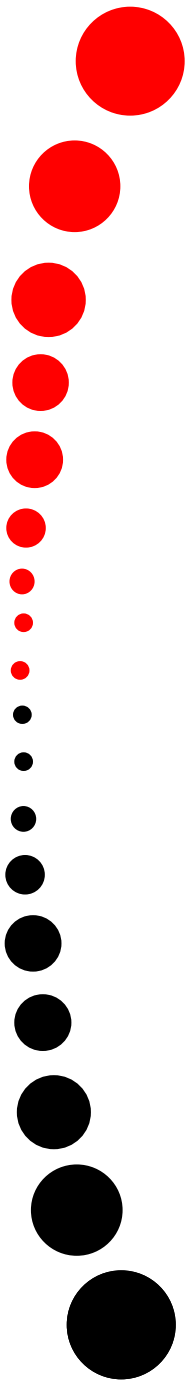




# Panacea Technologies

## Company Overview



# Topics

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- Panacea Introduction
- Accolades
- Capabilities
- Gene Therapy/CDMO Experience
- OpenBIO Overview

# Panacea Technologies Highlights

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- Founded in 1996
- Automation Solutions Company
  - Automation and validation services
    - Capabilities ranging from small system upgrades to turnkey solution delivery (\$1K to \$20M+) 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 Modernization & Migration, BAS, EMS, IT, Gene Therapy/CDMO, and Cyber-Security areas
  - Led the project to develop the largest Biotech facility in the world

## Accolades

engineering  
**leaders  
<40**

- 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

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- Complete suite of project capabilities including:
  - Feasibility Studies
  - SOP Creation
  - Design Document Authoring
  - Programming and Configuration
  - Hardware Design and Panel Fabrication (with partner)
  - Testing
  - Validation
  - Startup and Commissioning
  - Long Term Support
  - Project Management
- 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.)

# Validation Documentation for Regulated Industries

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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

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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**



**SIEMENS**



# Gene Therapy Experience

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- Our experience with gene therapy began with existing Pharma/Biotech clients that began to pursue cell lines and treatments relying on Gene Therapy
  - We were tasked with developing flexible process areas that could be rearranged during trial manufacturing and testing
  - This presented several challenges with data streams, reporting, and data availability as there were more cross functional stakeholders concerned with the data
  - We also had to make the manufacturing areas flexible as the treatments developed or were found to be affective for other diseases
- This experience led us to gene therapy focused companies as we brought our experience with manufacturers to the demanding and competitive gene therapy space
  - Our project scopes have ranged from multiple greenfield plant deployments to projects focusing on specific aspects of facility development or data layer creation.
    - Many projects started as FEED studies to put in an agnostic data layer to connect various pieces of equipment to have a unified source of data for reporting as well as a single visualization and control layer
    - They later expanded to include BAS/EMS and OpenBIO deployments along with typical System Integration services
    - Alternatively, we have held the entire deployment scope from project kickoff including electrical, mechanical, and calibration
- We have completed more than a dozen Gene Therapy/CDMO Greenfield and Brownfield projects in the past three years, most of which were won through word of mouth for successful projects.

# Gene Therapy Experience

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- We have held an edge in this Industry because of our previous project experience and Innovation focus
- Helping clients as they move cell lines and drug products through the different phases towards full scale manufacturing has helped us streamline the process to get there which has proved instrumental in helping gene therapy companies get from idea to patient in an effective, timely, and compliant manner
- Our focus on innovation has allowed us to bring cutting edge but proven technologies and methods into a space that relies on it for progress
- Gene therapy companies often like to have data available to everyone from the front-line scientist to the CEO, and we have been able to deliver that data, contextualized for the recipient, in many different forms including mobile
- Our ability to tie together multiple different equipment and software platforms as well as various data lakes and databases into a cohesive data stream and workflow has led to a great deal of additional business by word of mouth
- We provide IT services and lab equipment as well which has allowed us to sit at the table with automation, IT, scientists, and executive stakeholders and translate initiatives and goals to each group
- Recently we have helped gene therapy companies expand into the CDMO space as well for additional revenue streams
- All of our projects included equipment evaluation, integration, and stick-built projects (autoclaves, Utilities, Incubators, Freezers, Bioreactors, Filtration, etc.)

# 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

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- 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

# Panacea Update Manager

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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

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

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