



Concept of Modular Construction & Engineering Process for New GMP Facility
 (Tofflon + Bio-Support)



Concept of Modular Construction & Engineering Process for New GMP Facility (Tofflon + Bio-Support)										Bio-Support		Tofflon						Written by		Bio-Support & Tofflon			
										Document No.		TBD				Review No.		Draft00-01		Date		2025-04-16	
Project Stage	Time Line	GMP / End User/ Consulting(Bio-Support)			Site	Facility Design / 3rd Party		Production Equipment with a long production period / 3rd Party		Site	Engineering for Modular Construction/ Tofflon			Site	Construction / 3ry Party		Site						
		Process	User	Consulting		Job	Description	Job	Description		Process	Engineering	Engineering QA		Job	Description							
Project Planning	3~6 Month	Project Strategy	GMP Facility Site	Supporting		Project Strategy	Supporting				Project Strategy	Supporting	Supporting										
			Product & Production Capacity																				
			Target GMP	Supporting																			
			URS of Conceptual Design	Supporting																			
Facility Design	4~5 Month	Conceptual Design(CD)	Review & Approval	Execution & Document	On-site	Conceptual Design(CD)	Supporting	Conceptual Design(CD)	Supporting	On-site	Conceptual Design(CD)	Cowork with User	Review	Off & On-site									
	1 Month	VMP	Review & Approval	Execution & Document		Bidding Process & Contract	Supplier's Proposal																
	3~4 Month	URS of Utility System	Review & Approval	Execution & Document		Facility Basic Design (BD)	Execution & Document	URS of Production Equipment Request for Proposal(URS)	User/Consulting: Documentation		Facility Basic Design(BD)	Execution & Document(Eng. Area)	Review										
		Facility Basic Design(BD)	Review & Approval	Execution & Document				Bidding Process & Contract	Supplier's Proposal														
	3 Month	Facility Detailed Design(DD)	Review	Review		Facility Detailed Design(DD)	Execution & Document	Design Qualification	User/Consulting: Documentation		Facility Detailed Design(DD)	Execution & Document(Eng. Area)	Review										
	1 Month	Design Qualification U1(DD -Utility)	Review & Approval	Execution & Document		Design Qualification U1(DD -Utility)	DD Revision				Design Qualification U1(DD -Utility)	DD Revision(Eng. Area)	Review										
C&E Bidding Process & Contract	1~2 Month	Request for Proposal (URS + Detailed Design)	Prep., Review & Approval	Review		Request for Proposal (URS + Detailed Design)	Prep. and Review				Proposal, Bidding Process & Contract	Execution & Document	Review		Proposal, Bidding Process & Contract	Execution & Document							
Construction & Engineering 1	6 Month (Eng: 5~6M / Construction Work 1: 4~6 M)	Off-Site GMP/GEP Supervision & Inspection	Factory Modular Construction Process User Supervision	Consulting	Off-site			Equipment Production at Off-site	Supplier	Off-site				Off-site	Construction Work 1	Site Preparation Work Civil & Foundation Work Architectural Work Warehouse(high Rack) built(if necessary)	On-site						
		Design Qualification U2(Utility)	Review & Approval	Execution & Document					Factory Modular Construction Process (Fabrication, and modular assembly)		- HVAC System, Clean Room, Water & Steam system, gas System etc. - BMS - Production Equipment	Factory Modular Construction Process QA Supervision: Material Inspection, Assembly Inspection, Pre-Commissioning											
		Off-Site FAT & Pre-delivery Inspection	Review & Approval	Review							Design Qualification U2(Utility)	FDS Preparation	FDS Review										
								Off-Site FAT & Pre-delivery Inspection	Supplier Execution + User/Consulting Review		Off-Site FAT & Pre-delivery Inspection	Execution	Execution & Document										
Shipping	1 Month	Modular Shipping	Supervision	Supervision				Equipment Shipping	Supplier		Modular Shipping	Shipping Planning & Execution	Supervision & Document										
Construction & Engineering 2	2~4 Month	Modular Installation	Supervision	Supervision	On-site			Equipment Incoming at Site	Supplier	On-site	Modular Installation	Modular Structure	Field Quality Inspection Work	On-site	Construction Work 2	Modular Installation Cowork	On-site						
		As Built Document + Supplier's Document for Qualification	Review	Review				Equipment Installation at Site	Supplier(Cowork with Engineering)			Utilities & Production Equipment Installation +Hook Up				Architectural Finishing Work							
											As Built Document + Supplier's Document for Qualification	Preparation	Review		As Built Document + Supplier's Document for Qualification	Preparation							
	1~2 Month	준공허가	Review	-				Commissioning & SAT	Supplier Execution + User/Consulting Review		준공허가	Preparation	Review		준공허가	Preparation & Execution							
Commissioning & Qualification	1 Month	Commissioning & SAT	Review & Approval	Review	On-site					On-site	Commissioning & SAT	Execution	Execution & Document	On-site	Commissioning & SAT		On-site						
	2~3 Month	IQ, OQ + CSV	Review & Approval	Execution	On-site			IQ, OQ + CSV	Consulting Execution + User: Review & Approval	On-site	IQ, OQ + CSV	CAPA Execution	Deviation Control	On-site	IQ, OQ + CSV	Deviation Control Supporting	On-site						
Validation	2~4 Month	PQ(Phase 1)			On-site					On-site				On-site									
	6~12 Month	Validation			On-site					On-site				On-site									