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GMP & Validation Solution Consulting Service  
+ PharmaBio Supply & Value Chain Collaboration Business

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As of Dec 2024



GMP & Validation Solution Consulting Services  
(Project Reference: More than total 1,251 projects)

New/Remodeling GMP Facility Consulting(Turnkey Project); 신축/리모델링 GMP제조소 GMP&밸리데이션 종합컨설팅  
[Conceptual Design Execution, VMP, QRM(RA), URS, DQ, IQ, OQ, PQ, CSV, CV, PV and/or PQS Consulting]

GMP Facility Design Solution (Conceptual Design)	GMP Facility for Oral Solid Dosage Form, Liquids, Ointments, Eye Drops, Injections
	GMP Facility for API
	GMP Facility for Biopharmaceuticals, Cell Therapy & Gene Therapy(ATMP,CGT)
	GMP Facility for Health Functional Food & Medical Devices
Good Engineering Practice(GEP) Solution	Enhanced Design Review of Basic & Detailed Design/Facility Design
	GMP Facility Commissioning Consulting + Planning Execution & Reporting
	Utility System and Equipment Functional & Design Specification(FDS) Analysis & Documentation
	FAT / SAT and Pre-Delivery Inspection Planning, Execution & Reporting
	GMP Facility Engineering Management & Supervision Service
Qualification Consulting	Validation Master Planning + Quality Risk Management Master Planning
	QRM Planning, Execution & Reporting(Facility, Utility System, Equipment, Process etc.)
	URS & Design Qualification Execution & Documentation
	Installation & Operational Qualification Execution & Documentation
	Performance Qualification Consulting, Execution & Documentation
	Requalification & Revalidation Consulting, Execution & Documentation
Validation Solution	Cleaning Validation Consulting & Documentation
	Process Validation Consulting & Documentation
	Computerized System Validation Consulting, Execution & Documentation
GMP Solution Consulting	Validation Management System & Quality Risk Management System Consulting & Documentation
	GMP & Validation Training + Survival GMP Workshop(Knowledge Sharing)
	Data Integrity Management System & SOPs Consulting + Data Integrity Mock Inspection
	GMP Mock Inspection/ Vendor Audit
	Pharmaceutical Quality System(PQS) Consulting(Policy, SOPs, Form; Preparation, Review, Training)
제조 및 품질혁신	QbD Consulting(Partnership)
	Contamination Control Strategy (CCS) + Advanced EMP & Bioburden Control Consulting
	GMP Digital Transformation Solution Consulting
Collaboration	PharmaBio Supply & Value Chain Collaboration Business(제약바이오 공급망 및 밸류체인 협업)



**GMP컨설팅의 리더~~ 바이오써포트의 소중한 380 고객사!!!**

As of Dec 2024
