NovaBio Pharmaceutical AI Designer Example

Generate solutions using FrameworX AI Designer

This example demonstrates the solution **NovaBio_Cambridge** created by FrameworX AI Designer.

Solution download: NovaBio_Cambridge.dbsln

Technical Specification PDF: NovaBio_BioProcess_Spec.pdf

OPC-UA I/O Address Sheet: NovaBio_OPC_UA_IO_Addresses.xlsx

Showcases:

- Build a complete cGMP biopharmaceutical SCADA solution from a PDF specification and an Excel I/O sheet.
- Connect to an Emerson DeltaV DCS over OPC-UA with certificate-based security and a service account.
- Organize 23 tags across six manufacturing suites under an ISA-95 Unified Namespace rooted at NovaBio/Cambridge/Mfg/.
- Configure two-tier alarming with Critical (comment-required acknowledgment) and Warning groups for FDA 21 CFR Part 11 audit trails.
- Historize 20 analog tags across two tables with engineering-unit deadbands and 365-day retention.
- Compute rolling statistics through Calculation user-defined types to feed downstream ML pipelines.
- Visualize all six suites on one process overview screen with color-coded panels, tank visuals, vertical bargraphs, and a 30-minute trend strip.
- Identify five candidate ML opportunities across bioreactor, chromatography, and utility tags using the built-in ML.NET integration.

This solution was created as a demonstration of FrameworX AI Designer capabilities. It is not intended for production use. Device connections, alarm limits, and process values are illustrative only and have not been validated against real equipment or regulatory requirements.

Summary

This page contains the technical details for the NovaBio Therapeutics AI Designer demo. The AI reads the attached PDF specification and Excel I/O address sheet to build the complete SCADA solution covering all 6 process suites of a cGMP monoclonal antibody manufacturing facility in Cambridge, MA.

Item	Value
Solution Name	NovaBio_Cambridge
Platform	FrameworX fx-10.1 / Enterprise Unlimited
Industry	Biopharmaceutical / Life Sciences
Protocol	OPC-UA (Emerson DeltaV DCS)
UNS Root	`NovaBio/Cambridge/Mfg/`
Total Tags	23 (21 process + 2 Calculation UDT instances)
Alarm Items	24 (Critical and Warning groups)
Historian Tags	20 analog tags, 365-day retention

Approx. Build Time	~5 minutes (AI-assisted end-to-end)

Demo Prompt

The following prompt was submitted to FrameworX AI Designer along with the two attached documents. The AI read both files and built the entire solution autonomously based on this input.

```
<role>
You are an automation engineer in life and science business and specialized in FrameworX.
</role>

<context>
I have attached 2 files, one is the specification which describes how the project is actually planned in .
pdf, it mentions the UNS structure (tags), device information and alarms, and the other one is an excel
which defines the address for the device. And my final goal here is to create a FrameworX solution to
implement an automation project
</context>

<instruction>
1 - Read both files and understand the implementation
2 - Make the plan to implement the UNS, alarms, historian, 3x2 dashboard displays with 3 gauges, 2 trends, 1
alarmviewer.
3 - Wait for my approval to start creating the solution
4 - When building this FrameworX solutions module by module, always stop and wait for explicit confirmation
before starting the next module, no exceptions.
</instruction>
```

Attached documents with the prompt

1. **NovaBio_BioProcess_Spec.pdf** — cGMP equipment specification with facility suite descriptions, OPC-UA connection parameters, key instrument list with engineering ranges, and critical alarm limits (Warn/Crit Lo/Hi) per FDA/ICH guidelines
2. **NovaBio_OPC_UA_IO_Addresses.xlsx** — Two-sheet workbook: full I/O address list with OPC-UA Node IDs and FrameworX UNS paths per tag; plus a connection configuration sheet with endpoint URL, namespace index, security mode, and service account

Approximate creation time = 5 minutes.

Facility Overview

NovaBio Cambridge is a cGMP biopharmaceutical manufacturing site producing monoclonal antibodies for clinical and commercial supply. Two 2,000 L fed-batch bioreactor trains feed an integrated downstream purification and formulation suite. The facility is controlled by an **Emerson DeltaV DCS** connected to FrameworX SCADA via OPC-UA, organized around an ISA-95 Unified Namespace.

Suite	Name	Description
USP-SEED	Seed Train	20 L and 200 L single-use seed bioreactors
USP-PROD	Production Bioreactors	Two 2,000 L STRs — Trains A and B
DSP-HARV	Harvest & Recovery	Centrifugation and tangential flow filtration
DSP-CHROM	Chromatography	Protein A capture, CEX and AEX polishing columns
DSP-FORM	Formulation & UF/DF	Ultrafiltration, buffer exchange, concentration
UTIL-CIP/WFI	Utilities	CIP/SIP skids, clean steam, and WFI loops

Control System Architecture

DCS Connection

Parameter	Value	Notes

Protocol	OPC-UA	Connection from FrameworX to DeltaV DCS
Device / PLC	Emerson DeltaV v14.3 DCS	Main plant controller
Device IP Address	`10.10.1.5`	Static IP — plant network segment
OPC-UA Endpoint	`opc.tcp://10.10.1.5:4840`	Default DeltaV OPC-UA server port
Namespace	`ns=2`	NovaBio process namespace on DeltaV server
FrameworX Device Name	`NovaBio_DeltaV`	Node object name in FrameworX solution
FrameworX Channel	`NovaBio_OPC_Channel`	OPCUA protocol driver instance
UNS Root Path	`NovaBio/Cambridge/Mfg/`	ISA-95 hierarchy root for all tags
Subscription Rate	1000 ms analog / on-change digital	Matches historian logging rate
Security Mode	SignAndEncrypt / Basic256Sha256	Certificate auth; service account: `fxopc_svc`

Tag Database by Suite

USP-SEED - Seed Train BR-S20

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
`USP_SEED/BR_S20/Temperature`	TT-S01	AI	0–100	°C	`ns=2;s=NovaBio.USP.Seed.TT_S01.PV`
`USP_SEED/BR_S20/pH`	pHT-S01	AI	0–14	—	`ns=2;s=NovaBio.USP.Seed.pHT_S01.PV`
`USP_SEED/BR_S20/DO`	DOT-S01	AI	0–200	%sat	`ns=2;s=NovaBio.USP.Seed.DOT_S01.PV`

USP-PROD - Production Bioreactors (Train A and B)

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
`USP_PROD/BR_PA/Temperature`	TT-PA02	AI	0–100	°C	`ns=2;s=NovaBio.USP.Prod.TT_PA02.PV`
USP_PROD/BR_PA/pH	pHT-PA01	AI	0–14	—	`ns=2;s=NovaBio.USP.Prod.pHT_PA01.PV`
`USP_PROD/BR_PA/DO`	DOT-PA01	AI	0–200	%sat	`ns=2;s=NovaBio.USP.Prod.DOT_PA01.PV`
`USP_PROD/BR_PA/AgitatorSpeed`	AGT-PA01	AI	0–150	RPM	`ns=2;s=NovaBio.USP.Prod.AGT_PA01.PV`
`USP_PROD/BR_PA/HarvestFlow`	FT-PA01	AI	0–500	L/hr	`ns=2;s=NovaBio.USP.Prod.FT_PA01.PV`
`USP_PROD/BR_PB/Temperature`	TT-PB02	AI	0–100	°C	`ns=2;s=NovaBio.USP.Prod.TT_PB02.PV`
`USP_PROD/BR_PB/pH`	pHT-PB01	AI	0–14	—	`ns=2;s=NovaBio.USP.Prod.pHT_PB01.PV`
`USP_PROD/BR_PA/DOStats`	—	Calculation (UDT)	—	—	Computed — no device point

DSP-HARV - Harvest and Recovery

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
`DSP_HARV/CF_H01/BackPressure`	PT-H01	AI	0–6	bar	`ns=2;s=NovaBio.DSP.Harv.PT_H01.PV`
`DSP_HARV/CF_H01/BowlTemp`	TT-H01	AI	0–80	°C	`ns=2;s=NovaBio.DSP.Harv.TT_H01.PV`
`DSP_HARV/TFF_H01/Conductivity`	CON-H01	AI	0–200	mS/cm	`ns=2;s=NovaBio.DSP.Harv.CON_H01.PV`
`DSP_HARV/CF_H01/PressureStats`	—	Calculation (UDT)	—	—	Computed — no device point

DSP-CHROM - Chromatography

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
`DSP_CHROM/UV/Absorbance`	UV-C01	AI	0–3	AU	`ns=2;s=NovaBio.DSP.Chrom.UV_C01.PV`
`DSP_CHROM/InletPressure`	PT-C01	AI	0–5	bar	`ns=2;s=NovaBio.DSP.Chrom.PT_C01.PV`

DSP-FORM - Formulation and UF/DF

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
DSP_FORM/TFF_F01/Weight	WT-F01	AI	0–500	kg	ns=2;s=NovaBio.DSP.Form.WT_F01.PV
DSP_FORM/TFF_F01/Temperature	TT-F01	AI	0–25	°C	ns=2;s=NovaBio.DSP.Form.TT_F01.PV

UTIL-CIP/SIP & WFI

UNS Path	Instrument	Signal	Range	Units	OPC-UA Node ID
UTIL_CIP/SteamTemp	TT-U03	AI	0–150	°C	ns=2;s=NovaBio.Util.CIP.TT_U03.PV
UTIL_CIP/CIP_U01/Phase	CIP-U01	DI	—	—	ns=2;s=NovaBio.Util.CIP.CIP_U01.Phase
UTIL_WFI/LoopTemp	TT-U02	AI	0–100	°C	ns=2;s=NovaBio.Util.WFI.TT_U02.PV
UTIL_WFI/Conductivity	CON-U02	AI	0–5	µS/cm	ns=2;s=NovaBio.Util.WFI.CON_U02.PV

Devices and OPC-UA Connection

Field data flows in over OPC-UA from the DeltaV controller. The connection uses one channel feeding one node and 21 read-only points; the two computed Calculation tags do not map to a device address and are populated by server-side scripts.

Layer	Object	Key Parameters
Channel	NovaBio_OPC_Channel	Protocol: OPCUA, ReadGroupMaxSize: 100
Node	NovaBio_DeltaV	opc.tcp://10.10.1.5:4840, Refresh: 1000ms, User: fxopc_svc, Security: SignAndEncrypt /Basic256Sha256
Points	21 mapped tags	All AccessType: Read, Address format: ns=2;s=NovaBio.{Area}.{Tag}.PV

> **Certificate Setup Required**
>
> On first Runtime start, the OPC-UA connection requires manual certificate trust exchange between FrameworX and the DeltaV server. Use the OPC-UA Certificate Manager in FrameworX to trust the server certificate, and ensure the fxopc_svc account is configured on the DeltaV side with appropriate read permissions on all ns=2 nodes.

Critical Alarm Limits

Per the NovaBio cGMP process specification (NVBT-MFG-SPEC-2026-003). Train B mirrors Train A limits for all bioreactor parameters.

Parameter	Tag	Warn Lo	Warn Hi	Crit Lo	Crit Hi	Unit
Bioreactor Temperature	BR_PA/Temperature	36.5	37.5	36.0	38.0	°C
Bioreactor pH	BR_PA/pH	6.90	7.10	6.80	7.20	—
Dissolved Oxygen	BR_PA/DO	30	—	20	—	%sat
Centrifuge Back-Pressure	CF_H01/BackPressure	—	4.5	—	5.5	bar
Column Inlet Pressure	DSP_CHROM/InletPressure	—	3.5	—	4.5	bar
Product Temperature	TFF_F01/Temperature	2	8	1	10	°C
WFI Loop Temperature	UTIL_WFI/LoopTemp	72	85	70	88	°C
WFI Conductivity	UTIL_WFI/Conductivity	—	1.3	—	1.5	µS/cm

Alarm Groups

Group	AckRequired	Sound	LogEvents	Purpose
Critical	Comment (operator must type note)	Exclamation	All	cGMP critical parameter breaches — full audit trail
Warning	Yes	Beep	All	Approaching process limits — early warning

cGMP Design Note

The Critical alarm group requires operator comments on acknowledgment (**AckRequired: Comment**). This ensures every critical alarm acknowledgment generates an audit trail entry — a requirement under FDA 21 CFR Part 11 and EU Annex 11 for electronic records in pharmaceutical manufacturing.

Historian Configuration

The demo records 20 analog process values continuously, organized into two historian tables and kept on disk for 365 days using the built-in tag historian. Deadbands are set in engineering units so logged values reflect process-significant change rather than sensor noise.

Table	Tags	Suites	TimeDeadband	Retention
`Process_Tags`	17	USP-SEED, USP-PROD, DSP-HARV, DSP-CHROM, DSP-FORM	1000 ms	365 days
`Utility_Tags`	3	UTIL-CIP, UTIL-WFI	1000 ms	365 days

Deadband Configuration

Tag Type	Deadband	Rationale
Bioreactor pH	0.005	Small pH drift is biologically significant
UV Absorbance 280nm	0.005	Chromatography peak resolution
Bioreactor Temperature	0.05 °C	Process setpoint window is only ±1 °C
Pressure signals	0.05 bar	Alarm limits are 0.5–1.0 bar apart
WFI Conductivity	0.01 µS/cm	USP <1231> requires resolution to 0.1 µS/cm
Steam / Utility temperatures	0.2–0.5 °C	Looser — less regulatory significance

Quality Flag Logging

Both historian tables have **SaveQuality: true** — OPC-UA quality flags (Good/Bad/Uncertain) are stored alongside every value. Bad-quality readings must be excluded from batch records and process capability calculations.

Displays

The demo opens to a single process overview screen that shows all six suites at a glance. Suite panels are color-coded, each suite has tank visuals and vertical bargraphs for every process variable, and a full-width 30-minute trend strip runs across the bottom.

Display Layout

Region	Content
Header bar	Facility title + DCS connection info
Top row — left	USP-SEED: vertical tank (temperature) + bargraphs for pH and DO
Top row — center	USP-PROD: Train A and B tanks + bargraphs for Temp, pH, DO, Agitator RPM, Harvest Flow
Top row — right	DSP-CHROM: bargraphs for UV absorbance 280nm and column inlet pressure
Bottom row — left	DSP-HARV: bargraphs for centrifuge back-pressure, bowl temp, TFF conductivity
Bottom row — center	DSP-FORM: bargraphs for retentate weight and product temperature
Bottom row — right	UTIL: bargraphs for CIP steam temp, WFI loop temp, WFI conductivity
Footer trend strip	30-min TrendChart — Train A Temp (orange), pH (teal), DO (sky blue), Agitator RPM (green)

Symbols Used

Symbol	Used for	Instances
`HMI/Tanks/VerticalTank_Scale`	Bioreactor vessel visualization — fill level driven by temperature	4
`HMI/Linear_Gauge/LinearGauge2`	Vertical bargraphs for all process variables across all suites	14

Suite Color Coding

Suite	Panel Header Color
USP-SEED	Dark blue — #1E4976
USP-PROD	Dark green — #1B5E20
DSP-CHROM	Dark purple — #4A148C
DSP-HARV	Dark brown — #4E342E
DSP-FORM	Dark teal — #006064
UTIL-CIP/WFI	Dark indigo — #1A237E

Process Notes for SCADA Configuration

1. **OPC-UA Security:** All process tags use SignAndEncrypt / Basic256Sha256. Certificate exchange must be completed on first runtime start. The service account `fxopc_svc` must have read permissions on all ns=2 nodes in DeltaV.
2. **cGMP Audit Trail:** Critical alarms require operator comments on acknowledgment. All alarm events (active, acked, normalized) are logged to historian for regulatory compliance.
3. **Calculation UDT Tags:** The `DOStats` and `PressureStats` tags have no device points. They will be populated by server-side Script Tasks computing rolling statistics to feed ML.NET pipelines.
4. **Historian Quality Flags:** SaveQuality is enabled on both historian tables. OPC-UA Bad quality samples must be excluded from batch record analysis and process capability calculations.
5. **ML Opportunity:** Bioreactor DO and temperature, UV absorbance chromatography peaks, centrifuge pressure patterns, and WFI conductivity drift are the primary candidates for ML.NET anomaly detection and forecasting models.

ML Opportunities

Variable	ML Opportunity	Suggested Model
`BR_PA/DO` — Dissolved Oxygen	Detect oxygen transfer rate deviations — predict sparge/agitation adjustments before DO drops below warning threshold	SSA Spike Anomaly Detection
`BR_PA/Temperature` — Bioreactor Temp	Thermal drift forecasting during fed-batch — predict cooling demand before critical alarm	Time-Series Forecasting
`DSP_CHROM/UV/Absorbance` — UV 280nm	Chromatography peak shape classification — distinguish protein peaks from contaminant shoulders	FastTree Binary Classification
`CF_H01/BackPressure` — Centrifuge Pressure	Pressure trend anomaly before filter breakthrough — `PressureStats.Average` UDT member supports rolling stats	SSA Spike Anomaly Detection
`UTIL_WFI/Conductivity` — WFI Conductivity	Predict loop degradation — rising conductivity trend detection before USP limit breach	Time-Series Forecasting

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