

# Optimizing biologic development and manufacturing through key driver identification

During process development, establishing a cell culture medium formulation and supplementation strategy that helps you reach your product titer and quality targets is essential. Once you have scaled up to commercial production, maintaining the consistency of these formulations is vital for long-term manufacturing success.

Central to achieving both is a comprehensive understanding of your process, specifically the impact of critical formulation components on productivity and batch-to-batch variability. One emerging approach that can help you gain this insight is key driver identification (KDI).

## What are key drivers?

Key drivers are media or supplement components that have a significant impact on process performance and must be within a specific concentration range to achieve optimal results. Consequently, identifying key drivers and their ideal concentrations can have many benefits.

Key driver components can be grouped into two categories:



**Positive drivers**  
Components that increase process performance



**Negative drivers**  
Components that decrease process performance

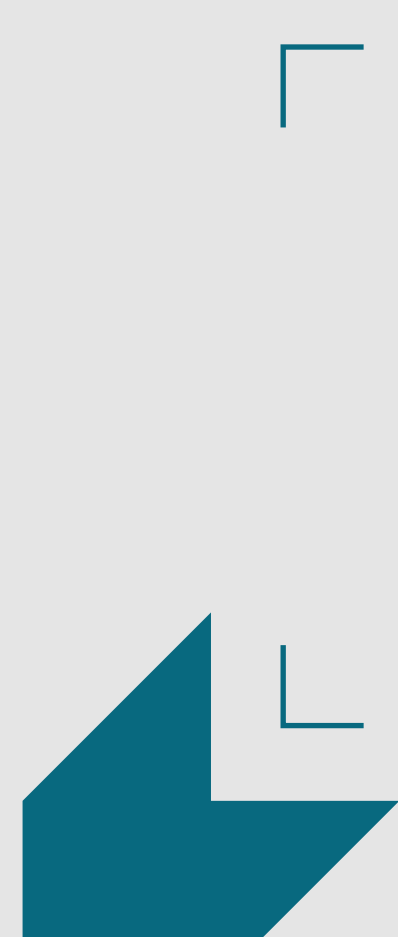
## KDI workflow

KDI is a holistic approach that uses analytical data and biostatistical modeling. A typical workflow includes:



### Data generation

Analytics are used to characterize the composition of multiple lots of cell culture media and supplements. The process is then run using these lots and performance data is collected.



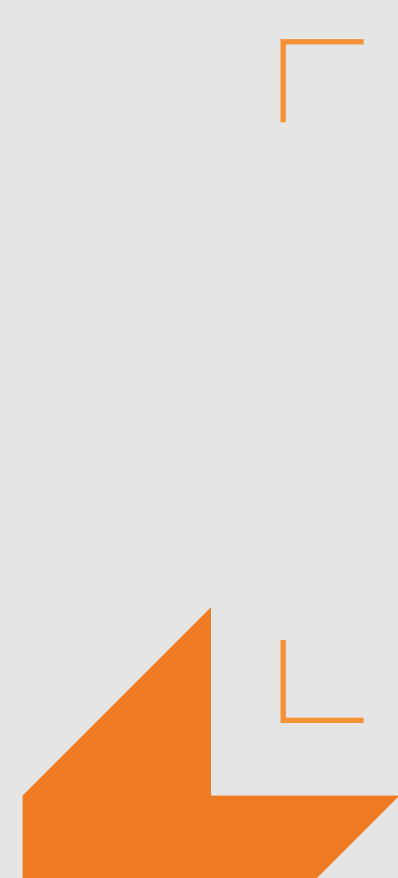
### Model discovery and development

By combining the performance and formulation data of each lot, initial biomimetic models are generated using statistical approaches. These models provide insights into potential key driver components.



### Key driver confirmation

To verify that the identified key drivers are having a causative effect on performance, prototype media or supplements—with enhanced levels of these components—are created. These prototypes are then tested in small-scale versions of the process.



### Model finalization

Data from the small-scale experiments are used to refine the models. This results in the development of a final, validated biomimetic process model.



### Implementation

The finalized model and insights into key driver components can be utilized to inform media development and process optimizations.



## Utilizing KDI within your process

By supporting you to optimize your formulation and help reduce the risk of variability, KDI can be a powerful analytical tool, providing substantial long-term benefits. Through its potentially transformative effect on process productivity, it can help you lower costs and improve the availability of your life-changing biopharmaceutical.

## Enhancing results through collaboration

To get the most from KDI, working with an experienced collaborator can be highly beneficial. In particular, given the complexity of the biostatistical modeling involved, a vendor with extensive KDI and in-house media development capabilities can support implementation of the data generated and the development of an optimized solution.

**Get in touch to learn more about our KDI analytics services.**

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