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
    o Capabilities ranging from small system upgrades to turnkey solution delivery ($1K to $XXM+) and long-term site support
  • Hardware and Software
    o 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

  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
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)
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
- Ignition
- Inductive Automation
- synTQ
- VMware
- OSIsoft
- Kepware
- Wonderware
- GE Intelligent Platforms
- THINMANAGER
- Matrikon
- OPTO 22

Expertise with available References:

- Yokogawa
- Honeywell
- DeltaV
- Siemens
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
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

<table>
<thead>
<tr>
<th>Days since inoculation</th>
<th>Hours since inoculation</th>
<th>Time Shift from Inoculation (Days)</th>
<th>SP (RPM)</th>
<th>Off</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.0</td>
<td>06-DEC-2019 17:32:08</td>
<td>200</td>
<td>X</td>
</tr>
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<td>1</td>
<td>0.0</td>
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<td>250</td>
<td></td>
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<td>0</td>
<td>0.0</td>
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<td></td>
<td></td>
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<td>0.0</td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>0.0</td>
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</tr>
<tr>
<td>0</td>
<td>0.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Alarm Limits**

- Deviation Limit (RPM): 5.0
- Alarm Enable Time (min): 1.0

**Control Mode:** Supervisory EM

## BRM Feed1 Equipment Module

<table>
<thead>
<tr>
<th>Days since inoculation</th>
<th>Hours since inoculation</th>
<th>Time Shift from Inoculation (Days)</th>
<th>Mode</th>
<th>Shots</th>
<th>SP</th>
<th>Units</th>
<th>Act Req’d</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.0</td>
<td>06-DEC-2019 17:09:27</td>
<td>Fixed Amount</td>
<td>10.00</td>
<td>g</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Control Mode:** 1 - Fixed amount based on Feed Scale

- Coarse Speed: 500.0 RPM
- Fine Speed Pct: 90.0 %
- Extra Fine Speed Pct: 50.0 %

**Feed Pump:** PU-01, NOT Running
Faceplate and Equipment Module Examples

<table>
<thead>
<tr>
<th>BRM DO Equipment Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Since Inoculation</td>
</tr>
<tr>
<td>Days since inoculation</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>0</td>
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<tr>
<td>0</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alarm Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Alarm Enable Time (min)</td>
</tr>
<tr>
<td>High Alarm Enable Time (min)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control Mode</th>
<th>Agitator</th>
<th>This EM</th>
<th>PV</th>
<th>SP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Sparge Flow</td>
<td>This EM</td>
<td>S2 (Micro)</td>
<td>0.0</td>
<td>mL/min</td>
</tr>
<tr>
<td>This EM</td>
<td>0</td>
<td>RPM</td>
<td>30</td>
<td>RPM</td>
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</table>
Faceplate and Equipment Module Examples

### BRM pH Equipment Module

<table>
<thead>
<tr>
<th>Days since Inoculation</th>
<th>Hours since Inoculation</th>
<th>Time Shift from Inoculation (Days)</th>
<th>Mode</th>
<th>SP Base</th>
<th>SP CO2</th>
<th>Basa Min</th>
<th>Base Max</th>
<th>CO2 Min</th>
<th>CO2 Max</th>
<th>Off</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>05-DEC-2019 17:31:10</td>
<td>Base and CO2 Overlay</td>
<td>6.50</td>
<td>7.40</td>
<td>0</td>
<td>2</td>
<td>0.0</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td>OFF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td>CO2 Overlay</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td>CO2 S1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td>CO2 S2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
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<td></td>
<td>Base</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td><strong>Base and CO2 Overlay</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td><strong>Base and CO2 S1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td></td>
<td><strong>Base and CO2 S2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Control Mode

- 5 - CO2 Overlay and Base

### Alarm Enable Time (min) Base Scale

- Low Deviation Limit: 0.00 1.0
- High Deviation Limit: 0.00 1.0

- Base Scale: Pump Speed 2 RPM 999
- 999: Prime Jog

- CO2 Flow: 0.0 mLpm
Setup Screen Example

- Assumed Glucose Feed Concentration (g/L): 204.0
- Weighing Scale Selector:
  - Feed 1: WE-0 1
  - Feed 2: WE-0 2
  - Antifoam: WE-0 3
  - Feed 3: WE-0 3
- Pump Selector:
  - Basal/Inoc. Drain: PU-01
  - Feed 1: PU-01
  - Feed 2: PU-02
  - Antifoam: PU-03
  - Base: PU-04
  - Feed 3: PU-05
- Reactor Type:
  - Fed Batch
  - Micro
- pH Bias:
  - Current pH reading: -0.50
  - Type the pH: 0.00
  - Adjusted pH: -0.50
  - Default Values for Fed Batch
DeltaV Reactor Screen Example
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

#### Formulas

<table>
<thead>
<tr>
<th>#</th>
<th>Formula Name</th>
<th>Description</th>
<th>Recipe Name</th>
<th>Validation Status</th>
<th>Commands</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fed Batch Training</td>
<td>Water Batches for Fed Batch Control</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:11:45 AM</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>FOG</td>
<td>Click to add a description</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:14:46 AM</td>
<td></td>
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<tr>
<td>3</td>
<td>Master Formula</td>
<td>Master Formula</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:11:57 AM</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Perfusion Training</td>
<td>Water Batches for Perfusion Control</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:11:59 AM</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Product A</td>
<td>Production of Product A</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:00 AM</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Product B</td>
<td>Production of Product B</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:01 AM</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Product C</td>
<td>Production of Product C</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:03 AM</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Vaccine A</td>
<td>Production of Vaccine A</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:04 AM</td>
<td></td>
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<tr>
<td>9</td>
<td>Vaccine A High DG</td>
<td>Experiment for Vaccine A, high DG</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:14:49 AM</td>
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<tr>
<td>10</td>
<td>Vaccine A High pH</td>
<td>Experiment for Vaccine A, high pH</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:05 AM</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Vaccine A High Temp</td>
<td>Experiment for Vaccine A, high Temp</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:14:51 AM</td>
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<tr>
<td>12</td>
<td>Vaccine A Low DG</td>
<td>Experiment for Vaccine A, low DG</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:14:53 AM</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Vaccine A Low pH</td>
<td>Experiment for Vaccine A, low pH</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:06 AM</td>
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</tr>
<tr>
<td>14</td>
<td>Vaccine A Low Temp</td>
<td>Experiment for Vaccine A, Low Temp</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:14:54 AM</td>
<td></td>
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<tr>
<td>15</td>
<td>Vaccine A Master Formula</td>
<td>Master Formula to product Vaccine A</td>
<td>FED BATCH</td>
<td>Successful at 1/21/2019 9:12:07 AM</td>
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</tbody>
</table>
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.