



# 6 Critical Considerations for Bioprocess Lab Equipment Selection

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Questions to consider when selecting bioprocess equipment

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# There are many factors to consider when selecting equipment for a bioprocess lab

As the market develops a need for more open and flexible systems, special attention should be paid to how your bioprocess equipment meets both present and future facility and process requirements.

Communication between instruments about critical process parameters is more important than ever, as speed-to-market for novel therapeutics depends on quick and agile availability of data. Carefully selecting equipment for the bioprocess lab assures that your present needs don't outweigh what might be valuable in the future. Here are a few factors to consider when selecting bioreactor and bioprocess equipment for the lab:

## **Is there a link between your research, clinical, and commercial manufacturing?**

If your lab is focused primarily on process development or R&D, then equipment with minimal data transferability could be a viable option. However, for those in commercial biotechnology organizations, it's likely that the process will be scaled up to clinical or commercial manufacturing. In this scenario, working with equipment that isolates data and creates "islands of automation" is not desirable, as time & financial resources are used to manually collect & integrate process data. The R&D technician might never intend for their process parameters to be scaled up, nor be subject to any tech transfer. However, the process development scientist at a pharma or biotech company is likely very interested in minimizing the complexity of their equipment so they may focus their time and energy on the robustness

of the bioprocess. Equipment that is proprietary and static or "closed" in design and operation may significantly limit future access to data when that access is most crucial.

Making an honest assessment of whether isolation of R&D from other bioprocess departments is potentially limiting is a very important first step in bioprocess equipment selection.

## **What are your scale-up and/or tech transfer requirements?**

Scaling bioprocesses is difficult. A lot of attention is paid to physical attributes like tip speed,  $k_L a$ , shear, and mass transfer. When switching between various pieces of non-open architecture equipment, extra effort must be devoted to linking unrelated control and software parameters. In contrast, the ability to seamlessly transfer development data to commercial production systems creates huge advantages in speed-to-market for novel therapies. A single software interface with one controller and control algorithm, from process development to commercialization, has inherent consistency in data management and transfer, allowing the scientist to focus on the biology and not the hardware.

If you're doing tech transfer, then seamlessness of data transfer and process automation are primary considerations. That's why it's crucial to look ahead and assess the role data plays in subsequent process steps. Will you need to share R&D data in the future? Will it be important to link R&D or process development data to production?

## **Is GMP compliance required?**

A stand-alone research application might not ever have the need for GMP compliance. However, as processes move towards commercial manufacturing, working in a GMP environment becomes a requirement. The continuity of data and software throughout processing from non-GMP to GMP environments helps to reduce time spent on validation, qualification, and operator training. That's why it's important to consider your process development systems data and how they are aggregated, managed, and transferred into systems that support cGMP environments.

Ultimately, if a molecule is successful in process development, clinical trials, FDA approvals, and audits, it will be manufactured in an environment that demonstrates cGMP compliance. Selecting equipment at the beginning that enables working seamlessly in a GMP environment can drastically reduce the cost of changing or implementing different systems at a later date.

## **Are there plans to work with a CDMO?**

For various reasons, biotech companies may consider transferring a molecule out of their own process environment and handing it over to a CDMO for further scale-up. Whether motivated by production capacity, reprioritization of a pipeline, or simple economics, the ability to seamlessly transfer data into a third-party infrastructure and replicate the process is crucial to production efficiency.

Tech transfer and scale-up efficiency can make or break the commercial viability of a therapy. Consider a developer of biosimilars, working on an alternative for a blockbuster drug that's coming off patent. There might be 10 other suppliers simultaneously working to replicate the same therapy. Without the ability to efficiently and seamlessly manage and transfer data, manual systems would need to be created to reestablish development work on a large scale. That can take months or years, time that often dictates which supplier finds success.

The supplier that has planned in advance the commercialization strategy in their process development phase is likely to advance as they are more agile and able to move quickly.

### **How important is it for the data to be in a digital environment?**

Data silos hamper scientists' abilities to generate reports, compare and transfer data. In these environments, users are often forced to manually transfer data from one system to another via USB drive to manipulate it. This manual method is not only inefficient but can also result in incomplete or unusable data. It also may not be GMP compliant.

The question to ask yourself is, how comfortable do you feel with months or years of bioprocessing data locked within a single instrument or memory stick?

In digital environments, recipes are set up once and pushed to all relevant and connected systems. Reports are aggregated, accurate, and readily available. cGMP compliance is satisfied, as are scientists and operators who are freed from the manipulation of data in programs such as Microsoft™ Excel™ or other software. The possibility also exists to freely move data around to advanced applications such as data lakes and analysis (i.e., MVDA) where the integrity of the data is paramount.

Enabling a digital factory is a complex task. Choosing equipment that is preconfigured to live in a digital world can both simplify and accelerate this effort.

### **How much time and what resources are you willing to invest in training?**

In siloed environments, operators are forced to learn and grasp multiple applications as they move from lab development to scale-up in a production environment. Many lab technicians and research scientists simply accept having to learn and re-learn repetitive tasks for multiple SCADA and software programs. Maintaining adequate training on disparate systems puts a costly burden on the business, especially in scenarios involving drugs developed on non-cGMP platforms moving into cGMP production environments, where operator training is documented.

For the average bioprocess lab, this might be simply considered a nuisance. For the biotech company racing towards the launch of a novel therapeutic, maintaining knowledge of several disparate systems is disruptive and riddled with inefficiency. Bioprocess equipment and software that standardize the user experience across multiple platforms and sizes minimize needless training and guard against institutional knowledge loss from "closed" software and systems.

Bioprocess development professionals armed with the inherent connectivity and native data collection capabilities found in modern, open bioprocess control systems are in a far better position to capture and leverage the data that drives process and production efficiency. Thermo Scientific™ bioprocess automation and control solutions address each of these key considerations.

Thermo Scientific™ TruBio™ Bioprocess Control Software, powered by Emerson™ DeltaV™ Distributed Control Platform, runs like an application, mitigating the need for users to learn multiple interfaces. Development and commercialization processes are supported by the SCADA functionality you expect for reporting and validation purposes, in addition to the historical process parameters and control loops, recipes, updates, set points, results, and trends that help you run more efficiently throughout your facility.

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