NovaBio Therapeutics, LLC

Bioprocess Facility — Equipment Specification & Process Variables | Cambridge, MA | April 2026

1. 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	CIP, SIP & WFI	Clean-in-place skids, steam, and water loops

Table 1 — Facility suites

2. Connection & Device Configuration

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	Device object name in FrameworX solution
UNS Root Path	NovaBio/Cambridge/Mfg/	ISA-95 hierarchy root for all tags
Subscription Rate	1 Hz analog / on-change digital	Matches historian logging rate
Security	SignAndEncrypt / Basic256Sha256	Certificate auth; service account: fxopc_svc

Table 2 — OPC-UA connection and device parameters

3. Key Equipment & Instruments

The table below lists the primary instruments per suite. Full tag databases are provided in the companion OPC-UA I/O Address sheet.

Tag	Suite	Description	Range
TT-PA02	USP-PROD	Vessel temperature — Train A	0–100 °C
pHT-PA01	USP-PROD	Vessel pH — Train A	0–14
DOT-PA01	USP-PROD	Dissolved oxygen — Train A	0–200 %sat
AGT-PA01	USP-PROD	Agitator speed — Train A	0–150 RPM
FT-PA01	USP-PROD	Harvest flow — Train A	0–500 L/hr

Tag	Suite	Description	Range
PT-H01	DSP-HARV	Centrifuge back-pressure	0–6 bar
TT-H01	DSP-HARV	Centrifuge bowl temperature	0–80 °C
CON-H01	DSP-HARV	TFF permeate conductivity	0–200 mS/cm
UV-C01	DSP-CHROM	UV absorbance 280 nm	0–3 AU
PT-C01	DSP-CHROM	Column inlet pressure	0–5 bar
WT-F01	DSP-FORM	Retentate net weight	0–500 kg
TT-F01	DSP-FORM	Product temperature	0–25 °C
TT-U02	UTIL-WFI	WFI loop temperature	0–100 °C
CON-U02	UTIL-WFI	WFI conductivity	0–5 µS/cm
TT-U03	UTIL-CIP	Clean steam temperature (SIP)	0–150 °C

Table 3 — Key instruments by suite

4. Critical Alarm Limits

Tag	Parameter	Warn Lo	Warn Hi	Crit Lo	Crit Hi	Unit
TT-PA02	Bioreactor Temperature	36.5	37.5	36.0	38.0	°C
pHT-PA01	Bioreactor pH	6.90	7.10	6.80	7.20	—
DOT-PA01	Dissolved Oxygen	30%	—	20%	—	% sat
PT-H01	Centrifuge Pressure	—	4.5	—	5.5	bar
PT-C01	Column Pressure	—	3.5	—	4.5	bar
TT-F01	Product Temperature	2	8	1	10	°C
TT-U02	WFI Temperature	72	85	70	88	°C
CON-U02	WFI Conductivity	—	1.3	—	1.5	µS/cm

Table 4 — Critical alarm limits. '—' = not applicable. Train B mirrors Train A limits.

End of Document — NVBT-MFG-SPEC-2026-003