

Our Core Values:
EXCELLENCE AND INTEGRITY

Pharma *Frontier*

Company Profile & Working References

Table of Contents

Our Core Values:
EXCELLENCE AND INTEGRITY

1. About Us	3
2. History	4
3. Organization	5
4. Quality Management System	7
5. Performance Summary	15
6. Project Portfolio	16
7. Working References	17

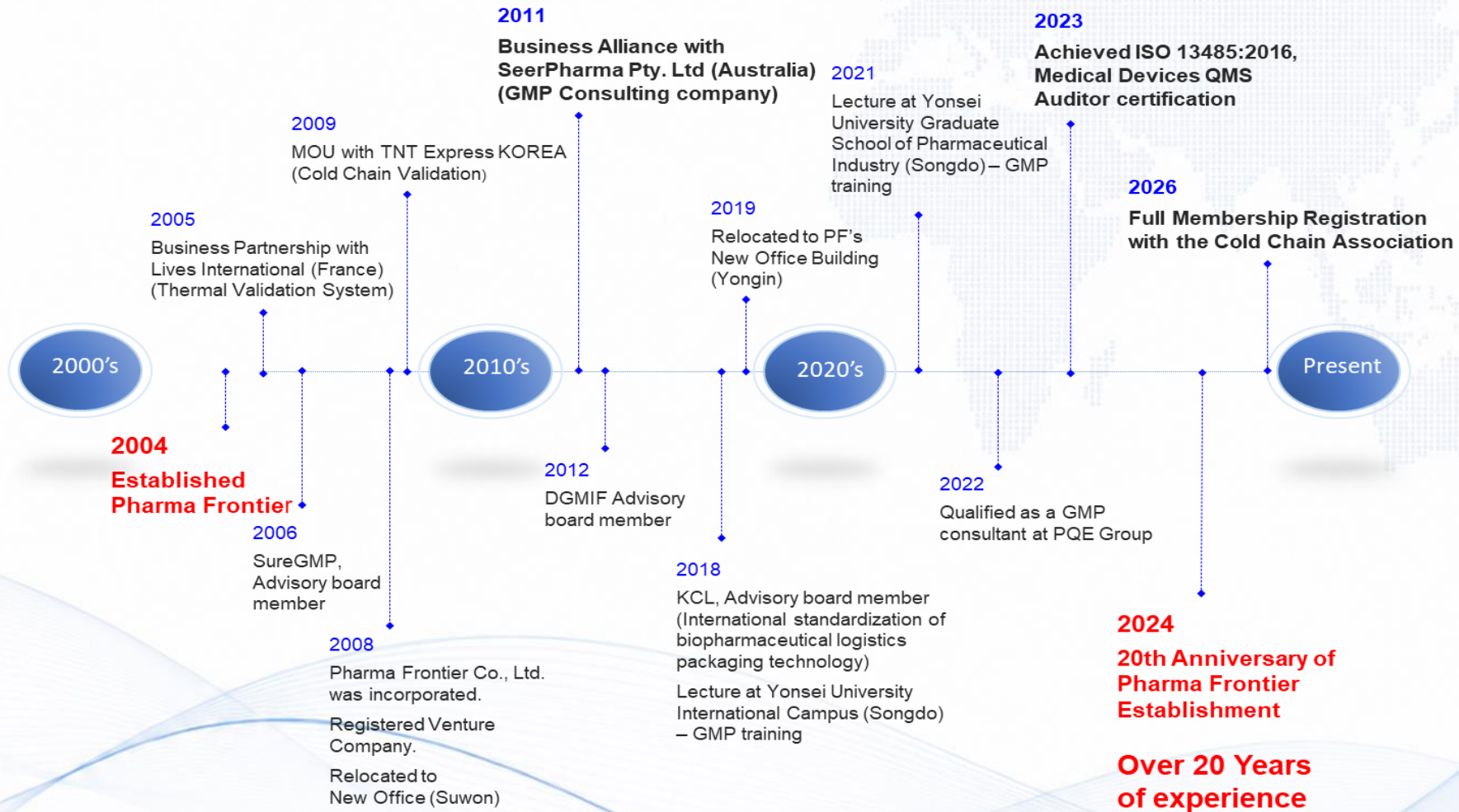
1. About Us

Our Core Values:
EXCELLENCE AND INTEGRITY

	Company Name	Pharma Frontier Co., Ltd.
	CEO	Yoo Tae-Hee / Han Kyu-Pil
	Date of Establishment	November 9, 2004 (Incorporated: June 24, 2008)
	Venture Registration	July 1, 2008
	Number of Employees	25
	Location	PF Building, 11-16, Giheungdanji-ro 24beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, 17086, Republic of Korea
	Phone	Tel. 031-8065-7080, Fax. 031-8065-7081
	Website	http://www.pfk.co.kr

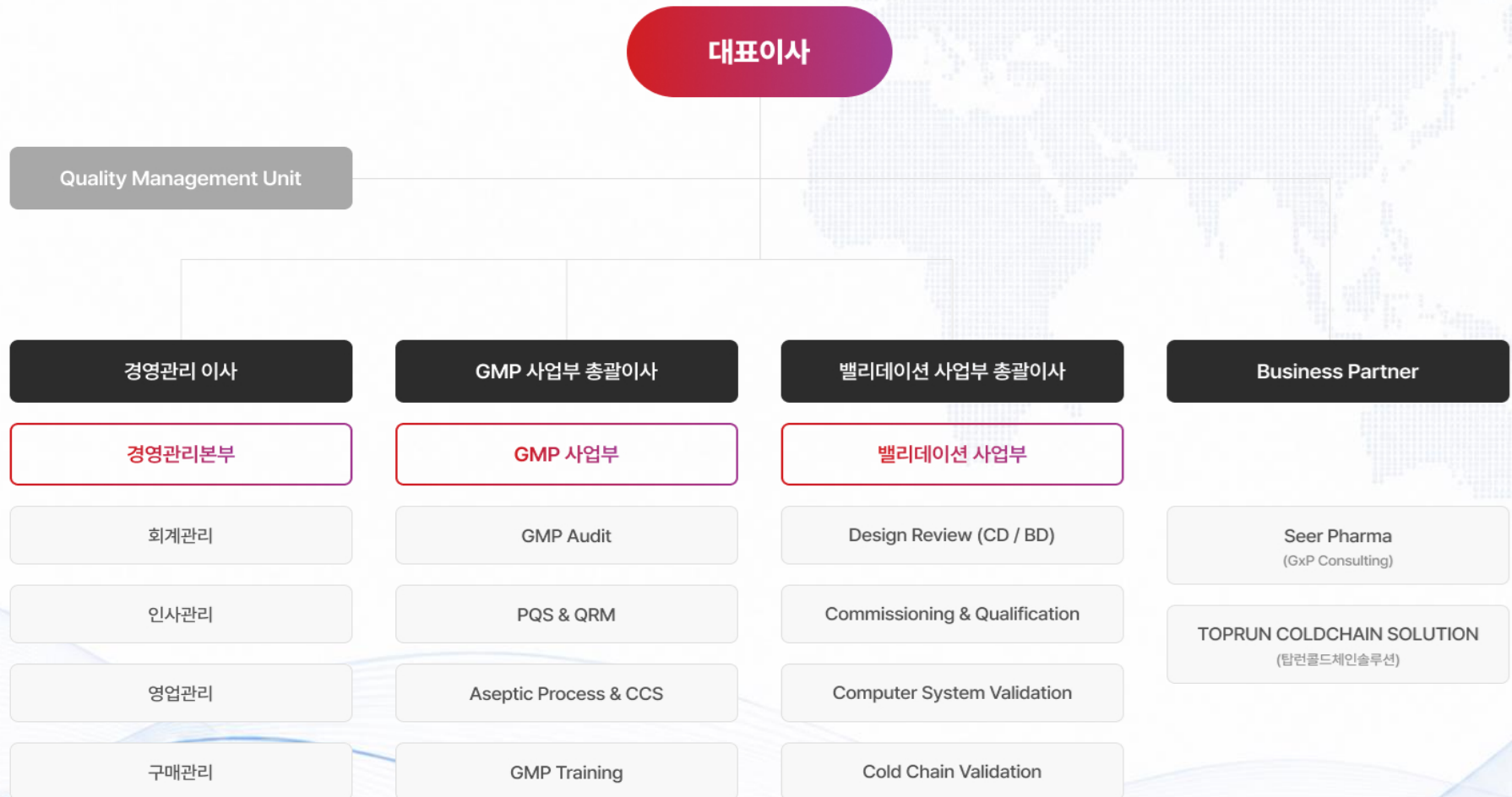
2. History

Our Core Values:
EXCELLENCE AND INTEGRITY



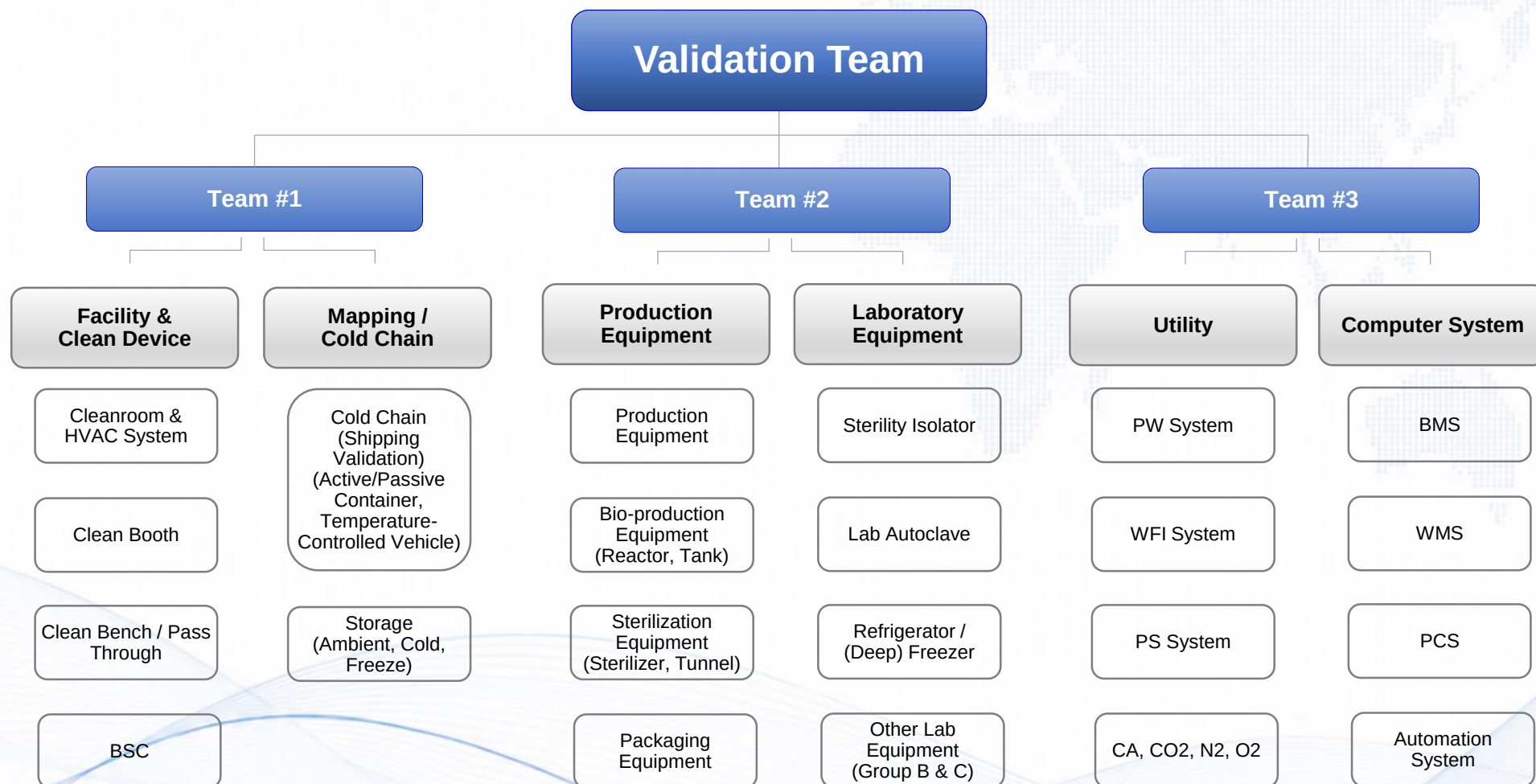
3. Organization

Our Core Values:
EXCELLENCE AND INTEGRITY



3. Organization

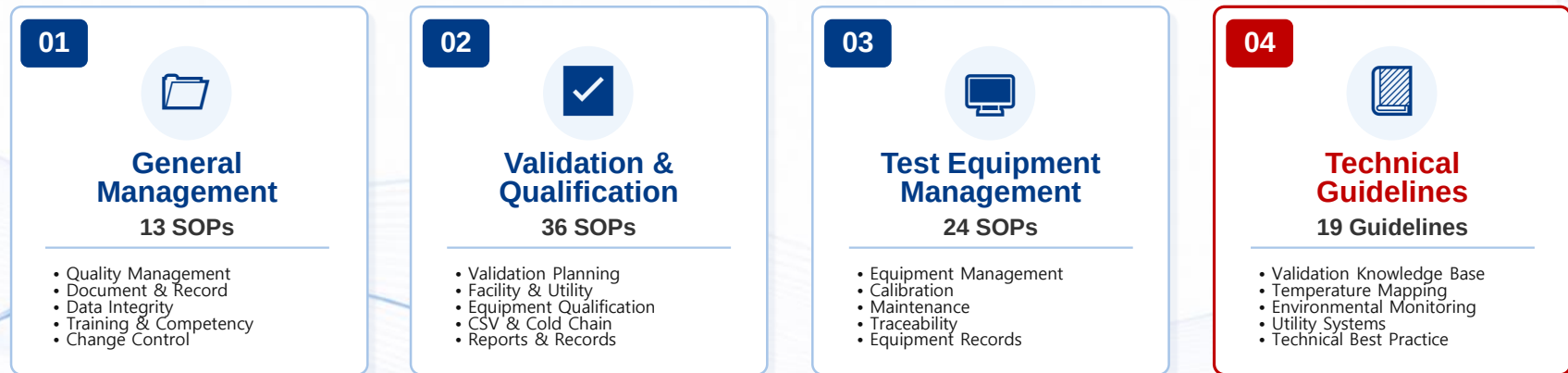
Our Core Values:
EXCELLENCE AND INTEGRITY



4. Quality Management System



QMS Document Structure



4-1. Standard Operating Procedures

Representative
Working References

01. General Management

No.	SOP No.	SOP Title
1	PFSOP-1001	표준작업규정 작성 및 사용
2	PFSOP-1002	규정관리자의 역할과 책임
3	PFSOP-1003	조직도 작성 및 관리
4	PFSOP-1004	직무기술서 작성 및 관리
5	PFSOP-1005	GMP문서 작성
6	PFSOP-1006	GMP전자기록의 보존
7	PFSOP-1007	품질 및 비정상 사안 사내 보고
8	PFSOP-1008	프로젝트 관리
9	PFSOP-1009	불만관리
10	PFSOP-1010	교육프로그램
11	PFSOP-1011	데이터 완전성
12	PFSOP-1012	반출문서 품질관리
13	PFSOP-1013	산업안전 보건관리

4-1. Standard Operating Procedures

Representative
Working References

02. Validation & Qualification

No.	SOP No.	SOP Title
14	PFSOP-2001	변경관리
15	PFSOP-2002	테스트 불일치 처리
16	PFSOP-2003	계획서 및 보고서 작성
17	PFSOP-2004	계획서 문서번호 부여
18	PFSOP-2005	Plan문서 작성
19	PFSOP-2006	Commissioning
20	PFSOP-2007	위험평가
21	PFSOP-2008	사용자요구사항 및 설계적격성평가
22	PFSOP-2009	설치, 운전 및 성능적격성평가(IQ,OQ & PQ)
23	PFSOP-2010	Cold Chain Validation
24	PFSOP-2011	Computer System Validation
25	PFSOP-2012	HVAC System 및 Cleanroom 적격성평가
26	PFSOP-2013	WFI System 적격성평가
27	PFSOP-2014	PW System 적격성평가
28	PFSOP-2015	Pure Steam System 적격성평가
29	PFSOP-2016	Compressed Air System 적격성평가
30	PFSOP-2017	Gases System 적격성평가

4-1. Standard Operating Procedures

Representative
Working References

02. Validation & Qualification (continued)

No.	SOP No.	SOP Title
34	PFSOP-2021	Freeze Dryer 적격성평가
35	PFSOP-2022	Clean Booth류(RABS, Bench) 적격성평가
36	PFSOP-2023	Pass Box, Pass Through 적격성평가
37	PFSOP-2024	Biosafety Cabinet 적격성평가
38	PFSOP-2025	Isolator 적격성평가
39	PFSOP-2026	챔버 적격성평가
40	PFSOP-2027	보관소 적격성평가
41	PFSOP-2028	차량(TCV) 적격성평가
42	PFSOP-2029	저울 적격성평가
43	PFSOP-2030	충전기 적격성평가
44	PFSOP-2031	BFS (Blow Fill Seal) 적격성평가
45	PFSOP-2032	탱크류 적격성평가
46	PFSOP-2033	유동층건조기 적격성평가
47	PFSOP-2034	Mill 적격성평가
48	PFSOP-2035	블리스터 적격성평가
49	PFSOP-2036	라벨러 적격성평가

4-1. Standard Operating Procedures

Representative
Working References

03. Test Equipment Management

No.	SOP No.	SOP Title
50	PFSOP-3001	테스트 장비 일반관리
51	PFSOP-3002	교정관리
52	PFSOP-3003	XpertVal System 사용 및 관리
53	PFSOP-3004	XpertLog System 사용 및 관리
54	PFSOP-3005	Particle Counter 사용 및 관리
55	PFSOP-3006	Air Sampler 사용 및 관리 - Single
56	PFSOP-3007	Air Sampler 사용 및 관리 - Double
57	PFSOP-3008	Air Velocity & DP Meter 사용 및 관리
58	PFSOP-3009	CO2 측정기 사용 및 관리
59	PFSOP-3010	Calibrator 사용 및 관리
60	PFSOP-3011	Dew Point Meter 사용 및 관리
61	PFSOP-3012	Smoke Generator 사용 및 관리
62	PFSOP-3013	Multi Tester 사용 및 관리
63	PFSOP-3014	Digital Level Meter 사용 및 관리
64	PFSOP-3015	Veriteq 사용 및 관리
65	PFSOP-3016	Ebro 사용 및 관리
66	PFSOP-3017	Aerotest Alpha (Drager) 사용 및 관리

4-1. Standard Operating Procedures

Representative
Working References

03. Test Equipment Management (continued)

No.	SOP No.	SOP Title
67	PFSOP-3018	Light Meter 사용 및 관리
68	PFSOP-3019	Sound Level Meter 사용 및 관리
69	PFSOP-3020	Tacho Meter 사용 및 관리
70	PFSOP-3021	Stop Watch 사용 및 관리
71	PFSOP-3022	High Pressure Diffuser 사용 및 관리
72	PFSOP-3023	Thermocouple 준비
73	PFSOP-3024	Air Sampler (Pinocchio) 사용 및 관리

4-2. Technical Guidelines

*Representative
Working References*

04. Technical Guidelines List

No.	Technical Guide No.	Technical Guide Title
1	PF-REF-1000	Validation Knowledge Base
2	PF-REF-1001	Utility and Building System Validation Guide for Drug Product Operations
3	PF-REF-1002	Collective Information for UDAF Velocity of 0.45 m/s
4	PF-REF-1003	High Purity Water Systems
5	PF-REF-1004	Open Door Test, Power Failure Test, and Recovery Test for Storage Areas
6	PF-REF-1005	6D Rule Summary
7	PF-REF-1006	Collective Information for Measurement of Equilibration Time for Steam Sterilizer
8	PF-REF-1007	Statistical Approach for Determination of Environmental Monitoring Alert Level and Action Level
9	PF-REF-1008	Temperature Mapping Test
10	PF-REF-1009	Temperature Mapping Test for TCV
11	PF-REF-1010	Cold Chain Validation
12	PF-REF-1011	Isolator System
13	PF-REF-1012	Validation of Moist Heat (Steam Sterilizer)
14	PF-REF-1013	RA for Cleanroom Classification and Environmental Monitoring
15	PF-REF-1014	HVAC System with Cleanroom Technology and Qualification

04. Technical Guidelines List (continued)

No.	Technical Guide No.	Technical Guide Title
16	PF-REF-1015	Pharmaceutical Water System
17	PF-REF-1016	Compressed Gas System
18	PF-REF-1017	Production Equipment
19	PF-REF-1018	Computer System Validation

5. Performance Summary

Our Core Values:
EXCELLENCE AND INTEGRITY

01

개념설계 (설계 검토)



Project Highlights

보락, 신풍제약, SK Chemicals,
함소아 제약, 스카이뉴팜 등

02

제약품질시스템 컨설팅



Project Highlights

SK Bioscience, 한국안센,
종근당, 휴온스, 인터제로스시스템,
APBL, 삼화에이스 등

03

품질위험경영컨설팅



Project Highlights

SK Bioscience, 종근당, 한국오츠카,
SK Plasma, SK Biotech, APBL 등

04

GMP 진단 및 CAPA 컨설팅



Project Highlights

한국안센, 보락, SK 바이오팜, SD바이오센서,
한미약품, 근화제약 등

05

적격성 평가 & 밸리데이션 컨설팅

1,000건 이상



Project Highlights

시설, 설비, 장비 등 1,000 건 이상

06

GMP 인허가 Support



Project Highlights

Lilly Korea (FDA), 한국안센(FDA),
한국백신(WHO), 한국 오츠카(EU),
APBL (FDA), SK Bioscience (WHO, EU),
SK Biotech (FDA), 휴온스글로벌(브라질) 등

07

CAR-T 세포처리업 허가 컨설팅

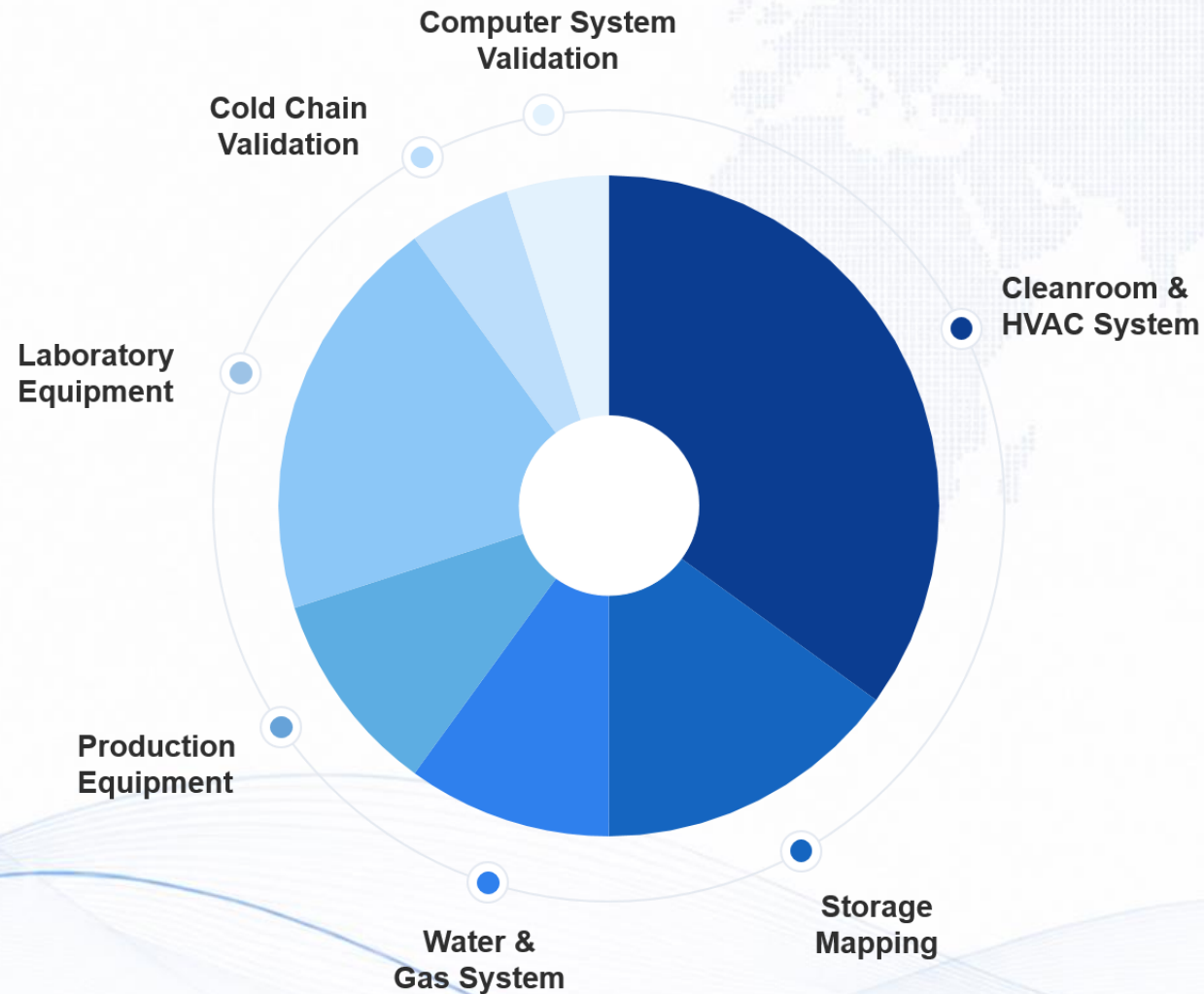


Project Highlights

분당서울대학교병원, 동아대학교병원,
가천대학교병원, 순천향대학교서울병원,
이대목동병원, 원주세브란스병원 등
인체세포관리업 설계, 시공, Qualification,
Quality system 구축 및 인허가

6. Project Portfolio

Our Core Values:
EXCELLENCE AND INTEGRITY



7. Working References

Our Core Values:
EXCELLENCE AND INTEGRITY

01

Cleanroom &
HVAC System



02

GSP / GDP
(Cold Chain)



03

Utility
(Water & Gas)



04

Laboratory
Equipment



05

Production
Equipment



06

Computer System
Validation (CSV)



07

New Construction
Project



08

CAR-T /
Advanced
Biopharmaceutical



09

GMP Audit &
Consulting



01. Cleanroom & HVAC System

Representative
Working References

Year 2021 ~ 2026

CLIENT	SCOPE OF WORK
Samsung Biologics (P4, P5 & ADC Project 외)	SAT / IOV / PV
Sartorius (송도 Campus - New Plant)	RA / DQ / IQ / OQ
SK bioscience (F1, G1, G2, G2+ Project 외)	RA / RTM / DQ / IQ / OQ / PQ
SK Plasma (안동)	RA / IQ / OQ / PQ / EMRA
SHIN POONG Pharma (제 1, 2, 5 공장)	RQ / PRQ
VAXCELL-Bio (화순 - New Plant)	RA / IQ / OQ / PQ / EMRA
Penmix (천안 생산 제 1, 2 본부)	IQ / OQ / PQ / PRQ
건일제약 (천안)	RA / IQ / OQ / PQ
CKD Pharm (천안)	IQ / OQ
SUHEUNG (오송)	PRQ
APR (평택)	IQ / OQ / PRQ
SK Chemicals (청주)	IQ / OQ / PQ
보령제약 (안산)	IQ / OQ
ENCell (1, 2, 3 공장)	RA / DQ / IQ / OQ / PQ / EM
한미약품 (팔탄)	RA / DQ / IQ / OQ / PQ
APROGEN Biologics (오송)	VMP / SAT / URS / DQ / IQ / OQ / PQ
서울대분당병원, 이대목동병원, 부산동아대병원, 경북대병원, 한림성심대학교병원 외 다수	IQ / OQ / PQ

"Selected from 200 + Projects Completed Since 2004"

02. GSP / GDP (Cold Chain)

*Representative
Working References*

Year 2021 ~ 2026 (Cold Chain)

CLIENT	SCOPE OF WORK
SK bioscience (Shipping Validation – Passive Container for WHO, PAHO)	HT, DT, OQ (Lab Test), PQ (Field Test)
SK bioscience (Shipping Validation – Temperature-Controlled Vehicle: 11-ton)	Temperature Mapping (Field Test)
Samsung Biologics (Shipping Validation - Active Container: Envirotainer)	OQ (Lab Test)
Huons Biopharma (Shipping Validation – Passive Container)	VMP / URS / DQ / DT / OQ (Lab Test) / PQ (Field Test)
Abbott Korea (Temperature-Controlled Vehicle)	IQ / OQ / PQ
CXL BIO (세종해운 바이오물류센터 – Temperature-Controlled Container for Temperature-Controlled Vehicle)	URS / DQ / IQ / OQ / PQ
DB Schenker (Temperature-Controlled Vehicle: 1, 3, 5, 11-ton)	IQ / OQ / PQ (Summer & Winter)
AccessPharma (Temperature-Controlled Vehicle: 1-ton)	IQ / OQ / PQ (Summer & Winter)
World Courier (Temperature-Controlled Vehicle: 1-ton)	Temperature Mapping / IQ / OQ / PQ (Summer & Winter)
CJ Logistics (Temperature-Controlled Vehicle)	Temperature Mapping Test

“Selected from 100 + Projects Completed Since 2004”

02. GSP / GDP (Cold Chain)

Representative
Working References

Year 2021 ~ 2026 (Storage)

CLIENT	SCOPE OF WORK
SK bioscience (Cold Room, Freezer Room, Ambient Storage, Temperature-Controlled Container)	Temperature Mapping / IQ / OQ / PQ / PRQ
Samsung Biologics (P2, P3, P4, P5 & ADC Project – Cold Room, Freezer Room, Storage, Automated Warehouse)	Temperature Mapping / IOV / PVT
CKD Pharm (천안 – 창고동)	RA / IQ / OQ
Abbott Korea (서울, 안산 – Cold Room, Product Storage)	IQ / OQ / PQ / Mapping Test
(주)한국애보트진단 (용인 보라, 하갈 클린룸 & 보관소 44개소)	T&H Mapping
J&J Medical Korea (서울, 김포 – Product Storage)	T&H Mapping
한미정밀화학 (안산 – Cold Room)	IQ / OQ / PQ / Mapping Test
SK Biotek (대전, 세종 – Cold Room, Freezer Room. Product Storage)	IQ / OQ / PQ / Mapping Test
ACT&CORE (김포, 인천 – Cold Room, Freezer Room. Product Storage)	IQ / OQ / PQ / Mapping Test
VAXCELL-Bio (화순 – Cold Room, Product Storage)	T&H Mapping
미쯔비씨다나베 (향남 – Cold Room, Product Storage)	IQ / OQ / PQ
CXL BIO (세종해운 바이오물류센터 – Cold Room)	URS / DQ / IQ / OQ / PQ
SG Medical (하남 - Product Storage)	T&H Mapping
용마로직스 (이천, 안성, 검단 - Cold Room, Warehouse)	T&H Mapping
DHL (인천, Warehouse)	T&H Mapping
한국초저온 (오산 – Cold Storage, Product Storage)	IQ / OQ / PQ / PRQ
APROGEN (오송, 성남 – Cold Room, Product Storage)	IQ / OQ / PQ / PRQ

"Selected from 300 + Projects Completed Since 2004"

03. Utility (Water & Gas)

Representative
Working References

Year 2021 ~ 2026

CLIENT	SCOPE OF WORK
SK bioscience (WFI, PS, PW, CA, CO2)	RA / RTM / DQ / SAT / IQ ~ PQ
SK biotek (대전, 세종 – N2, H2)	Quality Monitoring
Samsung Biologics (CA, N2)	FAT / SAT
CKD Pharma. (WFI, PW, CA, CO2, O2)	IQ / OQ
Sartorius (new plant – CA, N2)	IQ / OQ / PQ
APROGEN Biologics (PW, WFI, PS ,CA)	IQ / OQ / PQ
VAXCELL-Bio (CO2)	T&H Mapping
Penmix (CA, N2)	PQ
건일제약(CA)	RA / IQ / OQ / PQ
ENCell (1 & 2 공장 - CA, O2, N2, CO2)	DQ / IQ / OQ / PQ
이니스트ST (PW, WFI, PS, CA, N2)	IQ / OQ / PQ
GeneMedicine (CA, O2, N2, PA)	DQ / OQ/ OQ / PQ
얀센백신 (송도 – PW, WFI, CA, N2)	URS / DQ / IQ / OQ / PQ
보령제약 (CA)	IQ / OQ / PQ
SK Plasma (PS, CDA)	RA / IQ / OQ

"Selected from 100 + Projects Completed Since 2004"

04. Laboratory Equipment

Representative
Working References

Year 2021 ~ 2026

CLIENT	SCOPE OF WORK
SK bioscience (초저온 냉동고, 냉장고, 인큐베이터 등 약 100 여대, 10여 년간 정기 PRQ 수행 중)	RQ / PRQ
ENCell (초저온 냉동고, 멸균기, 냉동고 등 80여대)	PRQ
HLB Fab. (멸균기)	PRQ
VAXCELL-Bio (초저온 냉동고, 냉장고)	IQ / OQ / PQ
동물세포실증지원센터 (초저온냉동고, 인큐베이터 등 50여대 정기 PRQ 수행 중)	PQ / PRQ
JW크레아젠 (초저온 냉동고, 냉동고, 인큐베이터 등 40여대)	PRQ
얀센백신 (초저온 냉동고 20여대)	IQ / OQ / PQ
Genemedicine (냉동고, 냉장고)	IQ / OQ / PQ
테라베스트(멸균기 냉동고, 냉장고, 인큐베이터 40 여대)	PRQ
Abbott Korea (냉장고, 냉동고, Chamber 10여대)	IQ / OQ / PQ
찰스리버래보레토리 (냉장고, 인큐베이터 등)	IQ / OQ / PQ / PRQ
SK bioscience (4 glove Isolator)	PQ / PRQ
한국백신(Autoclave)	RA / DQ / IQ / OQ
SHIN POONG Pharm (BSC, Clean bench)	PRQ
서울대분당병원, 이대목동병원 외 다수 (Chamber, BSC, LN2 등)	IQ / OQ / PQ

“Selected from 150 + Projects Completed Since 2004”

05. Production Equipment

Representative
Working References

Year 2021 ~ 2026

CLIENT	SCOPE OF WORK
SK bioscience (G2+ 3 rd Party Project – Autoclave, Part Washer, UF/DF, Freezer Dryer, Fermenter, Reaction Tank 등 50여대)	RA / RTM / DQ / SAT / IQ ~ PQ
SK bioscience (이물검사대, 세포배양기, Centrifuger, Freeze Dryer 등)	IQ / OQ / PQ / RQ
SK Chemicals (생산 장비류)	RA / IQ / OQ
SK Plasma (Filling M/C and Packaging Line)	IQ / OQ / PQ
얀센백신 (주사제 생산장비 및 Packaging Line)	DQ / IQ / OQ / PQ
하나제약 (블리스터 자동 충전 포장 라인)	DQ / FAT / IQ / OQ
ENCell (생산장비 일체 약 80 여대)	PRQ
CKD Pharm (팔렛 타이징 M/C)	DQ / FAT / IQ / OQ
건일제약 (생산 장비 이전 관련 약 40여대)	RA / IQ / OQ / PQ
한미약품 (유동층 건조기, Oven Dryer, Packaging Equipment Line)	IQ / OQ
대웅제약 (세포치료센터 – 생산장비 30여대)	PRQ
SK biotek (Bio Reactor)	IQ / OQ
한국백신 (Packaging Line)	RQ
다수 장비 공급 업체 – Mixer & Tank 류	IQ / OQ / PQ

“Selected from 150 + Projects Completed Since 2004”

06. Computer System Validation

Representative
Working References

Year 2015 ~ 2026

CLIENT	SCOPE OF WORK
SK bioscience (G2+ Project - BMS, PCS, Historian)	VP / RA / RTM / DQ / IQ / OQ / PQ
SK bioscience (BMS, EMS, PCS, 수처리 시스템)	Re-Validation
APBL (냉실 온도 관리 시스템)	IQ / OQ
ENCell (BMS, Lab Equipment (Group C))	IQ / OQ
SK Chemicals (BMS, EMS)	IQ / OQ
듀캠바이오 (EMS, BMS)	IQ / OQ
보령제약 (EMS, BMS)	IQ / OQ
얀센백신 (BMS, EMS)	Re-Validation
대웅제약 (BMS, EMS)	IQ / OQ
용마로지스 (BMS)	IQ / OQ

“Excludes CSV for Automated Production Equipment”

07. New Construction Project

Representative
Working References

Year 2021 ~ 2026

CLIENT	SCOPE OF WORK
SK Plasma Core Indonesia - 인도네시아 New Plant	• Project Consultant & Coordinator • CCS Consulting • Process Tank (35), 멸균기, 살균기 - PQ
SK bioscience - 안동, G2+ 3 rd Party Project (with Sanofi)	• HVAC (8), Cold Room (3), Clean Device (27), Equipment (98), BMS, EMS, PCS, Clean Utility (11) • VP / QP / RA / RTM / DQ / SAT / IQ / OQ / PQ
Samsung Biologics - 송도, P5 Project	• HVAC (36), Cold Room (14), Freezer Room (10), CRT (3), Storage (8), WFI, CS) • SAT / IOV / PVT
Samsung Biologics - 송도, ADC Project	• HVAC (4), Cold Room (4), Freezer Room (10), CRT (3), Storage (4) • IOV / PVT
VACELL Bio - 화순, New Plant	• HVAC (7), CO2 (2), N2 (2), Storage (6), Chamber (6) • QP / RA / IQ / OQ / PQ
Sartorius - 송도 Campus	• HVAC (11), Storage (13), CA, N2 • VP / RA / DQ / IQ / OQ
Genemedicine - 하남, GMP 제조소 신축	• HVAC (13), PW, WFI, CDA, Storage (5), Clean Device (12), Chamber (11) • RA / URS / DQ / IQ / OQ / PQ
ENCell - 하남 3공장, New Plant	• HVAC (6), Clean Device (6), CA, O2, N2, CO2, LN2, Chamber (12), BMS 외 • QP / RA / DQ / IQ / OQ / PQ
APROGEN Biologics - 오송, New Plant	• HVAC (12), Automation Warehouse, Freezer Room (2), PW, WFI, PS, CA 외 • RA / DQ / SAT / IQ / OQ / PQ

"Selected from 30 + Projects Completed Since 2004"

08. CAR-T/Advanced Biopharmaceutical Representative Working References

Year 2023 ~ 2026

CLIENT	SCOPE OF WORK
분당서울대학교병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
부산동아대학교병원	- 인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting - 시설 – 주기적 재적격성평가
가천대학교병원	- 인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting - 시설 – 주기적 재적격성평가
순천향대학교서울병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
이대목동병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
원주세브란스병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
경북대학교병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
한림대성심병원	인체세포관리업 설계, 시공, Validation, Quality System 구축 및 인허가 Consulting
화순전남대학교병원	인체세포관리업 시설 – 주기적 재적격성평가

Year 2022 ~ 2026

CLIENT	Auditee	Nation
Assertio	Hamni Bio	Korea
Tenvie	Yuhan Chemical	Korea
HTL Biotechnology	Masung, Synex,	Korea
Deciphera Pharmaceuticals	ST Pharm	Korea
Angelini Pharma	Daewoong-Bio (Hagil Plant)	Korea
Rompharm Company S.R.L.	ScinoPharma	Korea
NEX-I	Samsung Biologics	Korea
Tekeda	SLS Bio, Samsung Biologics	Korea
ANNPOBIO	WEST	Singapore
VIANEX	ScinoPharm	Taiwan
Saike	CKD Bio	Korea
Alvogen	펜믹스, 중외생명과학	Korea

“Selected from 30 + Audit Completed Since 2022”

Our Core Values:
EXCELLENCE AND INTEGRITY

***“Your Success is Our Priority,
Providing Reliable Compliance and Validation Solutions”***

~ Thank You ~