# **CellQualia**<sup>™</sup> NTELLIGENT CELL PROCESSING SYSTEM

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

In regular cell manufacturing, the guality 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.





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

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-lavered 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 Set up in a Grade C/D Area Refrigeration module Culture/observation/analysis module Closed culture system CellQuali Morphology, Seeding Proliferation, Culture media Confluency Reagent Cell image analysis PAT Culturing Medium analysis pH, lactate, glucose Medium exchange **Biomarkers** (offline analysis) Passaging Harvest **Environmental management** Temp and humidity CO2

# CellQualia<sup>™</sup> Official Site



https://www.cellqualia.com Watch Us On YouTube Ver. QbD











### CellQualia IG SYSTEM

# 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.



#### **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. 18,000cm <sup>2</sup>
Shape analysis	CMOS camera
Culture media analysis	Inline: lactic acid, glucose, pH Offline: Biomarkers (2-aminoadipic acid, kynurenine) Measured with another device

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

#### **Disposable parts**

Disposable closed-system culture kit
Culture vessels



# 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 CellQualiaTM 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.

SINFONIA TECHNOLOGY has acquired a patent license from iPS Academia Japan, Inc. for instrument demonstration and user training use of prescribed iPS cells. Please contact us in advance if you want to use the other iPS cells.





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