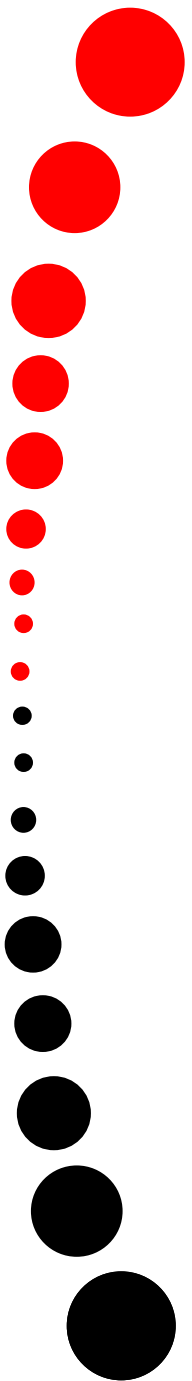




Panacea Technologies

Complete Overview



Topics

- Panacea Introduction
- Accolades
- Capabilities
- Experience Overview
- Demo
- Questions and Discussion

Panacea Technologies Highlights

- Founded in 1996
- Automation Solutions Company
 - Automation and validation services
 - Capabilities ranging from small system upgrades to turnkey solution delivery (\$1K to \$XXM+) and long-term site support
 - Hardware and Software
 - Successful portfolio of products including OpenPWR, OpenBIO, OpenBIO MAX, OpenBIO Lite, OpenBIO Harmonia, Panacea Update Manager, FHX File Viewer etc.
 - Batch Experts with an emphasis on regulated Industries
 - Specialization in solutions for the Pharmaceutical and Biotech Industries
 - Heavily focus on the importance of standards and project design/execution
 - Specialized services for Migration & Modernization BAS, EMS, IT, Gene Therapy/CDMO, Data Integrity initiatives and remediation, and Cyber-Security areas
 - Led the project to develop the largest Biotech facility in the world

Accolades



- Panacea had two engineers named in the Engineering Leaders Under 40 Program in 2017, 2018, 2019, 2020, and 2021.
- Less than forty engineers are named each year, and Panacea was honored to receive two of the nominations each of the last four years
 - Panacea was named Systems Integrator of the year by Control Engineering and Plant Engineering Magazine
 - Panacea was extremely honored by receiving this prestigious award and the endorsement it carries
- OpenBIO received an Innovator Award from Pharmaceutical Manufacturing Magazine in 2018.



Capabilities

- Complete suite of project capabilities including:
 - Feasibility Studies
 - SOP Creation
 - Design Document Authoring
 - Programming and Configuration
 - Hardware Design and Panel Fabrication
 - Testing
 - Validation
 - Startup and Commissioning
 - Long Term Support
 - Project Management
 - Electrical/Mechanical/Calibration Project Management and Installation
- Standalone services including the above items as well as:
 - Automation Network Design
 - Serialization
 - Virtualization
 - Legacy install base evaluations and migrations
 - Automation asset and code management
 - On-site support
 - Data Historization and Reporting
 - Integration with Enterprise Systems (ERP, MES, PLM, etc.)
 - Data Integrity Audits and Remediation Plan Creation/Execution

Validation Documentation for Regulated Industries

Panacea Technologies has generated the following documents for various customers:

- Project Implementation Plans
- Project Validation and Quality Plans
- User Requirement Specifications (URS)
- Functional Requirement Specifications (FRSs)
- Software Design Descriptions(SDSs) or Detail Design Descriptions (DDSs)
- Factory Acceptance Tests (FATs)
- Part 11 compliance tests
- Site Acceptance Tests (SATs)
- Installation Qualifications (IQs)
- Operational Qualifications (OQs)
- Requirements Trace Matrices (RTMs)

Validation Documentation for Regulated Industries

Panacea Technologies has also generated the following SOPs for various customers to execute validated projects and maintain these systems in a validated state

- Incident and Discrepancy Reporting SOPs
- Change Management and Control SOPs
- System Security procedures and SOPs
- Software modification SOPs
- Disaster Recovery SOPs

Platforms and Certifications

Certified Partnerships:

**Rockwell
Automation**



inductive
automation

synTQ
Application Partner

vmware®



 **kepware®**



GE
Intelligent Platforms



THINMANAGER®
A Rockwell Automation Technology



Matrikon®

OPTO 22
Automation made simple.

Expertise with available References:

YOKOGAWA



Honeywell



DELTA V

SIEMENS

Panacea Update Manager

Panacea Technologies recently launched the Panacea Update Manager, which automates the process of patching Operating Systems for Automation Platforms.

Panacea Update Manager works by taking vendor recommended patch definitions from GE, Rockwell Automation/Allen Bradley, Siemens, OSI soft, and Wonderware and ensures only vendor approved Microsoft OS patches are deployed on your networks.

The software ensures your Computer Networks receive the latest OS patches keeping your infrastructure secure, but it also ensures potential downtime events are eliminated by only deploying tested patches.

Visit <https://www.panaceatech.com> for more information.

Industry Recognition

- Featured in more than 30 Industry Publications in the past 3 years

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InTech

OpenBIO Product Family

The OpenBIO Product family is an open platform for modern bioreactor operations. Every member of the OpenBIO family is designed with non-proprietary, readily available hardware components as well as standard accessible software.



Pricing is transparent and available on our website. Together, the platforms are meant to integrate with each other making scale-up operations simpler and empowering users to have longer lifecycles and greater access to support and spare parts.

OpenBIO Product Family

Although each member of the OpenBIO family may contain different components or serve different purposes, they are all built utilizing the same set of standards.



OpenBIO Product Family

- OpenBIO
 - Bioreactor control for up to 250L vessels
 - Fed-batch, perfusion, and various shaker processes
- OpenBIO MAX
 - Bioreactor control for 250L+ vessels
 - Fed-batch, perfusion, and various shaker processes
- OpenBIO Lite
 - Platform for specialized cell processes, or for augmenting existing bioreactor operations
 - Example: Pump Control, DO Control, Capacitance Feedback Control, Low Shear Harvest, etc.
 - Built within the OpenBIO footprint
 - Contains one or several components of the base OpenBIO product
- OpenBIO Mini
 - Small-scale bioreactor control with limited configuration options designed for niche applications
- OpenBIO Harmonia
 - Supervisory software platform for third party bioreactors (example: Sartorius) providing batch, recipe, and formula functionality as well as centralized control and data acquisition for existing controllers and vessels
 - Provides a uniform platform for control of third-party bioreactors with the ability to integrate with any OpenBIO Product Family member

OpenBIO, OpenBIO MAX, and OpenBIO Lite Software Features

- Operation via Recipe & Formulas
- Schedule driven Equipment Modules that kick off from Inoculation
 - Temperature, Agitation, Mass Flow Control
 - pH Control with multiple control strategies
 - Dissolved Oxygen Control with multiple control strategies
 - Automatic Feeds
- Subscribe/Unsubscribe for personalized view and Text Message/Email Alarms Notification
- Flexibility to Change Pump and Scale Identity

OpenBIO, OpenBIO MAX, and OpenBIO Lite Standard Features

- Can do Mammalian (Fed Batch and Perfusion) or Microbial
- Can handle from ~1L to 250L vessels with OpenBIO, 250L+ with OpenBIO MAX
 - Supported Vessels Include; Glass, Disposable, and Rocker
- 2-8 Scales
- 2-8 Front-Mounted Peristaltic Pumps
- 3-6 Mass Flow Controllers with Gas Mixing assembly
- Variable Speed Agitator
- High Accuracy Temperature probe with Heating Blanket
- pH and Dissolved Oxygen Transmitters
- Tablet HMIs (Windows, Android or iOS)

OpenBIO, OpenBIO MAX, and OpenBIO Lite Hardware Features

- Open Hardware Platform built with non-proprietary components stocked locally
 - Available with Ignition, DeltaV, Rockwell Automation, and Opto 22
- Ethernet based architecture extends platform lifecycle allowing for component modernization as well as addition of external ethernet devices (example Raman Spectrometer or specialized peristaltic pump)
- Onsite hybrid-cloud architecture
- Premier integration with PAT platforms such as SynTQ and SIPAT
- Tablet based control
- Customization possible with both the hardware and the software/algorithms
- Designed for ideal functionality from scientists' point of view coupled with ideal standards from a manufacturing point of view

Faceplate and Equipment Module Examples

BRM Agit Equipment Module				
Time Since Inoculation		0 Days 0 Hours	PV	0
Days since Inoculation	Hours since inoculation	Time Shift from Inoculation (Days)	SP (RPM)	Off
0	0.0	06-DEC - 2019 17:32:08	200	<input type="checkbox"/>
1	0.0		250	<input type="checkbox"/>
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
0	0.0			
Alarm Limits		Control Mode: Supervisory EM		
Deviation Limit (RPM)		5.0		
Alarm Enable Time (min)		1.0		

BRM Feed1 Equipment Module									
Page1		Page2		Insert Row		Time Since Inoculation 0 Days 0 Hours			
Days since Inoculation	Hours since inoculation	Time Shift from Inoculation (Days)		Mode	Shots	SP	Units	Ack Req'd	
0	0.0	06-DEC - 2019 17:09:27		Fixed Amount		10.00	g		
0	0.0			NONE					
0	0.0			Fixed Amount					
0	0.0			% of Reactor Glu. Conc.					
0	0.0			Fixed Amount(Split)					
0	0.0			% of Reactor (Split) Glu. Conc. (Split)					
0	0.0			NONE					
0	0.0			NONE					
0	0.0			NONE					
0	0.0			NONE					
0	0.0			NONE					
0	0.0			NONE					
Offset		0.0		Control Mode 1 - Fixed amount based on Feed Scale					
Coarse Speed		500.0 RPM		Start EM		Not Executing		ACT TAR	
Fine Speed Pct		90.0 %		Feed Scale WI-01		2500 g		0 g (0 g)	
Extra Fine Speed Pct		50.0 %		Bioreactor Scale WIC-10		2.50 kg			
Tube		Prime		Jog		Feed Pump PU-01 NOT Running		FWD REV	

Faceplate and Equipment Module Examples

BRM DO Equipment Module														
Time Since Inoculation 0 Days 0 Hours			PV 60.0 %											
Days since Inoculation	Hours since inoculation	Time Shift from Inoculation (Days)	Mode	SP	DO Low	DO High	Agit Min	Agit Max	Air Min	Air Max	O2 Min	O2 Max	Off	
0	0.0	06-DEC - 2019 17:10:52	AG & O2 & Air S2	70.0	0.0	150.0	0	500	0.0	10.0	0.0	15.0	<input type="checkbox"/>	
0	0.0		Air S2											
0	0.0		AG & O2											
0	0.0		AG & Air S1											
0	0.0		AG & Air S2											
0	0.0		O2 & Air S1											
0	0.0		O2 & Air S2											
0	0.0		AG & O2 & Air S1											
0	0.0		AG & O2 & Air S2											
Alarm Limits			Control Mode Agitation, O2, and Air S2						PV		SP			
Low Alarm Enable Time (min)		1.0	Agitator	This EM					0	RPM	30	RPM		
High Alarm Enable Time (min)		1.0	O2 Flow	This EM					0.0	mL/min	6.2	mL/min		
			Air Sparge Flow	This EM S2 (Micro)					0.0	mL/min	10.0	mL/min		

Faceplate and Equipment Module Examples

BRM pH Equipment Module

X

Time Since Inoculation 0 Days 0 Hours

CO2 Base PV -0.50


Days since Inoculation	Hours since inoculation	Time Shift from Inoculation (Days)	Mode	SP Base	SP CO2	Base Min	Base Max	CO2 Min	CO2 Max	Off
0	0.0	06-DEC-2019 17:31:10	Base and CO2 Overlay	6.50	7.40	0	2	0.0	6.0	<input type="checkbox"/>
0	0.0		OFF							
0	0.0		CO2 Overlay							
0	0.0		CO2 S1							
0	0.0		CO2 S2							
0	0.0		Base							
0	0.0		Base and CO2 Overlay							
0	0.0		Base and CO2 S1							
0	0.0		Base and CO2 S2							

Control Mode

5 - CO2 to Overlay and Base

		Alarm Enable Time (min)	Base Scale	999			
Low Deviation Limit	0.00	1.0	Pump Speed	2 RPM	PU-04	Prime <input type="checkbox"/>	Jog <input type="checkbox"/>
High Deviation Limit	0.00	1.0	CO2 Flow	0.0 mLpm			

Setup Screen Example


Login Logout

10011-EWS\ADMINISTRATOR
BRT1000
My Bioreactors Bioreactors Overview Batch View Scan QR Code
06 - Dec - 2019
17 : 34 : 24

Assumed Glucose Feed Concentration (g/L)

204.0

Weighing Scale Selector

Weighing Scale

0

Feed 1

WE-0

1

Feed 2

WE-0

2

Antifoam

WE-0

3

Feed 3

WE-0

3

☒ Default Values for Fed Batch

PU-01

PU-02

PU-03

PU-04

PU-05

PU-06

Pump Selector

Selected Pump

Basal/Inoc/Drain

PU-01

Feed 1

PU-01

Feed 2

PU-02

Antifoam

PU-03

Base

PU-04

Feed 3

PU-05

☐ Default Values for Fed Batch

Reactor Type

Fed Batch

S1 Flow

Micro

S2 Flow

Micro

Unit Parameters

Linear Correlations

pH Bias

Current pH reading

-0.50

Type the pH

0.00

Adjust

Adjusted pH

-0.50

Clear Bias



DeltaV Setup Screen Example

Module: EM_O2
Main: Setup
Username: ADMIN
2:07:42 PM

Pump 5 Controller

EM_FEED5

Agit Mode

Manual SP

UX-002

Linear Tables

SIC-003

Remote

Local

SIC-005

Remote

Local

Feed 4 Visibility

Show Feed 4

Perfusate Flow

Manual SP

FIC-067

Linear Tables

SIC-004

Remote

Local

SIC-006

Remote

Local

Unit Parameters

Pressure HI Range: 140.00 mbar
Pressure ILK1: 30.00 mbar
Pressure ILK2: 30.00 mbar
pH ILK1: 4.00 pH
pH ILK2: 10.00 pH
Wt ILK1: 300 kg
Wt ILK2: 1100 kg
Temp ILK1: 38.0 °C
Temp ILK2: 4.0 °C
Temp ILK3: 60.0 °C

Glucose Data

	FEED 1	FEED 2	FEED 3	FEED 4	FEED 6
Glucose Feed Conc. (g/L)	0.00	0.00	0.00	0.00	0.00
Glucose Feed Density (kg/L)	1.00	1.00	1.00	1.00	1.00
Glucose Sample Conc. (g/L)	10.00				
Brx Density(kg/L)	1.00				

pH Bias

	AE-021A	AE-021B
Raw pH Reading	0.00	0.00
External pH Reading	0.00	Adjust
Adjusted pH	0.00	0.00

Clear Bias

pH Sensor Selection

AE-021A

DO Sensor Selection

AE-022A

AE-022B

0.0 %

AE-022A

0.0 %

Daily Check Trends

Custom Start Time: 8 /23/2019

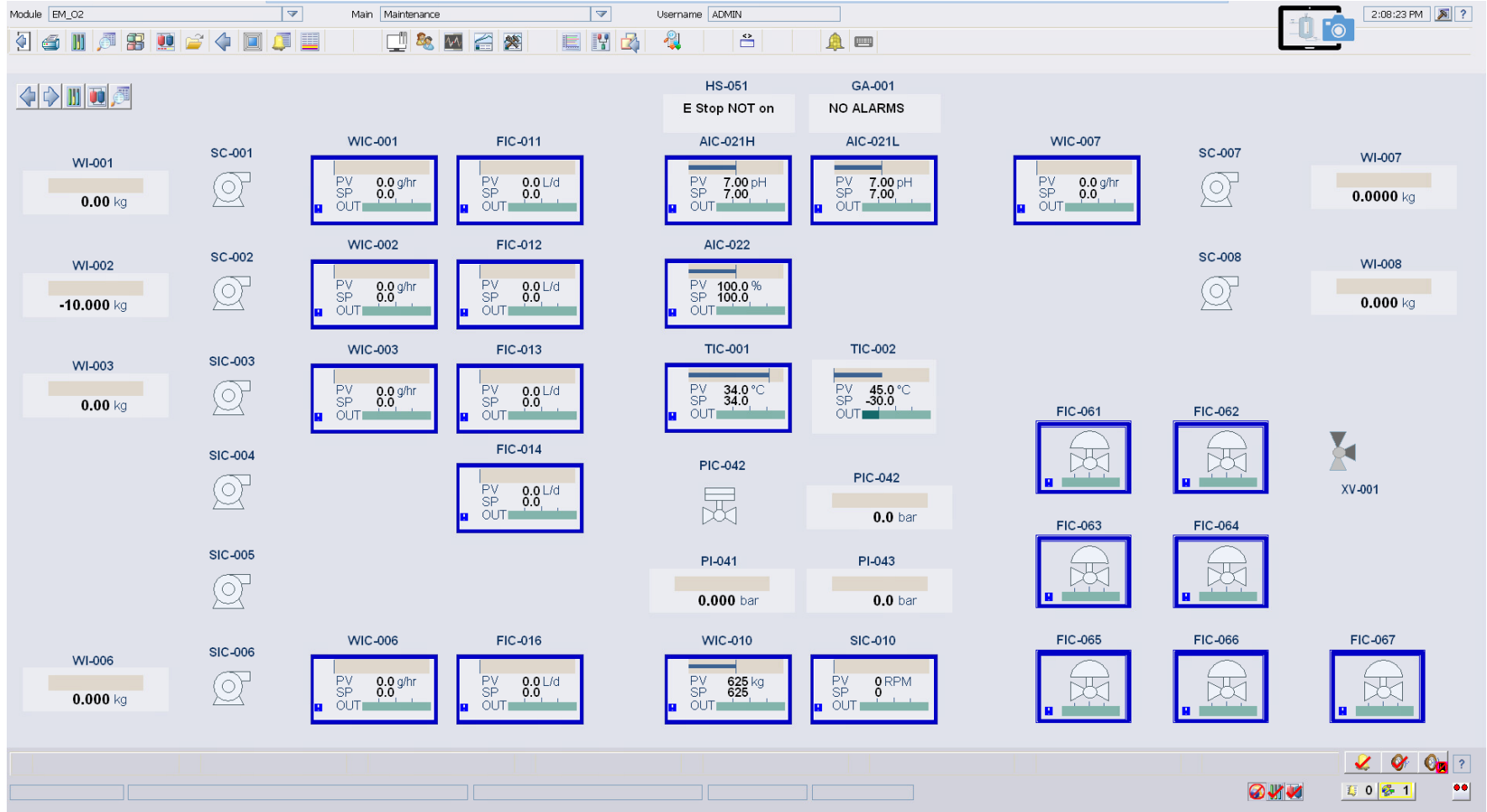
Temp, Press, Wt, Agit	Start Inoc	Custom	Air Micro, Air Macro	Start Inoc	Custom
pH A, pH B, AIC-021H	Start Inoc	Custom	High O2, Low O2	Start Inoc	Custom
DO A, DO B	Start Inoc	Custom	Feed 2 Weight, Feed 1 Flow	Start Inoc	Custom
Antifoam Weight	Start Inoc	Custom			

Batch Trends

Start Date (12 AM): 8 /23/2019
End Date (12 AM): 8 /23/2019

Temperature	Pressure	Brx Weight	Agitation
pH A	pH B	DO A	DO B
Air Micro	Air Macro	High O2	Low O2
Feed 2 Weight	Feed 1 Flow	A Foam Wt	

DeltaV Maintenance Screen Example



Multiple Media, Antifoam Feeds

- Fixed Amount based on Feed Scale
- Fixed Amount based on bioreactor Scale
- Fixed Amount based on % bioreactor Weight
- Targeted Glucose Feed Algorithm
- Above options in Daily Mode
- Custom feed algorithms can be created or copied from existing algorithms
- All feeds and additions can be triggered based on inoculation time

OpenBIO Formula Manager

- Formula manager comes standard with all deployments
- Allows for creation of formulas from master recipes
- Formulas can be locked so they may not be edited
- Multiple formulas can be created with slight edits and then run on multiple bioreactors (example, ten identical formulas run in succession with slight pH shifts)
- Any formula can be run on any bioreactor, and can be transferred to larger scale bioreactors

OpenBIO Formula Manager

[http://10.2.1.98/formulamanager/](#)
Home Page - OpenBIO For...

Panacea Formula Manager
Formulas
Recipes
Enumeration Sets
Configuration
System Logs
I0011-EWSAdministrator

Formulas

Filter by Formula Name

Filter by Recipe Name

		Formula Name	Description	Recipe Name	Validation Status	Commands
1		Fed Batch Training	Water Batches for Fed Batch Control	FED_BATCH	Successful at 1/21/2019 9:11:45 AM ✓	
2		FWG	Click to add a description	FED_BATCH	Successful at 1/21/2019 9:14:48 AM ✓	
3		Master Formula	Master Formula	FED_BATCH	Successful at 1/21/2019 9:11:57 AM ✓	
4		Perfusion Training	Water Batches for Perfusion Control	FED_BATCH	Successful at 1/21/2019 9:11:59 AM ✓	
5		Product A	Production of Product A	FED_BATCH	Successful at 1/21/2019 9:12:00 AM ✓	
6		Product B	Production of Product B	FED_BATCH	Successful at 1/21/2019 9:12:01 AM ✓	
7		Product C	Production of Product C	FED_BATCH	Successful at 1/21/2019 9:12:03 AM ✓	
8		Vaccine A	Production of Vaccine A	FED_BATCH	Successful at 1/21/2019 9:12:04 AM ✓	
9		Vaccine A High DO	Experiment for Vaccine A_high DO	FED_BATCH	Successful at 1/21/2019 9:14:49 AM ✓	
10		Vaccine A High pH	Experiment for Vaccine A_high pH	FED_BATCH	Successful at 1/21/2019 9:12:05 AM ✓	
11		Vaccine A High Temp	Experiment for Vaccine A_high Temp	FED_BATCH	Successful at 1/21/2019 9:14:51 AM ✓	
12		Vaccine A Low DO	Experiment for Vaccine A_low DO	FED_BATCH	Successful at 1/21/2019 9:14:52 AM ✓	
13		Vaccine A Low pH	Experiment for Vaccine A_low pH	FED_BATCH	Successful at 1/21/2019 9:12:06 AM ✓	
14		Vaccine A Low Temp	Experiment for Vaccine A_Low Temp	FED_BATCH	Successful at 1/21/2019 9:14:54 AM ✓	
15		Vaccine A Master Formula	Master Formula to product Vaccine A	FED_BATCH	Successful at 1/21/2019 9:12:07 AM ✓	

OpenBIO Mini

- OpenBIO Mini is currently in development expected to be released in late 2022
- This platform is meant to cover smaller scale operations with less extensive feature requirements
- The platform is less configurable and has a smaller amount of options as compared to the rest of the OpenBIO family
- The platform is meant to compete with similar competitive four pump bioreactors available in the market currently

OpenBIO Lite

- OpenBIO Lite is built with the same hardware and software features of OpenBIO and OpenBIO MAX
- The platform has a similar footprint to OpenBIO
- Contains one or several components of the base OpenBIO product
- OpenBIO Lite is typically deployed to augment existing fermentation operations or to perform a specific task such as:
 - Feeds based on a specific measurement not available on legacy bioreactors
 - Capacitance based feedback control
 - Dissolved Oxygen measurement and Control
 - Scale expansion and additional pump capacity

OpenBIO Harmonia

- OpenBIO Harmonia provides the software features including Batch Control as well as Recipe and Formula Management available in the OpenBIO Product Family for most third-party bioreactors
- In most cases, the HMI functionality and site wide control through tablets is also available depending on the third-party bioreactor vendor and model
- This platform is typically deployed on existing bioreactors or in situations where the functionality of OpenBIO is desired but regulatory filing or other limitations prevent deployment of an OpenBIO controller platform
- OpenBIO Harmonia can be integrated with other OpenBIO product family members