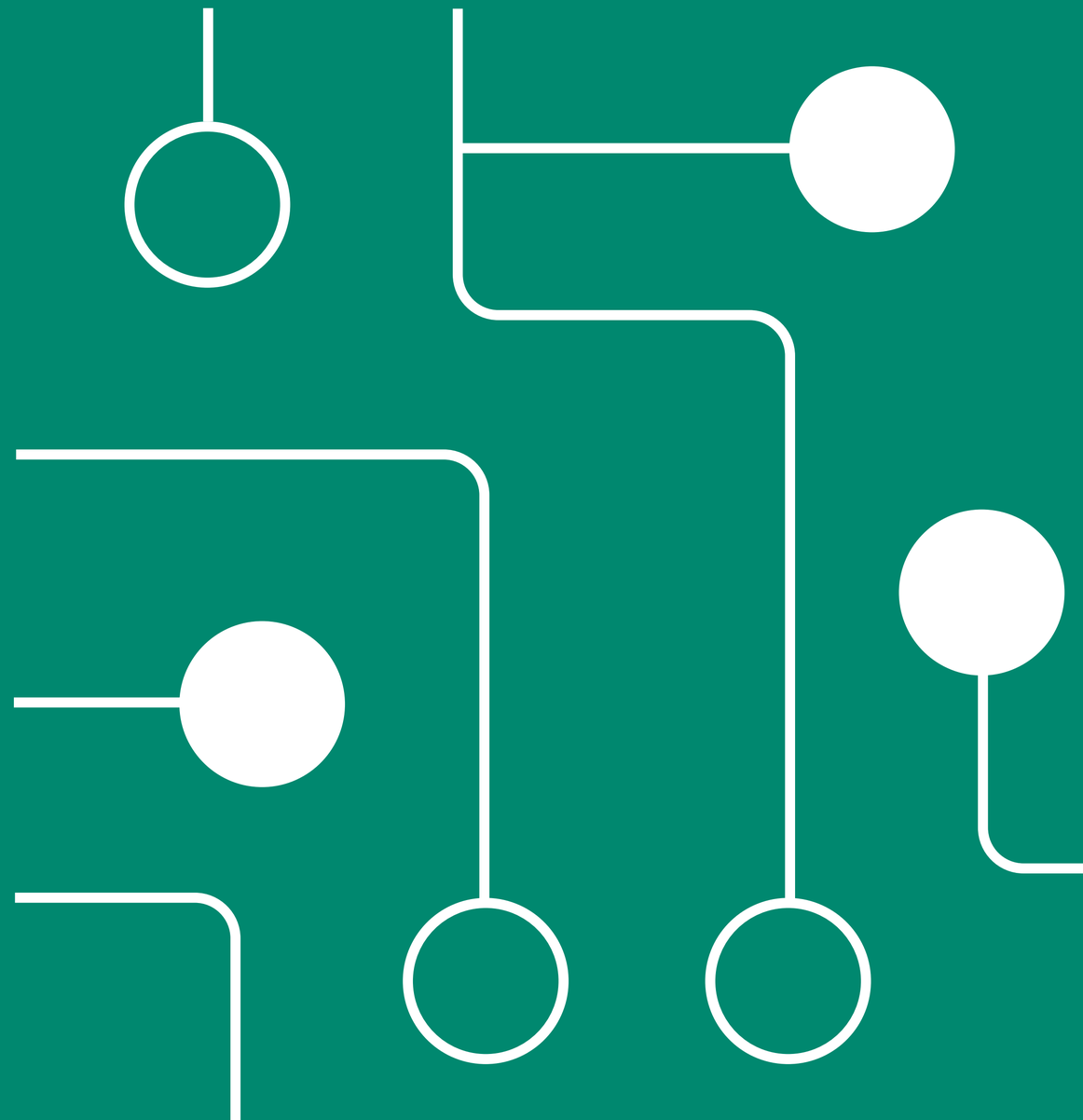
Figurate™ automation solutions



cytiva

Control your process, control your future

Biomanufacturers face many challenges, with speed to market, risk mitigation, and cost control being at the top of the list. Fortunately, recent advancements in digital automation can help address and overcome these challenges. As manufacturers strive to build digital maturity with enterprise automation, Cytiva's Figurate™ automation software offers a robust platform to streamline manufacturing operations and capture valuable data to improve process control.

Biomanufacturing inefficiencies still exist today

Recent industry reports confirm the US biopharma industry's slower adoption rates of enterprise-wide automation (1). Historically, high implementation costs and slow speed-to-market caused such slower adoption rates in addition to extremely high risks associated with quality problems.

Consider that:

- More than 80% of company time is spent collecting and cleansing data sets (2)
- 10% to 20% of the time, biopharma data cannot be accessed (3)
- Over 300 error-prone manual interventions occur in an average 200 L monoclonal antibody (mAb) single-use process
- Success of initial production runs can be as low as 47% (4)
- High batch failure rates and manufacturing deviations often result from human error (5)

Luckily, multi-industry adoption of automation and digitalization provides proven success factors in efficiency, operational maintenance, smarter workflows, and more to help biopharma embrace the benefits it provides.

By the numbers

100 sites with Cytiva FlexFactory™ configurable manufacturing trains

150 Emerson DeltaV™ unit operations implemented across Cytiva FlexFactory™ sites

100,000 Cytiva UNICORN™ software users

30 years that Cytiva UNICORN™ system control software has been helping users solve for their research, process development (PD), and manufacturing needs

Improved quality and yields

- Increased throughout
- Consistent control
- Optimized uptime

Optimized staffing

- Employee efficiency
- Easier maintenance and training
- Easier investigations and batch releases

Increased safety, reduced risk

- Reduced manual intervention
- Synchronization of units
- Minimized cybersecurity risks

Speed and flexibility

- Transfer processes
- Scale up and scale out
- Verify data

Automation and digital plant maturity results

Implementing a centralized control platform is a key building block for increasing digital plant maturity and realizing the associated advantages and benefits. Enabling electronic data capture, storage, access, and analysis can result in:

- Up to 75% reduction in paper handling and storage (6)
- Up to 85% reduction in batch review time (6)
- Up to 20% increase in employee efficiency (1)
- Up to 79% reduction in batch failures (5)
- Up to 38% reduction in labor (1)
- Up to 67% reduction in deviations (1)

Once operational, a distributed control system (DCS) is the foundation for improved process control and further increased digital maturity. With a modern DCS, manufacturers can work toward release by exception, which will save time and reduce costs as personnel will no longer have to gather and review disparate manufacturing data and manually approve the release of a batch—a process that can take weeks or months.

Figurate™ automation meets numerous strategic needs

Islands of automation and centralized control both enjoy advantages

Islands of automation run the individual control of all equipment

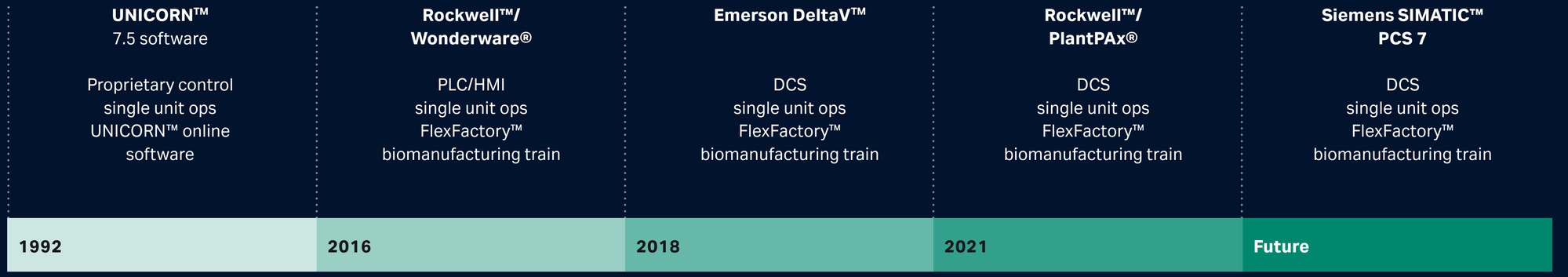
- Lowest up-front cost › saves capital expenses
- Shortest lead time › fastest time to milestone/market
- Lowest implementation complexity › lowest project risk

Distributed control system is the centralized control of all equipment

- Lowest cost of goods sold › improves profit margins
- Same look and feel for all equipment › saves time, reduces risk
- Modern advanced technology › accelerates path to digital maturity

Figurate™ automation family of products

Standard and custom solutions available



Biomanufacturing companies are complex organizations. They have many different goals and objectives, all of which must be supported by their automation strategy. Figurate™ automation solutions address the needs of all companies, from emerging biotechs to established drugmakers, contract development manufacturing organizations (CDMOs), and companies developing breakthrough therapeutics.

"Islands of Automation" is a phrase used to describe an approach to automation in which individual unit operations are controlled locally in the manufacturing suite by gowned operators. Data is collected and accessed locally. Many biomanufacturers successfully deploy this approach as the equipment can be delivered, qualified, and rapidly made operational. However, the manual nature of individually controlled unit operations generally requires additional labor, especially to support data collection, analysis, quality investigations, and lot release. For these reasons, many biopharma manufacturers are turning to more advanced automation and control solutions.

Centralized or distributed control is defined as an approach to control multiple pieces of manufacturing equipment using controllers and human-machine interfaces (HMIs) distributed throughout a manufacturing facility that are networked together to permit remote and/or centralized supervision and administration.

Data is collected in a central database and accessed via a network login.

Selecting Figurate™ automation DCS solutions utilizing either the Emerson DeltaV™ or Rockwell Automation PlantPAx® platform provides several advantages as compared to working with a traditional systems integrator.

Cytiva automation experts can discuss your specific current and future needs and determine the most appropriate approach for your unique situation.

Advancing your digital plant maturity

1 Pre-digital plant

- Paper based
- Manual operations

2 Digital silo

- Islands of automation
- Some manual processes

2.5 Integrated operation

- Distributed automation
- Centralized historian

3 Connected plant

- Vertical integration
- Electronic batch records

4 Predictive plant

- Enterprise integration
- Integrated PD and manufacturing

5 Adaptive plant

- Full end-to-end and value-chain integration
- Plug-n-play everything

Project risk	Figurate™ automation benefits
Time to design	Pre-defined standardized functionality
Time to test	Quality assured through pre-verification
Risks to scale-up or scale-out	Scalable from discrete unit operations
Design iterations for process change	Options readily available to deploy
Unknown cost	Costs known upfront
Time to implement	Enhanced speed to market
Limited expertise	Expertise in bioprocess, automation, and integration

Increasing digital plant maturity, throughput, and lower cost of goods sold

In 2016, the BioPhorum Operations Group (BPOG) developed a multi-level Digital Plant Maturity Model (DPMM) to provide the industry with a common framework for describing digital enablement. Cytiva embraced this model, adding a level 2.5 to represent the short-term goal of many manufactures deploying a DCS with central historian as an interim step to becoming a connected plant. Cytiva Figurate™ automation DCS solutions powered by either a Emerson DeltaV™ or Rockwell Automation PlantPAx® platform help companies achieve level 2.5.

Increased digital plant maturity provides many advantages that could drive down manufacturing costs by as much as 25% while increasing productivity by as much as 50% (1) as a result of:

- Reduced scrap
- Reduced labor
- Reduced deviations
- Reduced batch review time
- Increased facility utilization

Additional advantages include:

- Improved regulatory compliance and audit results
- Greatly simplified and less costly manufacturing transfers
- Faster and less costly regulatory filings
- Amortized automation costs in future clinical and commercial campaigns

Figurate™ automation solutions

Control your process, control your future

Advantages

Standardized

Process ready

Scalable

Benefits

Saves time

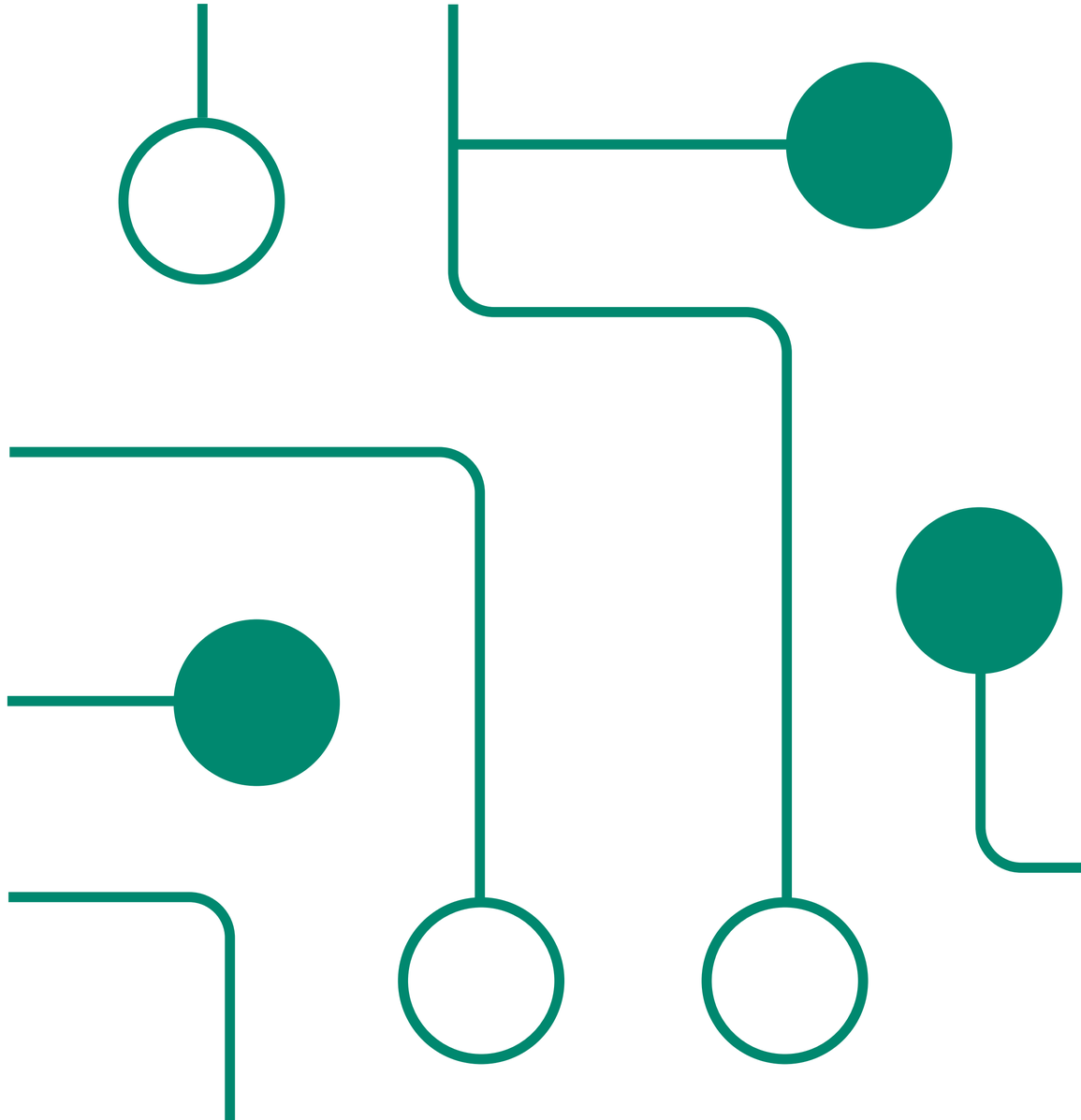
Saves money

Reduces risk

Accelerate speed to market, reduce costs and error

The FlexFactory™ configurable manufacturing train provides access to Current Good Manufacturing Practice (cGMP) biomanufacturing capacity in the shortest time possible by utilizing bioprocess equipment with pre-configured and pre-verified automation software. This approach mitigates risk by employing proven automation software that necessarily limits human interaction. Advantages of this approach include:

- Rapid scale-up, scale-out, or transfer production capacity
- Reduced implementation, documentation, test, and validation effort and time
- Consistent user interfaces help reduce human error and training time
- Flexible implementation of manufacturing execution system (MES) and other level 3 applications due to standardized data interface



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For local office contact information, visit cytiva.com/contact

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