



# Optimize data integrity during scale-up and tech transfer

Bioprocess automation solutions

# Consistent, accurate data management

Consistent, accurate data management should play an important role for organizations and individuals in bioprocessing process development and scale-up. Dedicated data management platforms and automation solutions are a vital component of data governance, and Thermo Fisher Scientific offers the flexible Thermo Scientific™ TruBio™ software solutions that are built on the robust and trusted Emerson™ DeltaV™ platform—to help manage your mammalian cell culture and microbial fermentation processes.

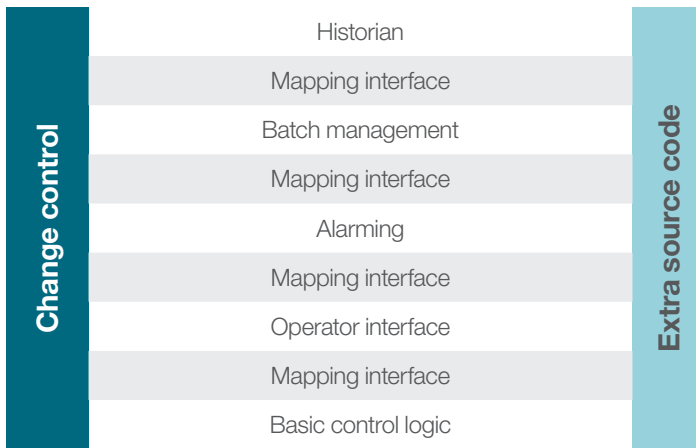
Robust data management helps to mitigate risks during all stages in biopharmaceutical scale up. Efficient, process-specific measuring of critical parameters as well as the aggregation of this data enables you to get your final product to market quickly. Thermo Fisher helps you focus on your process optimization and scale-up, rather than worry about the software tools needed to get you there.

# PLC versus DCS

Unlike programmable logic controllers (PLC) systems, our solution is based on a distributed control system (DCS). Both program languages are robust and provide little differentiation during research and development or process development usage. However, DCS is designed to help scale out your process network over time if more production capacity is required. By using a DCS, users avoid complicated reprogramming when system adjustments are being made. As a result, DCS eliminates the need for revalidation of adjusted processes, saving time and money.

## PLC system

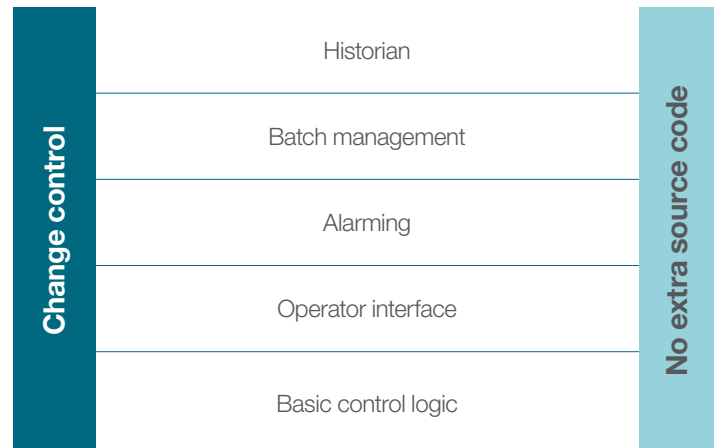
Changes require source code engineering and validation



- External change control
- Multiple suppliers
- Complex documentation

## TruBio Software, DeltaV System (DCS)

Changes don't require source code engineering and validation



- Integrated change control
- Approved and audited supplier
- Simplified documentation

Compared to PLC systems, a DCS can be optimized more easily

## Benefits at a glance

### Key benefits

- Focus on data quality due to stringent reporting requirements
- Ability to replicate processes during scale-up
- Reduce time and cost of identifying process inconsistencies
- Adopt data management best practices
- Easy to scale out

### Key features

- Data quality and traceability
- Reduced training requirement
- Standardized and repeatable processes at any scale
- Data risk mitigation during scale-up
- Standardized user interface eliminates relearning
- Solutions scalable from process development to commercial manufacturing

### Business drivers

- TruBio software based on Emerson DeltaV platform
- Easily track key cell culture performance indicators (DO, pH, etc.)
- Establish complex processes to automate application steps
- Robust data historian that meets cGMP manufacturing guidelines
- Transfer processes during scale-up to shorten learning curve and start-up times



## Common risk considerations during bioprocessing scale-up

Many potential risks during bioprocessing scale-up can be attributed to the lack of well-established, repeatable processes during the research and development phase. During bioprocessing scale-up, a molecule is transferred from process development to the next phase of pharmaceutical manufacturing, either in-house or through a contract manufacturer. More often than not, this requires that even well-defined processes and parameters will need to be re-established—this is when the lack of efficient, accurate data aggregation will become a significant, expensive setback.

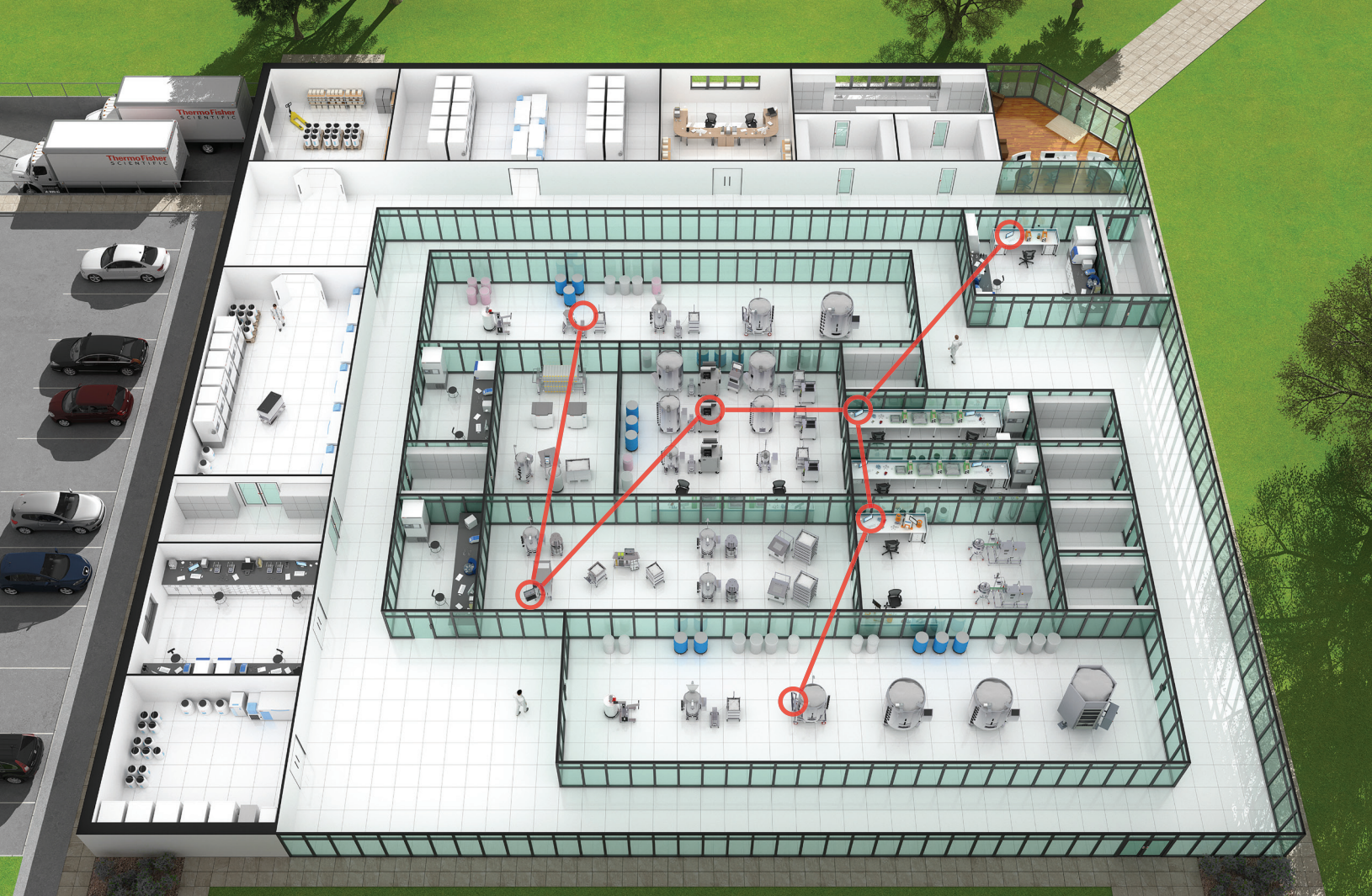
Fast-forward to the commercialization phase when biopharmaceutical developers race to deliver the finished bulk product to market—knowing that each delay could cause the manufacturer massive monetary losses, along with the risk of being second to market behind a more strategic developer. The availability of accurate, traceable, reportable data can make your business; the lack of it can ruin years of hard work.



## Intuitive, customized data management

The foundation of efficient data management is a robust platform that's easy to use and configurable. We have developed our TruBio software to enable users to manage all control processes from an intuitive user interface. The software can be easily integrated with bioprocessing equipment from any manufacturer through an application programming interface (API). The API is standardized for commonly used bioreactor systems, but can be custom-configured for less common bioreactors.

Whether you need to upgrade your existing data management and automation platform in your current facility, or fully furnish a new site, our DeltaV platform-based TruBio software can help you to improve and optimize your data acquisition, while enabling full compliance with Title 21 CFR Part 11.



# Important data tools to mitigate risks

Aggregating data and establishing a robust, scalable data management environment allows users to perform vital process functions while maintaining data that can be easily interpreted and saved for later use. Equally important is that regular, automated database backups are performed so that mission-critical data is saved.

When your business needs to adapt and grow, the data collected by TruBio software can easily be extracted and integrated for use with newer, larger systems—ensuring that historical data can be applied to the scaled-up process. TruBio software can be easily integrated with third-party reporting tools such as Dream Report™, OSIsoft™ PI, and other platforms.

To learn more about how Thermo Fisher can help your bioprocess development using our TruBio Software data management solution, contact your Bioproduction Account Manager or visit us at [thermofisher.com/datamanagement](https://thermofisher.com/datamanagement)

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