

# Model Construction

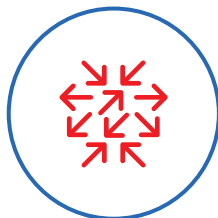
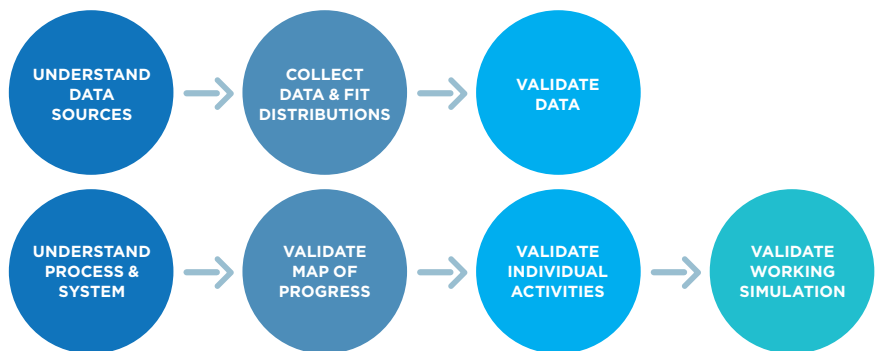
Build models that address your unique challenges with model construction

We've built models of some of the largest biomanufacturing facilities in the world. Customers consider us experts in biomanufacturing operations. Our core competencies in biotechnology, chemical and industrial engineering mean we bring fresh and expert perspectives to model building.

Our team has analyzed bulk facilities using both disposables and large-scale stainless steel. We are experts in making perfusion as well as batch-based processes work. We are familiar with multi-product facilities, optimizing changeover times, risk mitigation, and labor profiling.

We've also built filling and lyophilization models; packaging models; and supply chain and inventory flow models. We know how to build a platform process that maximizes flexibility and shortens tech transfer times. We can model the impact of WFI and other utilities in your facility to a high degree of accuracy.

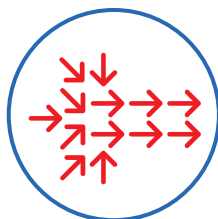
In short, we know biotech's unique challenges and complexities. Bio-G's Model Construction Service allows us to build models that exactly address your unique challenges.



## MANAGING COMPLEXITY

Biomanufacturing is characterized by significant complexity, from the intricacies of the technology itself to the need to understand many interacting processes and systems. Small process changes have big impacts. Modeling needs to envisage complexity, be highly accurate and yet be small enough to be manageable.

**“It’s all very complicated, suppliers, people, schedule and tons of data in different formats. Bio-G provides organization around the whole manufacturing process.”**



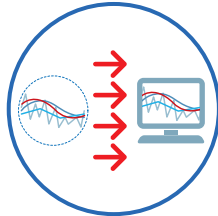
## SYSTEMS APPROACH

Bio-G has a “complete systems”-based approach to building models, collecting data from your enterprise first and analyzing it to ensure the right detail is added in the right places. Our process has been extensively tested and rigorously validated. That means your model will be accurate and comprehensive, first time around.

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**“We’re always trying to push more through the plant ... We need to model the plant to do what-if analysis. At the moment we look at only a few variables. We want to know more and understand that our plant will or will not work with more production runs.”**

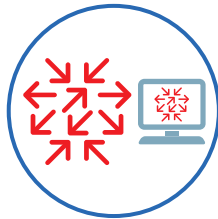
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## INTEGRATED DATA, MORE ACCURACY

Our models don't just use subject matter experts or estimates of process parameters. We go the extra mile to collect data directly from databases and other historians, storing data and in many cases making it publically available across the enterprise. That means enterprise data and real production data is integrated into your models, yielding accurate results.

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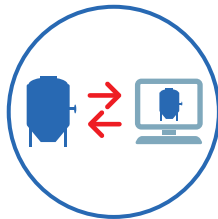
## VERIFICATION AND VALIDATION

Bioproduction Group has a unique approach to model construction: our models aren't considered complete until every nay-sayer agrees that the model is accurate. Our 'Turing Test' methodology is used to validate highly complex facilities, with a high degree of accuracy. That means models are accurate, and the outputs from the models are believed by the business.

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**“The focus is titer, titer, titer but most biotechnology firms don't understand how to manage the variables associated with making biotechnology products. Optimizing ... it is not all about the yields and titers ... it's building a whole process that is optimal.”**

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## EXPERIENCE AND PROVEN RESULTS

Bio-G specializes in biotech. That means when we build a model, that model matches the facility or process design. Period. If you've ever built a model before, you know that simple assumptions and tradeoffs can turn a highly accurate model, into a dangerously non-predictive one. Bio-G provides best-in-class model building using approaches that are proven to deliver high quality results.

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## BENEFITS

Our intimate understanding of biotechnology manufacturing processes, combined with our robust products and services have resulted in millions of dollars in annual savings for our clients. Our model construction service follows on from our audit service, and allows customers to find bottlenecks, maximize throughput, lower risk and accurately understand the outcomes that can be expected from process changes.