Figurate™ automation powered by PlantPAx® DCS

FLEXFACTORY™ SINGLE-USE BIOMANUFACTURING PLATFORM

The Cytiva Figurate™ automation framework with the Rockwell Automation PlantPAx® distributed control system (DCS) provides coordinated control and monitoring for the FlexFactory™ single-use biomanufacturing solution. Integrating Cytiva equipment with the PlantPAx® system to control individual systems and processes, the Figurate™ automation platform provides coordinated control to optimize processes across the entire biomanufacturing chain.

The PlantPAx® DCS implements the control and management of flexible processes, variable batch sizes and production locations on the Cytiva FlexFactory™ manufacturing platform. With agile, platform-based automation, you can rapidly adjust capacity across facilities and sites. Figurate™ automated single-use facilities reduce paper, facilitate investigations, and enable faster changeovers while maintaining safety and regulatory compliance, with additional staff utilization benefits. A Cytiva FlexFactory™ single-use processing platform with Figurate™ automation powered by PlantPAx® DCS is the optimal solution for startup to large-scale biomanufacturers who wish to initiate or expand manufacturing capacity quickly and cost-effectively.

Cytiva's Figurate™ automation framework enables rapid, pre-tested and pre-verified integration of automation platforms within the FlexFactory™ biomanufacturing platform. PlantPAx® DCS offered within the Figurate™ framework is a pre-configured integrated automation solution for FlexFactory™ biomanufacturing implementations. A solution for cost-conscious or startup biomanufacturers who do not currently have automation in place, PlantPAx® DCS helps such users realize the efficiencies and flexibility of an automation solution that can be scaled up to meet future operational requirements.

The Figurate™ automation framework integrates all hardware and software that controls and coordinates the biomanufacturing systems and functions, as well as data flows throughout the FlexFactory™ bioprocessing line. Our Figurate™ automation solutions are pre-designed and pre-verified, delivering pre-configured automation solutions for all supported Cytiva bioprocessing equipment. We have designed the bioprocessing equipment with common requirements across the platforms, ensuring consistent functional specifications and process operations. This design streamlines tech transfer and scale changes across platforms. Adhering to this design principle allows for similarity where it is needed and platform dependencies where required.

Fig 1. Designed for single unit, multiple units or a fully integrated facility with Rockwell automation's modern DCS platform, PlantPAx®.

Standardization drives speed, reduces expense and human error

By utilizing pre-configured and pre-verified equipment, software and integration libraries, the FlexFactory™ biomanufacturing platform provides access to cGMP biomanufacturing capacity much faster than traditional integrators, and helps lower project and product risk. Standardized configuration libraries are available for all units on the list of qualified equipment.

- Standardizing unit types and plug-and-play libraries within a facility creates flexibility to rapidly scale up, scale out or transfer production capacity.
- Use of standard communication protocols and networks reduces time to implement, document, test, and validate.
- Consistent user interfaces help reduce human error, training time and operator expense if all platforms look and feel the same.
- Standardized data interfaces permit flexible implementation of manufacturing execution system (MES) and other level 3 applications.

FlexFactory™ configurable manufacturing platform automation infrastructure

All process equipment is managed by the Figurate™ automation platform that includes control, data acquisition and storage, centralized user management, reporting, common human-machine interface (HMI), recipe creation and execution, and report generation.

The automation infrastructure includes the hardware and software required to run the biomanufacturing production line, designed to meet the high availability demands and data integrity requirements of all phases and commercial operations of biologics manufacturing. The standard configuration offers a cost-effective solution that can quickly and easily scale up, scale out and transition to new products.

The Figurate™ automation platform with PlantPAx® DCS includes the human-machine interface (HMI), Historian and data connectors necessary to provide a complete centralized automation solution. The Rockwell-controlled units are integrated under the FactoryTalk® View software HMI. UNICORN™ software provides unit-level control for ÄKTA™ and WAVE™ 25 systems. Redundancy is available within the automation architecture to mitigate the risk of losing the process or data in the event of server failures.

Optimize operational efficiency with robust automation

The Figurate™ automation platform powered by PlantPAx® DCS provides FlexFactory™ biomanufacturing the ability to optimize operational efficiency across the biomanufacturing process, from unit-level monitoring and control, through reporting, security and safety.

- Recipes and batch control
- Data connectivity
- Data historian
- Reporting
- Human-machine interface (HMI)
- Centralized user and account administration
- Alarms and events
- Cybersecurity

Recipes and batch control

Recipes provide the master bioprocessing instructions, which are implemented for each batch through batch control. The Figurate™ automation platform powered by PlantPAx® DCS utilizes both FactoryTalk® Batch and UNICORN™ software to create and manage recipes and batches for the control of unit operations. Unit operations controlled by FactoryTalk® Batch are implemented according to ANSI/ISA-88 guidelines. The FactoryTalk® Batch execution engine and UNICORN™ functions are accessed seamlessly through the HMI. The features include:

- Create, edit, modify, or delete a recipe or method
- Schedule, initialize and execute a batch, operation or method

As part of our comprehensive services, we can work with you to create and configure your recipe within the Figurate™ automation platform.

You can also manage individual unit operations via the HMI through individual loop control or Equipment Manager without a full recipe.

Data connectivity

The Figurate™ automation platform powered by PlantPAx® DCS utilizes industry standards-based architecture to enable integration with applications such as enterprise historians, MES, LIMS, and ERP systems.

The platform provides the necessary data flows and connectivity between units, skids, and servers via Ethernet/IP™, Ethernet and OPC DA/UA protocols. The system is configured to ensure the security and reliability of the data transfer and storage.

Data historian

The role of the historian is to aggregate and store time series data from all units and operations, providing an auditable, tamper-proof record of all batches that is 21 CFR part 11 compliant. The PlantPAx® DCS stores all batch-historical data for use in reporting, including time-stamped batch events such as start, hold, restart, abort, and operator interaction such as prompting and recipe parameter changes. The data is accessed by the reporting software, Microsoft® SSRS, for report generation. Centralized electronic data can streamline quality investigations and regulatory submissions.

Reporting

A robust reporting function is essential in a regulated manufacturing environment.

The Figurate™ automation platform powered by PlantPAx® DCS™ utilizes Microsoft® SQL Server Reporting Services (SSRS), a powerful, flexible reporting package widely used in industrial environments. SSRS connects directly to the PlantPAx® DCS historical data and central UNICORN™ database. You can configure reports for different types of users, allowing operators, supervisors, and managers to access the information that is relevant to their roles. Sample reports are provided to guide report configuration.

The reports generated by SSRS support manufacturing in a regulated environment, documenting the validated audit trail for each batch and process. Integration and verification of the reporting software with the automation platform reduces the opportunity for user errors in data handling.

Human-machine interface (HMI)

The HMI is the central point of operator interaction for the overall FlexFactory™ implementation. Each HMI allows an operator to monitor and control all individual unit operations by providing a window into the process through a common user interface. Operators can access all FlexFactory™ platform automation features, including unit operations systems and historical data in the form of trends and reports. The level and type of access for individual operators is secured through role-based user accounts.

Users can access units controlled by PlantPAx® DCS through the HMI. In addition, user interfaces for all key system components, for example UNICORN™ My Instruments and SSRS, are accessed through a web browser.

Centralized user and account administration

User accounts are administered through the PlantPAx® DCS leveraging Windows Active Directory. With centralized user and account administration, each user needs only one login to access the network according to their level and type of access. Windows security ensures traceability to user interactions and a familiar management interface.

Alarms

Alarms notify the operator of abnormal situations that require timely action, directing operator attention so they can take corrective action and prevent an undesired consequence. The operator is the focal point of the alarm system.

As an option, we can provide PI Notification, which enables alarm notification outside the FlexFactory™ platform to users within the wider corporate network. PI Notification is an optional software component of the FactoryTalk® Historian. It requires the use of an Industrial Demilitarized Zone (iDMZ) to safely allow the FlexFactory™ platform to pass data to the wider corporate network.

PlantPAx® DCS uses a tiered approach to classify process or equipment failures. Personnel safety is the highest tier of failure handling and alarming. Other alarms are designed to protect the equipment and process. You can configure process alarms to notify operators of process excursions or failures relevant to their process.

Interlocks

At the highest level, where personal or machine safety is a concern, interlocks are used to protect people, equipment, and the facility for each unit operation within the FlexFactory™ platform. The design of interlocks minimizes the opportunity for unintended change to interlock trip points, logic, or status. A unified approach to interlock configuration, monitoring, and response enables consistent and effective interlock implementations within the FlexFactory™ single-use manufacturing line. This also promotes understanding of and response to interlocks by operators and engineers working with the equipment.

E-stop: safety first

All FlexFactory™ unit operations include emergency stop (E-stop) push buttons for personnel safety. E-stop interlocks are hard wired to shut down the equipment immediately upon activation of an E-stop push button. The E-stop push buttons operate independently of any logic in the automation configuration. E-stop push buttons are monitored, and the automation will alarm and force setpoints and batch logic to safe states when an E-stop push button is activated.

Cybersecurity

PlantPAx® DCS is ICS designed from the start with cybersecurity in mind. Standard implementation of automation for FlexFactory™ bioprocessing is self-contained, and isolated from corporate and external networks. However, you may want to be able to send remote alerts or other information via corporate networks external to the FlexFactory™ network. As a custom option, we can support you in specifying and implementing the required capabilities, such as remote alarm alerts and IDMZ, the foundation for sound remote connectivity.

Automation enables and optimizes flexible biomanufacturing

Integrated automation in the Cytiva FlexFactory™ single-use bioprocessing platform delivers powerful benefits to biologics manufacturers.

- Supports increased efficiency and reduced operating costs.
- Provides control and consistency that is critical in a heavily regulated environment.
- Simplifies batch documentation and compliance reporting.
- Offers process transparency, minimizing operational and financial risks.
- Streamlines the time and effort required to implement a new process, enabling flexible capacity with high utilization.
- Enables scale- up and scale- out flexibility.

A FlexFactory™ platform with PlantPAx® DCS is pre-configured and verified to enable rapid integration and efficient manufacturing of biopharmaceuticals. The Figurate™ automation platform facilitates the flexible, configurable and scalable FlexFactory™ biomanufacturing solution.

Fig 2. Figurate automation combines automation, IT and single-use solution expertise to build bioprocessing operations for the digital age.

Included hardware and software

Automation software	• Microsoft® Windows® Server 2019 • Microsoft® Hypervisor virtualization infrastructure • Rockwell Automation PlantPAx® process objects library 4.10.X • FactoryTalk® View Site Edition • FactoryTalk® Batch • FactoryTalk® Historian Site Edition • FactoryTalk® Linx for communications gateway • PlantPAx SequenceManager™ • Microsoft® SQL Server Reporting Services (SSRS) • ThinManager® thin client management software

Server infrastructure	• Stratus™ zTC™ Edge or FT-Server, fault tolerant depending on configuration
	• The number and type of virtual images loaded on the host are determined by configuration
	• The main functions of the servers in the rack are:
	  • Store UNICORN™ and PlantPAx® data in databases supporting compliance with 21 CFR Part 11 and EU Annex 11
	  • Provide mobile workstations with screen images that display processes via Rockwell Automation ThinManager® thin client management software
	  • Communicate with the PlantPAx® DCS and UNICORN™ controlled units
	  • Control automation domain
	  • Verify security level associated with user account
	  • Permit administration
	  • Administrator's console with Keyboard-Video-Mouse (KVM)
	  • Optional Uninterruptible Power (UPS) and Power Distribution (PDU)

Network infrastructure	• Cisco Catalyst™ and Allen-Bradley® Stratix® Ethernet switches • Palo Alto Firewall • Ethernet wiring
Operator interface infrastructure	• HMI Human-machine interface (HMI), mobile operator interface terminals (OITs) running Rockwell Automation ThinManager® thin client management software
Control and IO Infrastructure	• Allen-Bradley® programmable automation controllers (PAC) deployed for each unit operation that is coordinated by PlantPAx® DCS • UNICORN™ software providing control and HMI for the UNICORN™ controlled devices
Control network infrastructure	• Ethernet switches and routers
Additional software	• Optional PI Notifications: Remote alarm notification • Optional OPC DA/UA connectivity: Connect automation platform to third-party equipment or enterprise systems
Additional infrastructure	• Optional configurable iDMZ supporting secure connection from FlexFactory™ to external corporate networks. Can support functions such as connections to Enterprise PI, corporate email servers, backup, and patch management
Exclusions	• Third-party equipment that is not listed above may be integrated to the automation platform as a customization. • The Figurate™ automation framework is available only with the FlexFactory™ bioprocessing platform and cannot be purchased separately

Ordering information

Contact your Cytiva representative

cytiva.com/FigurateAutomation

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