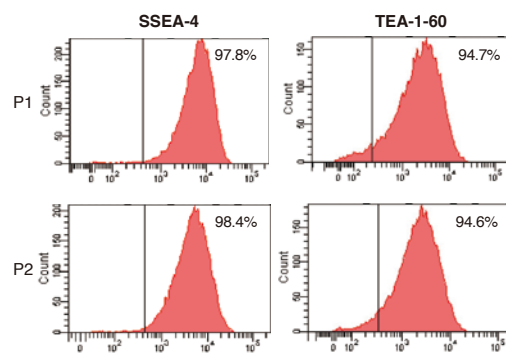
Culture Data

iPSC



Cell growth monitoring by imaging (iPS cells)

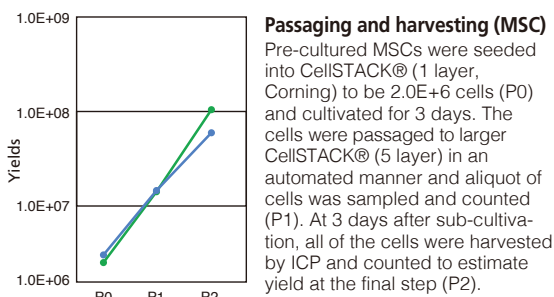
Cellular images were taken at each day by CMOS camera at the bottom of multi-layer flask. The edge of iPS cell colony (pink lines) was drawn by image analysis system and growth curve was predicted by confluency.



Influence of automated expansion (iPS cells)

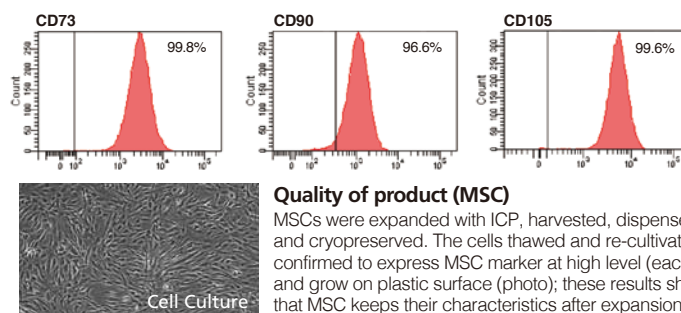
Cells were sampled at passaging (P1) and harvesting (P2); expression of pluripotent stem cell markers were confirmed to be expressed at high throughout automated expansion.

MSC



Passaging and harvesting (MSC)

Pre-cultured MSCs were seeded into CellSTACK® (1 layer, Corning) to be 2.0E+6 cells (P0) and cultivated for 3 days. The cells were passaged to larger CellSTACK® (5 layer) in an automated manner and aliquot of cells was sampled and counted (P1). At 3 days after sub-cultivation, all of the cells were harvested by ICP and counted to estimate yield at the final step (P2).



Quality of product (MSC)

MSCs were expanded with ICP, harvested, dispensed in vials and cryopreserved. The cells thawed and re-cultivated were confirmed to express MSC marker at high level (each graph) and grow on plastic surface (photo); these results showed that MSC keeps their characteristics after expansion with ICP.

Specifications

Cell types	Adherent cells (iPS cells, MSC)
Function (culture)	Seeding, medium exchange, passage, harvest
Function (analysis)	Image observation, culture media analysis
Culture container	Multi-layered container
Culture surface	Max. 6,300cm ²
Shape analysis	CMOS camera
Culture media analysis	Inline: lactic acid, glucose, pH Offline: Biomarkers (2-aminoadipic acid, kynurenine) Measured with another device

Power consumption	Typical 2.0kW Max 3.7kW (at 200V) Typical 2.2kW Max 3.8kW (at 240V)
Power supply	AC200V-AC240V 1φ 50Hz/60Hz
UPS	Optional (MAX 3,000VA)
Ambient environment	Temp:18-25°C Humidity:75% or less (no condensation) Cleanliness: Grade C
Outer dimensions	W 2,670× D 931× H 1,995mm (no protruding parts)
Weight	Approx. 1,300kg
Air supply	CO ₂ , clean-dry air (both should be 0.3-0.5MPaG)
Standard	CE, UKCA, UL

Disposable parts

- ◆ Disposable closed-system culture kit
- ◆ Culture vessels



CellQualia™ SOLUTION LAB

SINFONIA TECHNOLOGY's Solution Lab is a base for cell production-related customer services, such as user training, demo / paid runs and contract manufacturing, by our resident staff. The facility is a compact CPC at the Grade C level, which is a recommended environment for CellQualia™ Intelligent Cell Processing System installation. We believe that an efficient use of our Solution Lab can accelerated the realization of QbD in your cell manufacturing.

CellQualia™ CellQualia is the brand name for Sinfonia Technology's system products for regenerative medicine.



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