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# Resilient Biomanufacturing: Operations and Supply Chain




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# Resilient Biomanufacturing: Operations and Supply Chain

## Industry Challenge ↘

Novel biologic medicines, like cell and gene therapies, have increased the complexity and cost of process development and manufacturing at scale. The rapid pace of discovery means that best practices are still evolving and thus process flexibility and cost effectiveness can be key differentiators. Novel specialized processes also mean programs are more likely to span an organization's boundaries, requiring efficient collaboration between multiple material vendors, Contract Manufacturing Organizations (CMOs), and internal facilities. Variability in quality or yield at any stage of these processes can add significant cost to the product, and delays in development or rigidity in the supply chain can prolong time to market or even derail a clinical program.

## Solution Summary ↘

To rapidly scale their manufacturing, our clients need the ability to investigate issues and model the effects of process changes. Foundry integrates data and logic from every stage & every team, from input materials to reactor conditions, and creates a digital twin of the entire development and manufacturing process. This foundation opens the door to virtual experimentation — our clients can use scenario analyses to plan vendor changes, optimize bioreactor yield, and compare quality metrics through time. The net result is a dramatic increase in process development velocity to achieve more consistent yields and efficient ramp-up of new therapies.

## Data Sources ↘

Raw material / supplier info

- → Enterprise Resource Planning (ERP) (NetSuite, Salesforce, SAP, Dynamic GP, etc.)
- → Acceptance Testing and QA Records

Lab data

- → Electronic lab notebooks
- → Cell Counts and Phenotypes (FCS)
- → Expression Profiles (RNAseq)
- → Bioprofile Panels
- → Imaging

CMO

- → In-process assay result exports (xls, pdf)
- → Live batch status updates (API integration)

Finished product

- → Electronic Batch Record Repository
- → Quality Management Systems

Trial data

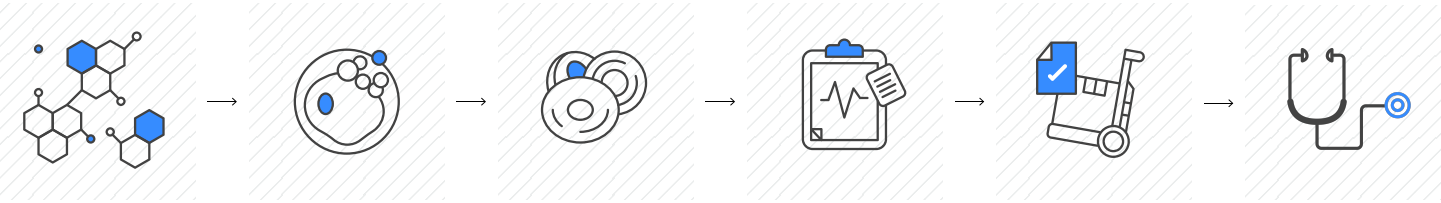
- → EDC
- → CTMS
- → SDTM Exports

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## PROCESS



TISSUE / CELL SOURCING

CELL ISOLATION AND/OR MODIFICATION

CELL EXPANSION

QA REVIEW AND RELEASE

PRODUCT INVENTORY

CLINICAL USE

## DATA



MATERIAL ACCEPTANCE TESTING

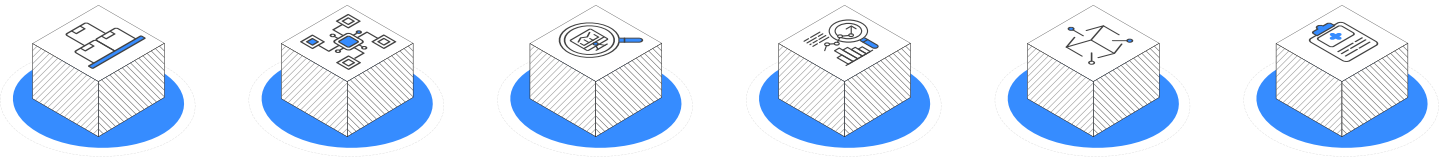
IN-PROCESS ASSAYS AND ENVIRONMENTAL MONITORING

RELEASE ASSAYS

PRODUCT INVENTORY

TRANSLATIONAL ASSAYS

## WORKFLOWS



MATERIAL INVENTORY MANAGEMENT

YIELD PREDICTIONS

DEVIATION MONITORING

HISTORICAL BENCHMARKING

SUPPLY SCENARIO MODELING

CLINICAL RESPONSE CORRELATION MODELING

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CASE STUDY 1: RESILIENT SUPPLY CHAIN

## CHALLENGE

A client developing novel cell therapies needed a supply chain that was both flexible and highly controlled to account for raw material shortages, vendor backlogs, and other shocks, without compromising quality. Teams across the company operated in siloed systems with little visibility into the downstream impact of any system changes. Making effective resource allocation decisions also proved difficult due to disparate inventory and operational records. They required the ability to dynamically re-route resources as needed along with visibility into their internal testing team's future capacity to better understand when additional vendor services were needed.

## SOLUTION

Within Foundry, this client has integrated disparate ERP systems into a single source of truth. They migrated paper and email based manufacturing processes into an electronic batch record. The granular details are then recorded by technicians or integrated from IoT sensors, such as environmental monitoring. Both in-process and release assays are tracked, and equivalent data from CMO vendors is imported to achieve end-to-end visibility, spanning from raw material sourcing to cell modification, expansion, and quality assurance. Automated alerts, both threshold rules and ML-model based, ensure that troubling patterns in a batch are immediately brought to the attention of manufacturing teams in time to intervene. When deviations are severe enough to warrant discarding a batch, the lineage of shared materials (media, equipment, etc.) allows for confident predictions to be made regarding other batches which may have been affected. Regardless of their technical ability, Foundry's suite of analytical tools enables subject matter experts to carry out such analysis with clear visibility into the process at hand.

As batches progress into inventory or are held for investigation, projections of product supply automatically adjust to inform planning. Scenario analysis tools allow the supply chain teams to experiment with adjusting raw materials and staff time allocations across programs to limit the impact of disruptions and adapt to changes in clinical demand. All of these scenarios and plans are created from inventory data collected through live connections with ERP systems. Projections can be written back to such systems, taking advantage of existing infrastructure investments while avoiding silos and enabling collaborative planning and visibility by teams across the organization.

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CASE STUDY 2: YIELD OPTIMIZATION

## CHALLENGE

A Pharma client faced high variability of biologic product yield for key clinical programs. Investigating individual batches was a time-consuming, manual process that was often ultimately inconclusive. Different teams across the company had partial perspective with limited ability for collaborative analysis and attribution. Even when hypotheses for contributing factors were identified, there was no mechanism for conducting confirmatory experiments to validate that the desired improvement was achieved. Furthermore, the ultimate clinical impact of various yield metrics was unclear, and it was difficult to answer which metrics, if optimized, would maximize the effectiveness of the new therapy.

## SOLUTION

With Foundry, historical manufacturing yields were matched with raw material metadata. A robust analysis pipeline was configured to correlate batch yields with input characteristics. Review of this analysis resulted in reprioritization of raw material vendors and reconsideration of material handling best practices. Going forward, this analysis runs automatically as new data becomes available, enabling continuous monitoring for unexpected relationships between input material characteristics and production quality. This can be used to optimize raw material acceptance criteria and material handling procedures over time.

Beyond analysis of raw inputs, the capture of more granular details from each team as the manufacturing progresses enables determination of which process elements have an impact on final product quality and intermediates along the way. This infrastructure also empowers process development teams to carry out controlled experiments, where adjustments are made to a randomized set of batches to validate parity or improvement over the status quo. Over time, as more historical data is gathered, analysis can be complemented by machine learning models able to spot deviations earlier and provide enhanced projections of realized yield, in turn improving resource allocation decisions.

Better ability to understand the drivers of yield extends beyond the internal processes and includes collaboration with third party partners. For instance, a client's manufacturing team is in the process of bringing additional functions in-house. During this transition, QA assays are performed by a mix of in-house teams and CMO partners, making it difficult to create a complete picture of batch quality throughout the workflow. With Foundry, assay results from the CMO partner are uploaded and parsed automatically to achieve an end-to-end record of all batches, allowing benchmarking and optimization to occur regardless of the path a product took.

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