

CellQualia™

INTELLIGENT CELL PROCESSING SYSTEM

全自動化細胞製造系統

品質驅動設計 (Quality by Design, QbD)
打造細胞製造新標準



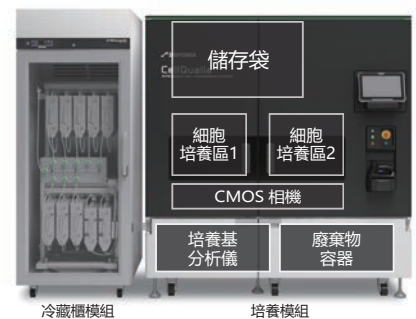
特點

- ◆ 全封閉式細胞培養系統
- ◆ 全程無需從培養箱內取出細胞培養容器
- ◆ 使用金屬匣保護培養基與試劑免受光照影響
- ◆ 快速上手，輕鬆設定
 - 提供預先組裝並已消毒的一次性套件（管線和儲存袋）
 - 圖形化操作介面（引導耗材安裝與系統操作）
- ◆ 無需手動介入
 - 自動完成細胞接種、培養基更換、收集、繼代及細胞外基質塗層（若有需求）
 - 全程即時監控細胞生長狀態
 - 提供細胞和培養基的取樣功能
- ◆ 使用已紀錄的配程序再次進行操作，達到一致性結果
- ◆ 系統設備的分析技術
 - 監控培養環境（溫度與 CO₂）
 - 提供細胞影像拍攝功能
 - 培養基即時分析（葡萄糖、乳酸與 pH 值）
 - 細胞與培養基的採樣以便後續檢驗分析
- ◆ 可連接電子製造管理系統

 **SINFONIA** SINFONIA TECHNOLOGY CO., LTD.

系統配置

- 1 全封閉式系統：經由滅菌處理後的一次性套組（管線、儲存袋及多層細胞培養瓶）連接完成無菌的培養環境
- 2 原料登錄：可使用條碼掃描器進行數位記錄
- 3 培養基與試劑儲存：袋裝培養基與試劑存放於金屬匣內，置入冷藏櫃儲存
- 4 細胞接種袋：繼代細胞暫存區位於儲存袋區
- 5 預熱培養基：儲存袋區內設有板式加熱器，預先回溫培養基，以便進行培養基更換
- 6 雙細胞培養區：用於細胞繼代；在三代細胞擴增程序中，將已使用過的第一代細胞培養層瓶替換為新的多層細胞培養瓶
- 7 環境監測：在細胞培養過程中，全程即時監測環境變化，並可依預先排程設定，定時進行培養基分析及細胞和培養基取樣收集
- 8 自動排程細胞繼代時間：以乳酸累積量作為細胞數量的相對應指標，實現自動化預測控管
- 9 細胞影像拍攝：細胞培養模組底部設置移動式 CMOS 相機，可按時擷取細胞影像
- 10 儀器狀態監控：可使用平板電腦即時監控儀器狀態



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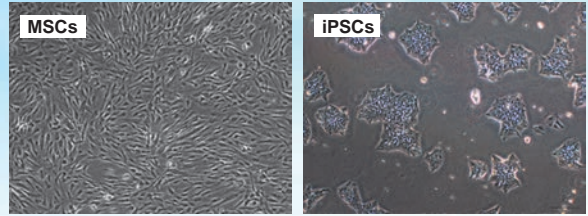


以穩定製程達到卓越品質 用數據累積驅動產品升級



應用範圍

- 細胞庫準備：主細胞庫與工作細胞庫的製備 (MSC, iPSC/ESC)
- 細胞療法應用：用於細胞療法的細胞製造 (MSC)
- 大規模製備可用於引導分化的全能幹細胞 (iPSC/ESC)
- 外泌體培養基製備 (MSC)
- 製程開發與改善：適用於以上所有項目



Specifications

Product Name	Intelligent Cell Processing System
Product configuration	Main body (refrigerator and incubator modules), data server, and UPS
Additional devices to be prepared by users	Biowelder® TC (Sartorius, 16389) Biosealer® (Sartorius, 16391-000) Mobile deck lifter (generic product)
Consumables supplied by Sinfonia	Templates (pre-assembled line and bags) Multilayer cell culture flasks with line
Consumables to be prepared by users	Cell culture media and reagents Biowelder® TC Disposable Blades (Sartorius, 16389-012) Tube sets and reagents for BioPAT® Trace (Sartorius)
Power consumption	Typical 2.0kW Max 3.7kW (at 200V) Typical 2.2kW Max 3.8kW (at 240V)
Power supply	AC200V/240V, 1φ50Hz/60Hz
Required gas	CO ₂ (0.3-0.5MPaG)
Air supply	Clean dry air (0.3-0.5MPaG)
Installation environment	Temp 18-25 °C Humidity 75% or less (no condensation) Cleanness Grade C
Outer dimensions	W2,670 × D931 × H1,995 (no protruding parts)
Weight	Approx. 1,300kg
Standard	CE, UKCA, UL

Culture surface	Max. 18,000cm ² (36-layer)	
Feasible serial cell expansion patterns	1-layer – 5-layer	
	2-layers – 10-layer	
	1-layer – 5-layer – 36-layer	
ECM coating	Feasible	
Process analysis	Culture environment	temperature and CO ₂ concentration monitors
	Cell imaging	CMOS camera
	Culture media analysis	glucose, lactate, and pH sensors
	Samples for off-line analysis	cells at harvesting and culture media at any time
Applicable cell types	Adherent cells	
Available applications	Mesenchymal stem cells (MSCs)	
	Pluripotent stem cells (iPSCs/ESCs)	

This product and applications were jointly developed with the Foundation for Biomedical Research and Innovation (FBRI) at Kobe.

Sinfonia Technology Co., Ltd. is cooperated with Cyto-Facto Inc. (<https://www.cytofacto.com>) to realize QbD-based cell manufacturing for clinical use with ICP System.

CellQualia™ official Site




<https://www.cellqualia.com>

Watch Us On YouTube



- ▶ Ver. QbD
- ▶ Ver. System overview & How to manufacture cell



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.

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.



CellQualia™ Intelligent Cell Processing System

設備展示於台北生技園區15F

■ 台灣預約培養試驗聯絡人

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