



MASTER THE COURSE IN CELL CULTURE

DRIVE YOUR MAB PROCESSES FORWARD

To successfully develop and bring a monoclonal antibody (mAb) to market, it is essential that your process meets the highest quality standards. By incorporating quality from the very start, you can build a strong foundation for long-term success. This will guide you through the essential steps to build a quality-driven foundation for mastering your mAb production.



STEP 1: TEEING UP FOR SUCCESS

Successful processes are built on strong foundations, which is why quality must be incorporated from the start.

- **Set clear quality goals**
Establish specific, measurable objectives for product and process quality at each phase of development to guide decision-making and help ensure alignment with regulatory standards.
- **Monitor your progress**
Continuously track and measure key quality parameters throughout the development process to identify and correct any deviations early, reducing risk during later stages.
- **Incorporate quality at every stage**
Make sure that quality is integrated from R&D through to manufacturing and commercialization, so that the final product consistently meets high standards.



STEP 2: CHOOSE THE BEST CADDY FOR THE JOB

Cell culture media and feeds are the backbone of biologic production, and selecting the right supplier can streamline processes and reduce the risk of disruptions during scale-up.

- **Evaluate your media supplier**
Choose a supplier with a proven track record of consistent products, a reliable sourcing strategy, and the ability to meet tight timelines.
- **Assess quality standards**
Work with suppliers who implement strong quality control measures and equivalency programs across manufacturing sites.
- **Look for media scalability options**
Select a supplier that can scale its products and services as your production demands grow, helping to avoid supply bottlenecks or inconsistencies.



STEP 3: NAVIGATE THE BUNKERS

In biologic production, even minor inconsistencies can add up as production scales increase, impacting process performance and product quality.

- **Identify sources of variability**
Identify and address sources of variability early to help deliver a more consistent and reliable process.
- **Look for thorough supplier validation**
Choose suppliers that conduct extensive raw material characterization and validation to help make sure their media performs consistently.
- **Implement controls for raw material consistency**
Work with suppliers that can effectively manage and monitor the levels of trace elements in their materials to reduce variability.



STEP 4: MAKE YOUR SUPPLY CHAIN STAY THE COURSE

A resilient supply chain is essential to help overcome unexpected disruptions, keeping production on track and reducing risks to commercialization timelines.

- **Prioritize redundant manufacturing**
Minimize the risk of supply disruptions by selecting suppliers with multiple, geographically dispersed production facilities.
- **Maintain transparency and traceability**
Make sure your supplier provides clear, robust traceability in their sourcing and supply practices—this will help mitigate risk and facilitate quick adjustments.



STEP 5: STAY ON TOP OF YOUR GAME FOR LONG-TERM SUCCESS

Planning for the future is just as important as managing current production needs.

- **Choose quality-driven suppliers**
Establish long-term collaborations with suppliers who are ready to meet your evolving requirements as production scales grow.
- **Invest in scalable quality systems**
Implement flexible, scalable quality systems that can seamlessly transition from early-phase development to large-scale commercial production without compromising on quality.
- **Plan for future growth**
Anticipate the changing needs of your production as it grows and make sure your systems, processes, and supplier relationships are capable of meeting those demands while maintaining high product quality.

To master the course in cell culture and achieve your goals, read the full article at [thermofisher.com/drivenbyperformance](https://www.thermofisher.com/drivenbyperformance)

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