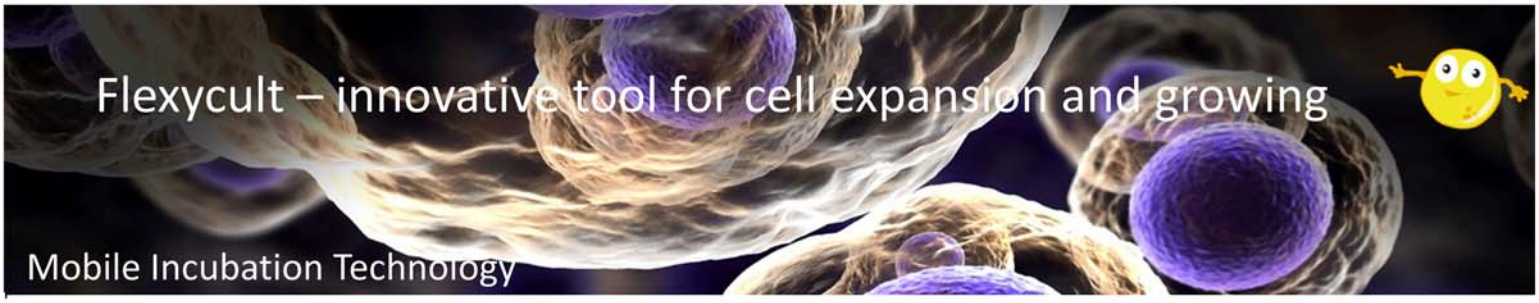
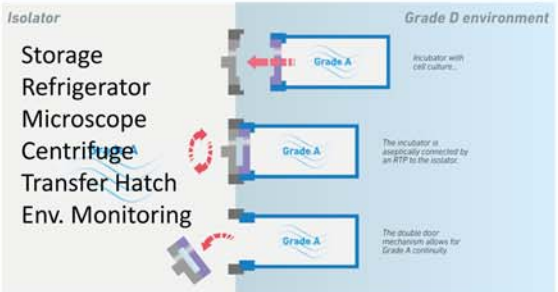
(주)파라테크

Sterility Testing Isolator

PIC/S	•Pharmaceutical Inspection Co-operation Scheme
ISPE - Guidelines	•International Society for Pharmaceutical Engineering
PDA - Guidelines	•Parenteral Drug Association



- Incubation under Grade A
- No Cross contamination at all
- Reduced cell transportation
- Expandable according to needs
- Cost effective w/r to other tech
- Easy to be implemented



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Dispensing & Weighing Isolator

COMECER

The toxicity of the APIs is measured using the OEB/OEL levels. *** SMEPAC Test ***
For each of these levels a different containment system is required.

OEB: Occupational Exposure Band (Isolator 4,5,6)
OEL: Occupational Exposure Level (ug/m3)
PDE: Permitted Daily Exposure (ug/day)

The MDWI has been conceived to satisfy the requirements related to the handling process of highgly toxic ***API***

Quality Excellence

ISO 9001 & ISO 13485 Certified Quality System

COMECER Health and Safety Management System

REFERENCE STANDARD

- GMP (Good Manufacturing Practice)
- ISO 14644 (Cleanrooms and associated controlled Environments)
- ISO 10648 (Containment enclosures)
- ISO 13408-6 - Aseptic processing of health care products
- ISO 11933 – Component for Containment Enclosures
- PDA – TR Nr 34 (Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products)
- ISPE Guidelines
- Eudralex – Volume 4 – EU Guidelines to Good Manufacturing Practice (GMP) – Medicinal Products for Human and Veterinary Use, 2015.
- Eudralex – Volume 4 – EU Guidelines to Good Manufacturing Practice (GMP) – Annex 1: Manufacture of Sterile Medicinal Products, 2008
- GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems
- ISO 14644-7:2004 Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

Reference of Isolator

Company Name	Country	Company Name	Country
GSK BIO	Belgium	SAMSUNG BIOLOGICS	Korea
PFIZER	Belgium	DGMIF (대구첨복임상센터)	Korea
NOVARTIS	Italy	BORYUNG PHARM.	Korea
PFIZER	Italy	PEPTRON INC.	Korea
NCPC	China	PROCOS	Italy
SANOFI	China	SYNTECO	Italy
SIPB	China	TEVA	Italy
BIOCEN	Cuba	THALES ALENIA SPACE	Italy
CIDEM	Cuba	CHUGAI	Japan
ONCOMED	Czech	TAKARA BIO	Japan
TEVA	Czech	CHEMI PHARMA	Malta
CATALENT	France	PSICOPHARMA	Mexico
PIERRE FABRE	France	GSK	UK
DKFZ	Germany	ELI LILLY	USA
GSK	Germany	BAYER	Norway
PFIZER	Germany	GSK	Poland
TEVA	Hungary	WYETH	Puerto Rico
FDC	India	ROMPHARM	Romania
ABBVIE	Italy	CELLTHERA	Russia
ACTAVIS	Italy	NANOLEK	Russia
BSP	Italy	PHARMASTANDARD	Russia
CHIESI	Italy	ITALFARMACO	Spain

취급품목 :

COMECER: ISOLATOR, RABS, GLOVE LEAK TESTER, FILLING MACHINE, VPHP CHAMBER
ANEST IWATA: OIL FREE AIR COMPRESSOR, VACUUM PUMP, N2 GENERATOR
실험테이블, 흄후드, 시약장, LAB 장비, VALIDATION, SMEPAC TEST, 베타컨테이너