

SECTION 17000
AUTOMATION BASIS OF DESIGN

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SECTION 17000

AUTOMATION BASIS OF DESIGN

1 Introduction

The purpose of this document is to prescribe the Automation Basis of Design for the new Korean Institute of Industrial Technology (Kitech) facility. This Basis of Design is based upon the results of the Preliminary Engineering Phase of this project performed by CDI Engineering Solutions (CDI). The requirements are driven by the project goals and the overall project schedule.

Instrumentation and Control Systems information is based on the Process and Instrumentation Diagrams (P&IDs).

The purpose of this document is to:

- Ensure that all vendor supplied equipment control system packages are seamlessly interfaced to a Process Control System (PCS) workstation used for monitoring and alarming of the Process.
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- Ensure that the necessary data for electronic batch records are appropriately acquired and maintained to comply with 21 CFR Part 11 Electronic Batch Records.
- Establish a communication network according to current Good Manufacturing Practice Regulations (cGMPs) in Title 21 Code of the Federal Regulations (CFR) made substantive law by Section 501 of the Food, Drug and Cosmetic Act which will permit validation and GAMP requirements.

2 Executive Summary

The Process Automation objectives are established to be as follows:

- System is to meet FDA requirements and be a validated system.
- Interface Equipment Vendor Supplied Control Systems and other specified Automation Equipment to a PCS workstation.
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- Provide a continuous window into the process and batch recipes.
- Minimize operator input.
- Have the capability to provide electronic batch recording compliant with 21 CFR Part 11.
- Have the capability to develop and maintain electronic batch recipes without disrupting process.
- Monitor and control instrumentation not part of an equipment vendor control system.
- Provide safety interlocks for personnel and equipment safety and protection.
- Have the capability to seamlessly expand the PCS to meet Kitech's future expansion requirements.

2.1 Process Control System

The equipment being purchased for Kitech will be monitored and controlled utilizing Programmable Logic Controllers (PLCs) and Operator Interfaces (OIs) provided by each equipment vendor. Table 1 is a list of the equipment vendor supplied control systems.

Table 1 – Equipment Vendor Supplied Control Systems

P&ID	EQUIPMENT
CGMPCCPI1101	30L Media Prep Tank
CGMPCCPI1102	300L Media Prep Tank
CGMPCCPI1103	1500L Media Prep Tank
CGMPCCPI1104	30L Bioreactor Package: BX-1030
CGMPCCPI1105	300L Bioreactor Package: BX-1050
CGMPCCPI1106	1500L Bioreactor Package: BX-1070
CGMPCCPI1107	1500L Fed Batch Cell Culture Centrifugation: CE-1110
CGMPCCPI1108	Ultrafiltration/Diafiltration Skid: UF-1140
CGMPCCPI1109	Protein A Chromatography Skid: CL-1181
CGMPCCPI1110	Eluate Tank Package: VE-1190
CGMPCCPI1111	Neutralization Tank Package: VE-1200
CGMPCCPI1112	Chromatography Skid: CL-1231
CGMPCCPI1113	Ultrafiltration/Diafiltration Skid: UF-1240
CGMPCCPI1114	Ultrafiltration/Diafiltration Skid: UF-1270
CGMPCCPI1115	Chromatography Skid: CL-1301
CGMPCCPI1116	Ultrafiltration/Diafiltration Skid: UF-1310
CGMPCCPI1117	Chromatography Skid: CL-1321
CGMPCCPI1119	100L Buffer Prep Tank Package: VE-1500
CGMPCCPI1120	250L Buffer Prep Tank Package: VE-1530
CGMPCCPI1121	800L Buffer Prep Tank Package: VE-1560
CGMPCCPI1122	CIP Skid: XM-1680
CGMPCCPI1124	Portable Column Packing Skid: XM-1800
CGMPCCPI2201	50L Media Prep Tank: VE-2590
CGMPCCPI2202	500L Media Prep Tank: VE-2620
CGMPCCPI2203	CIP Skid: XM-2680
CGMPCCPI2204	50L Bioreactor Package: BX-2030
CGMPCCPI2205	500L Bioreactor Package: BX-2050
CGMPCCPI2206	Harvest Tank Skids: XM-2090
CGMPCCPI2207	Ultrafiltration/Diafiltration Skid: UF-2110
CGMPCCPI2208	Pool Tank: VE-2140
CGMPCCPI2209	Chromatography Skid: CL-2151
CGMPCCPI2210	Eluate Tank: VE-2160
CGMPCCPI2211	Neutralization Tank: VE-2170
CGMPCCPI2212	Chromatography Skid: CL-2191
CGMPCCPI2213	Ultrafiltration/Diafiltration Skid: UF-2200

CGMPCCPI2214	Ultrafiltration/Diafiltration Skid: UF-2230
CGMPCCPI2215	Chromatography Skid: CL-2261
CGMPCCPI2216	Chromatography Skid: CL-2281
CGMPCCPI2218	80L Buffer Prep Tank: VE-2500
CGMPCCPI2219	200L Buffer Prep Tank: VE-2530
CGMPCCPI2220	600L Buffer Prep Tank: VE-2560
CGMPCCPI2222	Portable Column Packing Skid: XM-2800
CGMPCCPI3301	100L Buffer Prep Tank: VE-3500
CGMPCCPI3302	250L Buffer Prep Tank: VE-3530
CGMPCCPI3303	800L Buffer Prep Tank: VE-3560
CGMPCCPI3304	25L Fermentation Package: FE-3040
CGMPCCPI3305	500L Fermentation Package: FE-3060
CGMPCCPI3306	Drop Tank: VE-3080
CGMPCCPI3307	Harvest Centrifuge: CE-3090
CGMPCCPI3308	Harvest Tank: VE-3120
CGMPCCPI3309	Hold Tank: VE-3110
CGMPCCPI3310	Homogenizer Skid: HO-3130
CGMPCCPI3311	Harvest Tank: VE-3170
CGMPCCPI3312	Dissolution Tank: VE-3180
CGMPCCPI3313	Ultrafiltration/Diafiltration Skid: UF-3190
CGMPCCPI3314	Ultrafiltration/Diafiltration Skid: UF-3210
CGMPCCPI3315	Ultrafiltration/Diafiltration Skid: UF-3250
CGMPCCPI3316	Chromatography Skid: CL-3201
CGMPCCPI3318	Chromatography Skid: CL-3271
CGMPCCPI3319	Chromatography Skid: CL-3331
CGMPCCPI3320	Portable Eluate Tank: VE-3300
CGMPCCPI3323	25L Media Prep Tank: VE-3590
CGMPCCPI3324	500L Media Prep Tank: VE-3620
CGMPCCPI3325	CIP Skid: XM-3680
CGMPCCPI3327	Autoclave: AU-3410
CGMPCCPI3328	Parts Washer: PW-3400
CGMPCCPI3329	150L Media Prep Tank VE-3650
CGMPCCPI3330	Portable Column Packing Skid: XM-3800
CGMPCCPI3331	Autoclave: AU-3430
CGMPCCPI4401	Autoclave: AU-4170
CGMPCCPI4402	Parts Washer: PW-4140
CGMPCCPI4403	Sterile Hold Tank: VE-4180
CGMPCCPI4404	Vial Washer: VW-4150
CGMPCCPI4405	Depyrogenation Tunnel: DP-4160
CGMPCCPI4406	Lyophilizer: LY-4030
CGMPCCPI4407	Portable Formulation Tank: VE-4190
CGMPCCPI4408	Vial Filling Line: XM-4210
CGMPCCPI4409	Hypak Filling Line: XM-4100

CGMPCCPI4410	Stopper Washer: SW-4220 FUTURE
CGMPCCPI4411	CIP Skid: XM-4230
CGMPCCPI4412	Dry Heat Oven: DP-4240
CGMPCCPI5501	Autoclave: AU-5010
CGMPCCPI5502	Parts Washer: PW-5020
CGMPCCU9901	Compressed Air Generation
CGMPCCU9903	Oxygen Delivery System: XM-9030
CGMPCCU9904	Nitrogen Delivery System: XM-9040
CGMPCCU9905	Carbon Dioxide Delivery System: XM-9050
CGMPCCU9907	USP Purified Water Generation Skid: XM-8250
CGMPCCU9908	USP PW Storage: VE-8130
CGMPCCU9909	WFI Still: WF-8160
CGMPCCU9910	Hot WFI Storage: VE-8170
CGMPCCU9913	Clean Steam Generator: CS-8210
CGMPCCU9916	Bio- Waste Surge Tank Skids: XM-9400 & XM-9410
CGMPCCU9918	Bio-Waste Inactivation: XM-9430
CGMPCCU9919	Waste Neutralization System: XM-9480

Field instrumentation not provided as part of the individual vendor supplied equipment packages will be monitored and controlled by one or more of the vendor supplied control systems. The physical location of the field instrumentation will determine which vendor supplied control system(s) will be utilized.. Appendix II contains the preliminary instrument index based on the P&IDs. This index contains the instrument tag number, P&ID, Service description, line number, loop number, instrument type, equipment number, comments, I/O, calibrated range, units, measuring range and units.

All of the individual vendor supplied control system packages will interface with a PCS Workstation via an Object Linking and Embedding Process Control (OPC) compliant Ethernet Local Area Network (LAN), where applicable. The PCS Workstation will provide process monitoring and alarm recognition. The individual equipment vendor supplied control system packages are presumed to be Allen Bradley SLC 5/05 PLCs and 21 CFR Part 11 Compliant Operator Interfaces, or approved equals. The integration of the equipment vendor supplied control systems and the PCS Workstation shall facilitate the following:

- Reliable and industrial proven communication technology and protocol.
- Communication compatibility advantage of OPC compliant Ethernet communications.
- Monitoring process data and alarms from the equipment vendor supplied control systems.
- Ability to view equipment vendor supplied control systems alarms via the central Workstation.
- Create a central depository for tracking of electronic signatures against batch records.
- Create a central depository for batch recording and reporting.
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2.2 Instrumentation

See Appendix II for the instrument index based on the P&IDs.

2.3 Implementation Strategy

The PCS will be designed to facilitate validation, factory acceptance testing, installation, site acceptance testing, start-up and commissioning. The following is a list of phases:

- Define User Requirement Specification
- Develop Functional Requirement Specification
- Develop Quality Assurance Plan
- Configuration of PCS
- Factory Acceptance Testing
- Ethernet LAN Installation
-
- PCS Server and Server Applications Installation
- Installation of Equipment Vendor Supplied Control Systems
-
- Integration of appropriate process instruments with Building Automation System (BAS)
- Site Acceptance Testing
- Commissioning
- Validation

3 Overview

3.1 Automation Concept Design Requirements

3.2.1 Process Automation Objectives

The PCS must be flexible, modular, cost effective and meet cGMP. It must be designed, installed and fully operational within the project schedule. The PCS must be flexible to allow easy implementation of campaign changes based on contract manufacturing and to adapt to future manufacturing needs.

The PCS must also be expandable to meet future expansion requirements. The PCS shall be designed such that future expansions are seamless and do not interfere with current productions.

The primary automation objective for this project is to automate manufacturing functions that result in maximizing the number of released batches. This includes enforcing procedural compliance through recipe driven manufacturing and product/batch tracking. The PCS will have the capability to monitor multiple batches running simultaneously.

The following benefits will result from the envisioned level of automation:

- Adherence to FDA Compliance
- Enhanced safety through automated monitoring and alarming
- Minimized operator interactions
- Minimized data entry through use of bar code scanners for product tracking
- Elimination of manual batch records through the implementation of Electronic Batch Records (EBRs)
- Controlled access for activation of process steps/cycles for security and electronic signatures for traceability
- Reduced cycle time through automated operations
- Automated data acquisition and availability
- Ease of recipe additions and changes without production interruptions
- Ease of PCS expansion
- Integration of all of the Equipment Vendor Supplied Control Systems with a PCS Workstation

3.2.2 Process Automation Design Constraints

The design methodology must address both the practical operation of this facility from a technician's perspective and the management of the resources required for manufacturing quality products. The following is a list of design constraints for the process automation system.

- Utilize an appropriate manufacturing control system platform to achieve the automation objectives.
- Provide modular software structure to reduce time required for start-up, validation and maintainability.
-
- Allow for continued operation of systems during failure of a single component and limited disruption when multiple failures occur.
- Utilize the models and terminology provided in the ISA standard S88.01 Batch Control.

4 System Architecture

4.1 Process Automation Architecture

The PCS communication OPC compliant Ethernet will integrate all equipment vendor supplied control systems to the PCS Workstation.

The PCS shall be configured in accordance with ANSI/ISA S-88.01, and Standard for Batch Models and Terminology and comply with 21 CFR Part 11. The use of these standards will support application of industry standard software packages, provide for flexibility and modularity required by the Process Automation Objectives, and facilitate direct comparisons between these concepts and the capabilities of the automation platforms under consideration.

4.1.1 Production Information Management

Production Information Management activities will be performed with a real-time relational database for data collection. The activities will include the following:

- Storing Master Recipe genealogy information for each batch
- Collecting Control Recipe information, including mode and parameter changes for each batch
- Collecting Equipment Allocation information for each batch
- Collecting batch data, including predictable events, non-predictable events, operator interventions, and operator comments for each batch
- Collecting batch support data (continuous data) such as quality control (QC) and quality assurance (QA) data.
- Provide a means for late entries to the Batch Record
- Management of Electronic Batch Records (EBR) and Batch Support Data, including ability to process queries and produce batch reports

4.1.2 Process Management

Process Management includes all control functions that manage batches, recipes and process materials. Process Management will be performed within the Process Control System (PCS). Process Management activities will include the following:

- Creation, management, monitoring, and execution of the control recipe(s).
- Assigning unique batch numbers to the control recipes.
- Monitoring and management of materials, including arbitration and allocation as well as “real-time” status management for materials and assets involved in the production process.
- Receiving Batch and Status information for batch reporting.
-

4.2 Power Supply Backup

The PCS shall remain operable through any loss of power or transfer of power. All controllers and Workstations will be served by an uninterruptible power supply (UPS). The equipment vendor supplied control systems will also be on UPS.

4.3 PCS Workstation

A PCS Workstation will be provided for the facility. The Workstation shall be contained in 316 SST NEMA 4X, water tight construction as a minimum, and as required by the electrical classification of the area. Enclosures shall be for a clean-room environment and sloped for cleanability. Exterior screw-type clamps are not permitted.

4.4 Support Equipment/Devices

Weigh scales shall be interfaced to the PCS through serial ports. Devices such as bar code readers shall be interfaced to the PCS via the OPC compliant Ethernet. Network printers will be integrated on the LAN using the OPC compliant Ethernet Network.

5 Instrumentation

5.1 Documentation

5.1.1 Instrument Calibration Sheets

Instrument Calibration Sheets and calibration stickers shall be provided by the equipment vendor showing the calibration data, results, calibration date, test equipment serial number and technician's initials. All calibrations shall be traceable to the National Institute of Standards Technology (NIST). Calibration stickers shall be applied to each device.

5.1.2 Test Documentation

Test documentation shall be supplied for any computer based system to demonstrate that the system which was delivered operates the way it was designed to operate. This documentation shall also include software test protocols and software development QC records.

5.1.3 User Requirement Specification

The User Requirement Specification will provide a detailed description of PCS needs and expectations.

5.1.4 Functional Description

The functional description will provide a detailed sequence of operation providing all required actions and expected results.

5.1.5 Validation Documentation

Validation documentation shall be provided to include Installation Qualification and Operational Qualification Protocols, description of validation experiments, list of summary data and documented evidence that the design intentions are met.

5.2 Preferred Instrument Manufacturers

Appendix I contains a list of suggested preferred instrument manufacturers.

Appendix I

Suggested Preferred I&C Manufacturers

Flow Transmitters

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Coriolis- Mass Flow	Micromotion	Krohne	Endress & Hauser
Positive Displacement	Badger	Brooks Instruments	Neptune
Vortex	Rosemount	Foxboro	Fischer & Porter
Thermal	FCI	Thermal Instrument	Sierra
Orifice Plates	Daniel	Foxboro	
Magnetic	Rosemount	ABB	Bailey Fisher Porter
Turbine	Brooks Instruments	Fischer & Porter	Flow Technology

Level Transmitters

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
D/P	Rosemount	Viatran	Honeywell
Radar	Rosemount	Ohmart Vega	Endress & Hauser
Ultrasonic	Krohne	Ohmart Vega	Endress & Hauser
Float	MTS	GEMS	Krohne

Pressure Transmitters

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Gauge	Rosemount	Anderson	Honeywell
Absolute	Rosemount	Anderson	Honeywell
Vacuum	Rosemount	Anderson	Honeywell
D/P	Rosemount	Anderson	Honeywell

Temperature Transmitters

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Transmitter	Rosemount	Anderson	Pyromation
RTD	Burns	Pyromation	Anderson

Flow Gauges

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Rotometer	Brooks Instrument	Fischer & Porter	

Pressure Gauges

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Standard	US Gauge	Ashcroft	Chicago
Absolute	US Gauge	Ashcroft	Chicago
Vacuum	US Gauge	Ashcroft	Chicago
Compound	US Gauge	Ashcroft	Chicago
Sanitary	Anderson	Ashcroft	Chicago

Thermometers

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Standard	Ashcroft	Tel-Tru	Wika
Sanitary	Ashcroft	Tel-Tru	

Pressure Switches

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Standard	United Electric	Ashcroft	SOR
Absolute	United Electric	Ashcroft	SOR
Vacuum	United Electric	Ashcroft	SOR
Compound	United Electric	Ashcroft	SOR
Sanitary	SOR	Ashcroft	United Electric

Ball Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Metal (Process)	Worchester	Fisher	Whitey
Metal (Utility)	Worchester	Fisher	Whitey
Lined	Xomox	Atomic	Neotecha
Plastic (TFE)	George Fisher	Asahi	
Sanitary	MCF	SVF	Jordan Valve

Tank Sampling Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Sampling Valves	Asepco		

Diaphragm Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Sanitary	ITT	Gemu	

Tank Bottom Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Flush	Asepco	ITT	

Solenoid Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Solenoid	ASCO	Burkert	Skinner

Modulating Valves

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Globe	Fisher	Jamesbury	Valtek
Diaphragm	ITT	Gemu	Saunders
Ball	Fisher	Jamesbury	Worcester

I/P Transducers

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
I/P	Action Instruments	Conoflow	Fisher

Regulators

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Non-Sanitary	Fisher	Jordan	Tescom
Sanitary	Jordan	Baumann	Tescom

Weighing Systems

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Load Cells	Toledo	Kistler-Morse	BLH
Platform Scales	Toledo	Fairbanks	General Electronic Sys.
Bench Scales	Toledo	Ohaus	Sartorius

Analytical Instruments

Section 8.1 Analytical Instruments:				pH Instruments
Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3	Manufacturer # 4
pH	Thornton	Rosemount	Ingold	
Conductivity	Thornton	Rosemount	Ingold	

Density	Canty			
TOC	Sievers	Anatol	Rosemount	
Dissolved Oxygen	Rosemount	Ingold	Phoenix	
Resistivity	Thornton	Rosemount		

Recording Instruments

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Circular Chart	Partlow	Yokogawa	Honeywell
Strip Chart	Yokogawa	Partlow	Honeywell

Miscellaneous

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
Thermowells	Rosemount	Anderson	
Proximity Switches	Allen Bradley	Pepperl & Fuchs	Turks
Control Panels	Hoffmann	Rittal	Crouse-Hinds
Terminal Blocks	Allen Bradley	Weidmuller	
Relays	Allen Bradley	Struthers-Dunn	Deltrol Controls
Fuses	Littlefuse		
Power Supplies	Sola	Acopian	Lamda
Panel Meters	Digital		
Annunciators	Ronan	Panalarm	
Alarm Horn	Federal	Crouse-Hinds	
Alarm/Pilot Lights	Allen Bradley	Crouse-Hinds	
Pushbuttons and Switches	Allen Bradley	Couse-Hinds	

Control Systems

Type	Manufacturer # 1	Manufacturer # 2	Manufacturer # 3
PLC	Allen Bradley	Siemens	
Software	Intellution	Siemens	Wonderware
Printers	HP Laserjet	Cannon Laserjet	
Operator Interfaces	AB Panelview 1000	AB Panelview 1400	
Workstations	Daisy Data	Modular Industrial	Strongram
Operating Systems	MS Windows		
Database Software	MS Sequel	Oracle	Informix

Appendix II

Instrument Index