

FlexFactory Automation

AUTOMATION SOFTWARE

FlexFactory™ Automation is developed and verified to enable efficient design of facilities for development and manufacturing of biopharmaceuticals (Fig 1). This automation platform is the foundation of the flexible, configurable, and scalable FlexFactory biomanufacturing solution. The FlexFactory biomanufacturing solution can be delivered as either an integral part of the prefabricated KUBio™ biomanufacturing facility or installed and qualified in your own manufacturing environment. To enable compliance with regulatory requirements, FlexFactory Automation is designed according to GAMP™ 5 guidelines (ISPE).

Reduce risks in manufacturing with FlexFactory Automation:

- Unifies development activities to accelerate commercialization
- Supports increased efficiency and reduced operating costs
- Offers process transparency, minimizing operational and financial risks

FlexFactory Automation overview

Design space

FlexFactory Automation is based on a verified design space concept, enabling full flexibility within an already optimized range of process parameters. The design space principle provides configurability and flexibility in biomanufacturing. Process hardware required for production are included in the design space and preconfigured with the software. Included hardware units are scalable based on both size and number (Fig 2).

Streamlined route to obtain and maintain a validated state

Process automation is imperative when operating in a lean manufacturing plant from both efficacy and quality perspectives. Your integrated automation process should be flexible and adapt to your evolving business requirements.

FlexFactory Automation is designed for efficient integration of your current process and can be adapted to your changing needs. The software platform lets you configure and control your process via



Fig 1. FlexFactory Automation software.

batch operations and recipes. FlexFactory Automation includes integrated real-time monitoring and reporting tools that provide full visibility into your production and its performance.

Independent of scale

FlexFactory Automation is independent of process scale. Any standardized process, from 2 × 200 L to 4 × 2000 L scale can be configured on the software platform. As a consequence, efforts to reconfigure the equipment for future scale-up of production volumes are substantially reduced with FlexFactory Automation.

Data integrity

FlexFactory Automation enables compliance with 21 CFR part 11 and EU Annex 11. The software platform supports full data integrity and consistency throughout your process, enabling a digitized and validated manufacturing process. Process data is reliably stored in a database repository. For access control, the software is secured by password-protected user login. User activities are logged in audit trails for usage history.

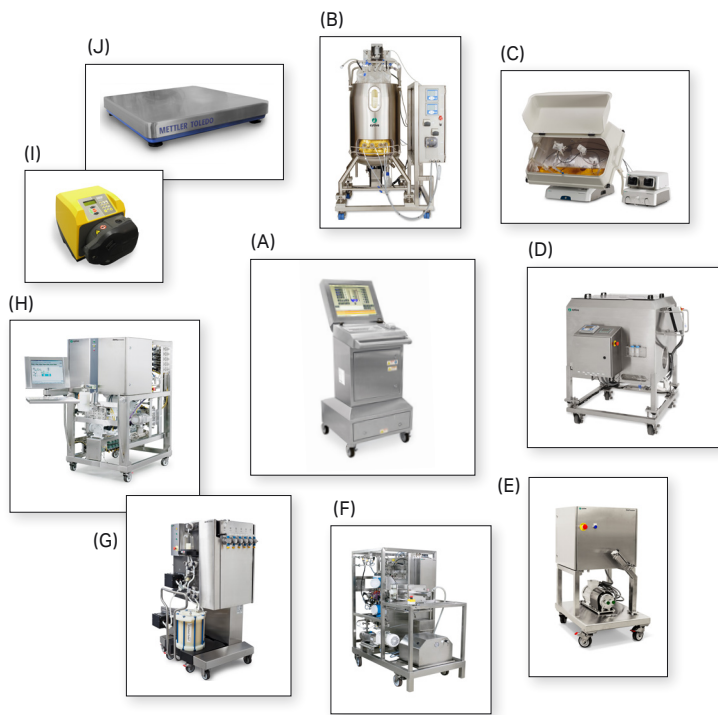


Fig 2. FlexFactory Automation design space.

Life cycle management

The design space concept incorporates a plan for inevitable changes in your manufacturing strategy, preventing business disruptions when redesign requires a restart from the beginning. Cytiva's life cycle management approach enables hardware and software upgrades to allow for business continuity throughout the life span of your production line.

FlexFactory Automation characteristics

FlexFactory Automation controls and monitors your FlexFactory process equipment, ensuring maximized performance, configurability, and flexibility in production. The automation platform encompasses Cytiva's approved automation hardware and software, and includes documentation that supports GAMP 5 (Fig 3). FlexFactory Automation offers the benefits of a standardized, verified, and configurable platform.

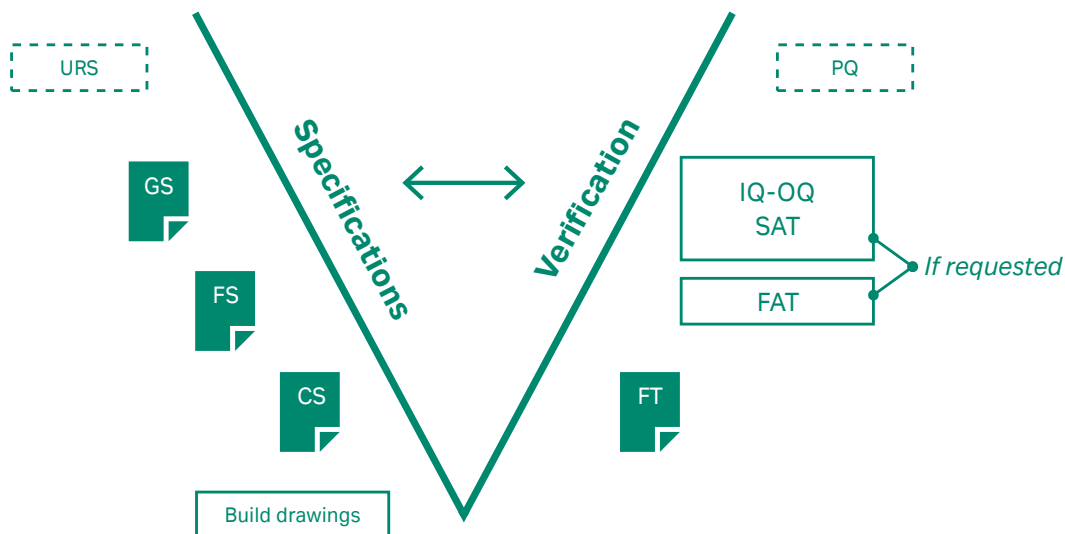


Fig 3. V-MODEL of documentation to support GAMP 5. URS = user requirements specification, GS = general specification, FS = functional specification, CS = configuration specification, FT = functional test, FAT = factory acceptance test, SAT = site acceptance test, IQ/OQ = installation and operational qualification, PQ = performance qualification.

| FlexFactory process equipment | Max. no. |
|--|----------|
| Operator interface terminal | |
| (A) M-Station OIT | 10 |
| Bioreactors | |
| (B) Xcellerex™ XDR-50, XDR-200, XDR-500, XDR-1000, XDR-2000 | 9 |
| (C) ReadyToProcess WAVE™ 25 | 3 |
| Mixers | |
| (D) Xcellerex XDUO-100, XDUO-200, XDUO-500, XDUO-1000 | 25 |
| Filtration | |
| (E) BioProcess™ NFF Pump System | 4 |
| (F) UniFlux™ 30, UniFlux 120 | 2 |
| Chromatography | |
| (G) ÄKTA™ ready system (gradient) | 3 |
| (H) ÄKTAprocess™ system (gradient and isocratic) | 4 |
| Pump | |
| (I) Peristaltic pumps in the flow range 4–2000 L/h | 20 |
| Scale | |
| (J) Benchtop and floor scales with maximum range up to 1000 kg | 10 |

Configurable or customized automation platform

FlexFactory Automation offers the functionality and flexibility required to support a wide range of bioprocessing needs. The automation platform has the ability to efficiently and securely operate and monitor production. FlexFactory Automation allows you to change and optimize your operations with minimized risk, enabling process scaling to meet increasing production volume demands while reusing equipment.

For specific applications, customized software or equipment might be needed to leverage the uniqueness of your product. Even in such situations, you can benefit from this predesigned automation platform and its configurability. FlexFactory Automation helps minimize development time of customized high-quality automation solutions.

Software

FlexFactory Automation is based on a combination of Wonderware® (Schneider Electric) and UNICORN™ software, recognized for engineering simplicity, operational agility, and information empowerment. The software helps you protect the operational integrity of your plant, enhance the operational insight of your resources, and facilitate process improvements and changes without costly revalidation work. Software features include:

Flexible batch operations

The automation platform comes with predesigned and verified phases and instructions to model your recipes and methods for your batch runs. Using these already verified building blocks allows for rapid deployment and running of new or revised product recipes without system changes, reducing time to market and recipe validation efforts. Batch execution is handled by Wonderware InBatch™ controller and with the UNICORN **Method** functionality.

Batch library

To streamline installation and validation and provide flexibility in production, phases and methods are developed for equipment and configurations within the design space of the platform.

Single station monitor

The preconfigured automation solution supports process monitoring and control from one single operator station.

Historized data

All process data are saved in a database repository.

Data integrity

Data security and control enable compliance with 21 CFR part 11 and EU Annex 11.

Seamless integration of batch reports

Batch reporting is seamlessly integrated for the entire process. This extensive and flexible reporting functionality enables process transparency and facilitates decision making.

Hardware

FlexFactory Automation hardware is designed for robust process control in GMP environments, and has been carefully tested and validated (Fig 4).

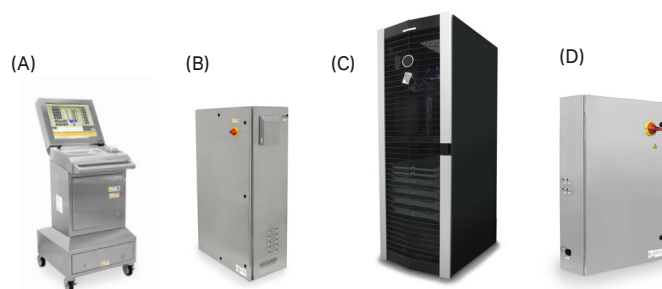


Fig 4. FlexFactory Automation hardware includes (A) M-Station OIT, (B) PLC Cabinet, (C) Server Rack, and (D) Repeater Cabinet.

Automation support

To reduce downtime, enable regulatory compliance, and decrease training demands, Cytiva's automation engineers provide varying degrees of automation support to complement the expertise of your in-house team. Along with our global network of automation partners, Cytiva's specialized experts ensure your service needs are met, from basic triage and troubleshooting to more advanced automation tasks such as support with configuration, reports, or recipes.

Single point of contact

When investing in the FlexFactory manufacturing solution, you will automatically gain access to the knowledge and experience of Cytiva. With a single point of contact and our service commitment, we support your needs wherever your facility is located. We can bring a global understanding to your manufacturing process and provide the commitment of sourcing, quality, and manufacturing professionals working to support your success. Contact us to discuss how incorporating FlexFactory Automation can add profitable growth to your biomanufacturing processes.

Ordering information

To order FlexFactory Automation, please contact your local sales representative.

cytiva.com/flexfactory

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