mPath™ Link

SCADA PLATFORM

The mPath Link platform is a comprehensive supervisory control and data acquisition (SCADA) platform, designed to accelerate go-to-market strategies by enabling real-time monitoring, efficient process control, and rapid issue resolution. With our optimized production performance, reduced downtime, and enhanced decision-making, your business can adapt quickly to market demands and deliver products faster.

As our industry has shifted towards more flexible, scalable, efficient, and configurable automated systems, having access to a reliable, reproducible SCADA platform has become more important than ever.

System overview

The mPath Link platform is designed to scale up from the lab environment to cGMP manufacturing. The system allows you to write recipes in one common, central location while maintaining a state of control in accordance with cGMP requirements.

The mPath Link platform automation ecosystem supports our genomic product lines, including iCELLis™ Nano bioreactor, iCELLis 50 bioreactor and LevMixer™ 10 L single-use mixing system. The software is designed to help operators and supervisors get an overview of integrated systems with an operator centric view.

The mPath Link platform offers the following benefits:

- Automated:
  – Data acquisition and storage
  – Supervisory control
  – Process value alarms
  – Recipe management
  – System event monitoring
  – Configuration management
  – Standard reporting
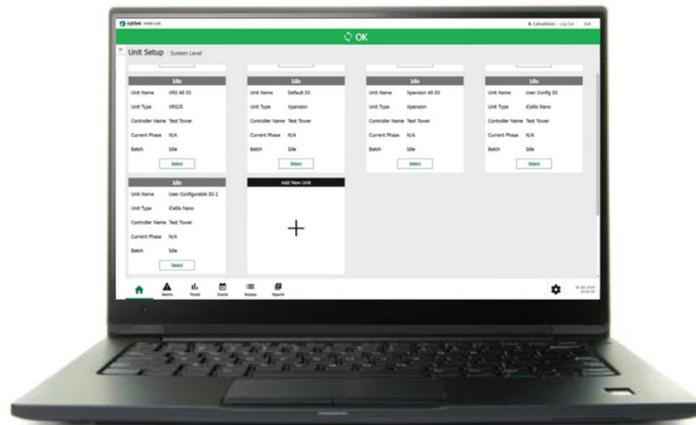 – Real-time and historical trending/charting

Fig 1. General overview of the mPath Link software.

- A user-oriented approach:
  – Operator-centric view for a quick and easy overview of ongoing operations
  – Predefined roles (e.g., administration, operator, supervisor, services)
  – Ability to connect to domain controller
  – Optimized for PC, tablet and mobile
  – Easy and efficient navigation
  – Easy equipment integration and recipe orchestration
- Compatible virtual environments.
- Representational state transfer application programming interface (REST API) for communication.
- Data integrity prioritization and instant access to audit trails
- Compliance to 21 CFR Part 11, EudraLex Chapter 4 Annex 11, and GAMP 5 standard. Meets regulatory requirements after implementation of required toolsets.

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Workflow

The mPath Link server workflow is a SCADA ecosystem that promotes the overall shortening of time to market for new biotech therapies or drugs.

The home dashboard provides high-level supervision through a centralized view of all connected equipment.
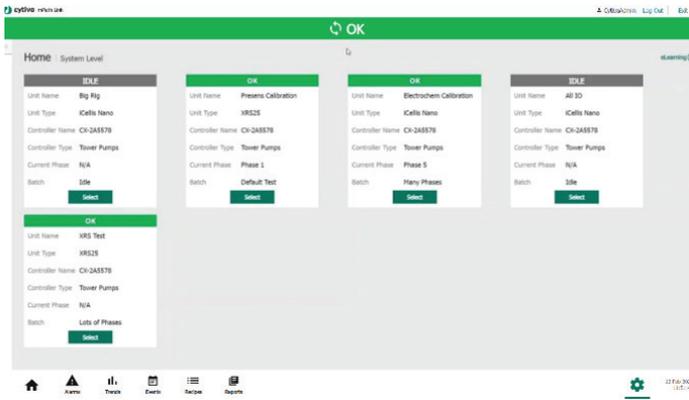

Fig 2. Systems level home screen.

When more information is required, you can access detailed dashboards for your configured equipment. Depending on preference, two options are available for graphical representation: piping and instrumentation diagram (P&ID) or tabular view. These screens are designed to enhance operational efficiency and increase process awareness.
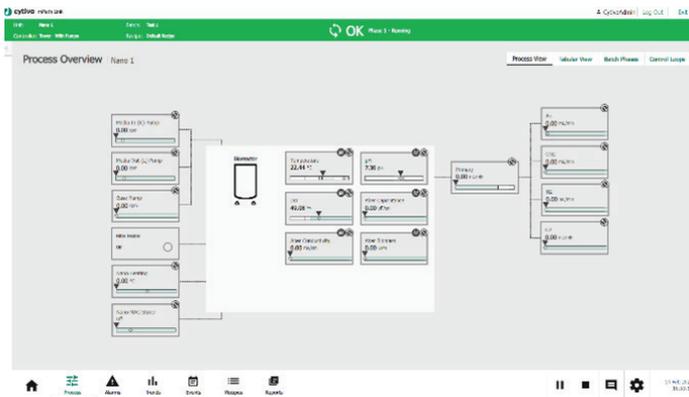

Fig 3. Process view.

The mPath Link platform has a built-in, easy-to-use alarm system. These screens are designed to enhance situational awareness, reduce response times, and improve overall system efficiency and safety.
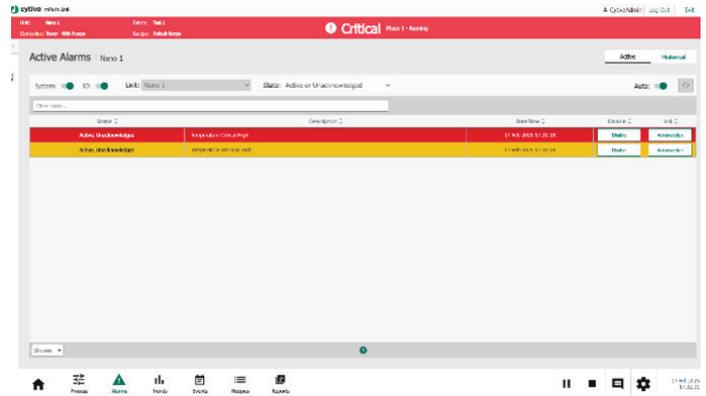

Fig 4. Alarms screen with active alarms in red and active warnings in yellow.

Event, audit trail, and reporting screens provide a comprehensive log of system activities and operator actions. The events screen, for example, helps your organization meet regulatory requirements while maintaining compliance with industry standards.
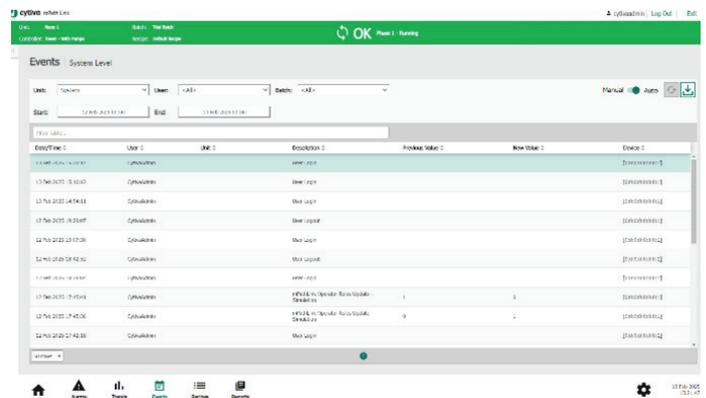

Fig 5. Events screen with generated batch report.

The mPath Link platform sends real-time, remote alarm notifications, so you can stay informed about important updates and changes to your process no matter where you are.
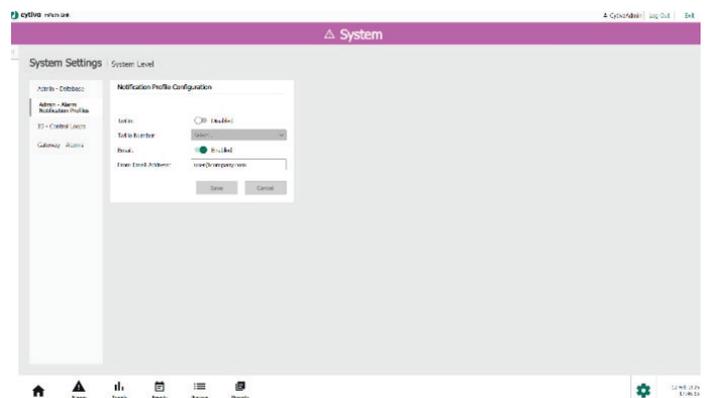

Fig 6. Example of remote notification.

Real-time and historical trending screens help you visualize and analyze process data, bolstering operational efficiency, reliability and quality, and supporting internal decision making.
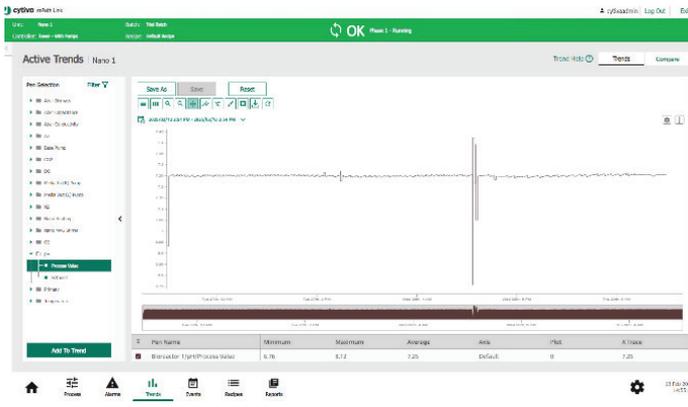

Fig 7. Trending screen to display real-time or historical trends.

The mPath Link platform gives you the means to compare recipes between batches for further insight into your process development. For improved quality and increased process awareness, use the batch comparison tool to compare your validated and production batches.
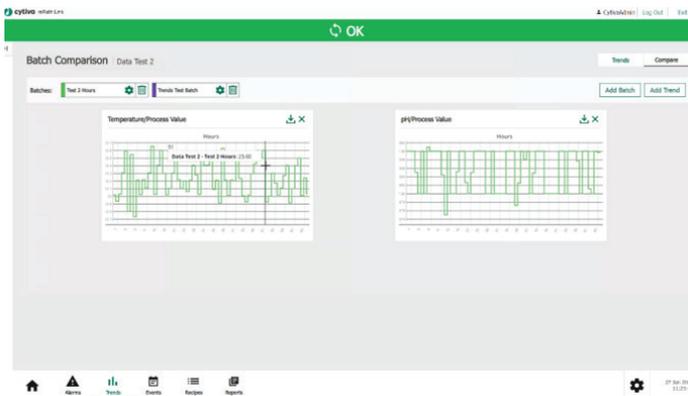

Fig 8. Compare tool for recipe or batches.

Cytiva supplies predefined equipment templates to save you time on the set up and configuration of your process environment. Our plug-and-play experience requires minimal integration and re-validation.
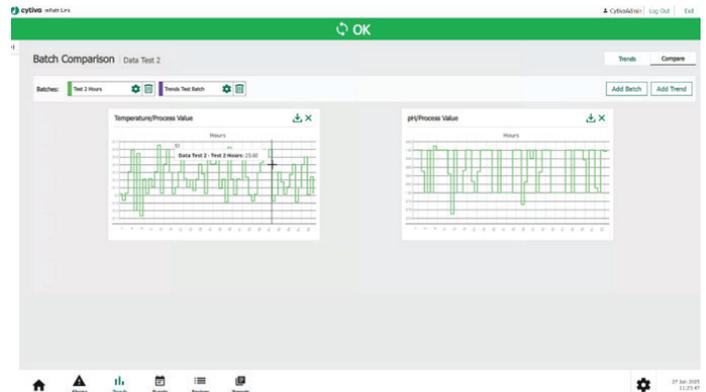

Fig 9. Setting up new controller.

Our built-in, user-friendly recipe tool maintains interface flexibility, version control and simplicity. The recipe editor module allows you to both create or adjust recipes and use a previous recipe as a template to reduce or iterate your recipe instructions.
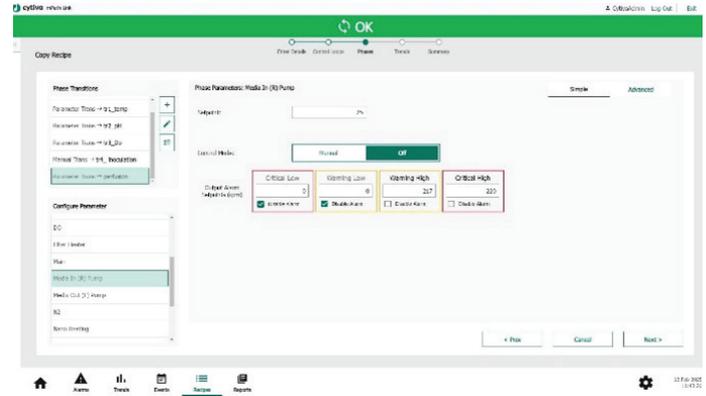

Fig 10. Controller setup windows with configurable controller templates.

The recipe scheduler is a crucial feature to streamline and automate the management of your experiments or production processes. This screen allows you to efficiently schedule, monitor, and control recipe execution for the optimal performance and consistency of your operations.
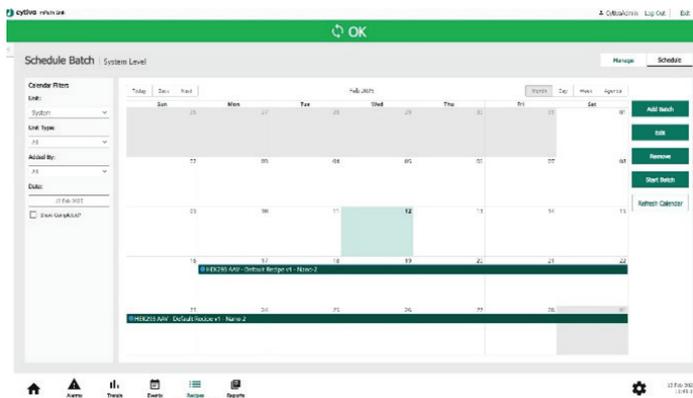

Fig 11. Batch or recipe scheduling.

For additional support, a built-in link gives you access to E-learning modules. You can access datafiles and training videos we've provided or even upload PDFs of your own standard operating procedures (SOPs). Cytiva also offers a subscription-based online training platform.
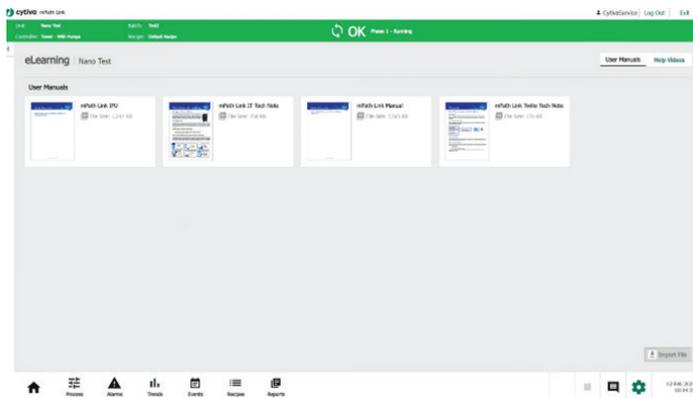

Fig 12. E-learning platform providing information on how to use the system.

Compliance

The mPath Link platform is designed to operate in a process development or GMP compliant environment.

The software captures all data needed for audit purposes, facilitating the review process for regulated companies while complying with all data integrity requirements issued by the FDA[1], MHRA[2] and EMA[3]. The mPath Link platform fulfils attributable, legible, contemporaneous, original and accurate (ALCOA+) principles for good data management and data integrity within the pharmaceutical and biotechnology industries.

1. Food and Drug Administration (US based)
2. Medicines and Healthcare products Regulatory Agency (UK based)
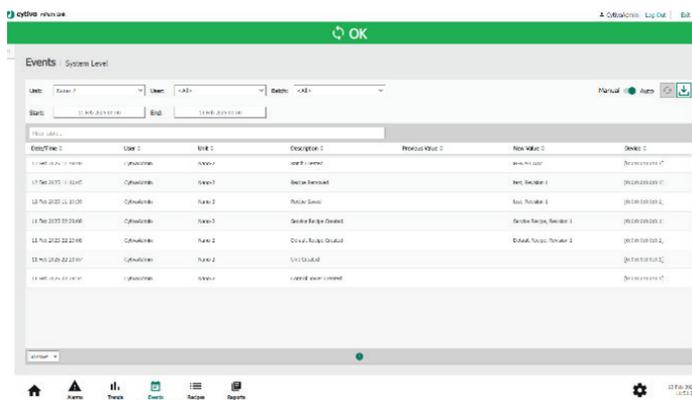3. European Medicines Agency (EU based)

Fig 13. Event screen containing event data.

System architecture

The mPath Link platform utilizes client-server architecture.

The application clients are installed on Windows, MacOS or Linux based systems and connected to the same network as the server.
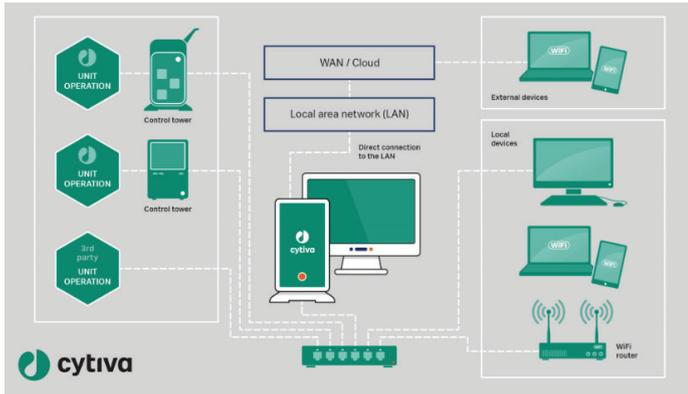

Fig 14. System architecture overview.

The mPath Link server supports both standalone and connection to an active directory. By default, the software is supplied in its standalone configuration. In its active domain directory configuration, the mPath Link server can be used in a local or the domain infrastructure. The mPath Link server includes multiple connections which are available on the local area network and their devices.

Technical specifications

Software/process specifications

Equipment	Specification
Functionality	Control multiple units through one system Recipe management PC, tablet and mobile compatible
Optional functionality	Remote alarm notifications
Configurations	Server installation and configuration Client installation

Minimum system specifications

mPath Link software

System	Specification
Operating system	Microsoft Windows 10 or higher
Processor (CPU)	4 Cores
Memory	16 GB RAM
Storage requirement	100 GB
SCADA software	Ignition Perspective License Ignition OPC UA Server Module Ignition Tag Historian License
SQL server	Microsoft SQL Server 2019 Standard

Recommended system specifications

mPath Link software

System	Specification
Operating system	Microsoft 10 IoT Ent 2019 LTSC or higher
Processor (CPU)	4 Cores
Memory	16 GB RAM
Storage requirement	500 GB
SCADA software	Ignition Perspective License Ignition OPC UA Server Module Ignition Tag Historian License
SQL server	Microsoft SQL Server 2019 Standard

mPath Link server minimum hardware specifications

Server

System	Specification
System	Specification
Operating system	Microsoft 10 IoT Ent 2019 LTSC
Processor (CPU)	4 Cores
Memory	16 GB RAM
Hardware	500 GB or higher
Ethernet port(s)	2 × Gigabit LAN

Compatible equipment

See our **website** for up to date list of equipment compatible with mPath Link software.

Ordering information

The standard mPath Link solution package includes the mPath Link SCADA software installed on an mPath Link server.

It is also feasible to install the software in a virtual environment and connect to the devices via your network infrastructure. The verification and installation must be done by Cytiva service personnel. Additional services for the equipment can be ordered for installation verification (IV) and operation verification (OV). Please consult the data sheets of the compatible equipment for these part numbers.

mPath Link platform with server

Description	Product code
3rd generation mPath Link server and SCADA — full version	MPATHLINKV3
3rd generation mPath Link server and SCADA — lite version	MPATHLINKV3-LT

mPath Link platform with software only

Description	Product code
3rd generation mPath Link SCADA (software only) — full version	MPATHLINKV3-S
3rd generation mPath Link SCADA (software only) — lite version	MPATHLINKV3-S-LT

mPath Link HMI for single LevMixer system

Description	Product code
3rd generation mPath Link HMI for LevMixer 10 L single-use mixing system	MPATHLINKV3-LEV

mPath Link HMI for single LevMixer system with software only

Description	Product code
3rd generation mPath Link HMI for LevMixer 10 L single-use mixing system (software only)	MPATHLINKV3-S-LEV

Services and accessories

Description	Specification
Upgrade to 3rd generation mPath Link software — full version	MPATHLINKV3-U
Upgrade to 3rd generation mPath Link software — lite version	MPATHLINKV3-U–LT
mPath link server hardware (spare part)	KMPATHLINK-PC

Note: The mPath Link server is pre-installed within the iCELLis or Allegro systems or can be installed on a virtualized server via aftersales. If the mPath Link platform is required as software only, the installation and configuration will require assistance from Cytiva service personnel.

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