WHITEPAPER

# A Unified Development Blueprint: Aligning Scientific Expertise to Accelerate Complex Biologics Programs

## Accelerating Timelines, DNA to DS Bulk Fill in 8.5 months

LOTTE BIOLOGICS
Possibilities Beyond Limits

ASIMOV

## OVERVIEW

As complex biologics are entering pipelines at a dizzying pace, sponsors and their development partners are facing new challenges in expression, purification, and characterization. Non-standard architectures behave differently than the traditional monoclonal antibodies (mAbs) that defined earlier platform strategies, and without careful planning, programs can be delayed or even sidelined due to low expression and difficult developability.

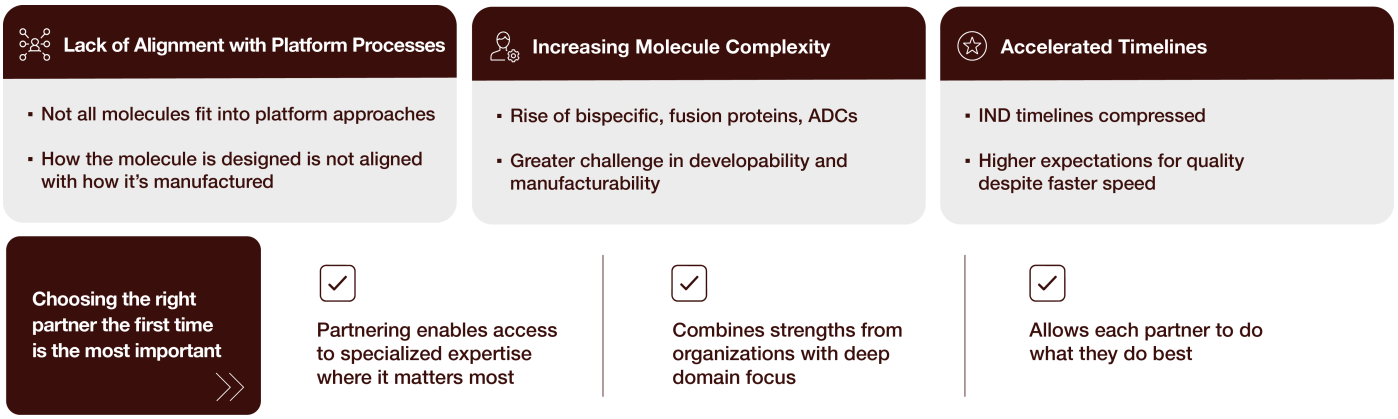
While conventional platform approaches have accelerated timelines for traditional mAbs by using standardized vectors, templated processes, and minimal early adjustment, these methods often fall short for next-generation architectures. When the underlying molecule falls outside standard platform assumptions, the consequences often emerge later in development, when changes are slower and more costly. What looks like acceleration at the beginning can become a constraint further downstream.

For therapeutic developers seeking both high performance and accelerated timelines, one option is to rely on a single development partner to reduce the number of interfaces and handoffs. That structure can remove certain sources of delay, but it does not eliminate the underlying tension; standardization remains the mechanism that makes those models efficient, though it has limitations when molecules do not conform.

A more effective strategy is to focus on how development activities are connected rather than where they are housed. A pioneering collaboration between Asimov and LOTTE Biologics illustrates how early integration across these functions can accelerate development while reducing risk. By aligning cell line engineering, process development, analytical readiness, and manufacturing strategy from the outset, the partnership enabled a complex antibody program to progress from transfection to drug substance bulk fill in approximately 8.5 months.

> “Importantly, this timeline was achieved for a molecule that fell outside the boundaries of a conventional platform antibody”

## EMERGING PROBLEMS IN EARLY-STAGE DEVELOPMENT




## INTEGRATED INNOVATION:
## Aligning Biological Design with Process Execution

A consistent challenge in biologics development is the disconnect between how a molecule is designed and how it ultimately needs to be manufactured. Upstream and downstream activities are often treated as discrete phases, each optimized within its own boundaries. In practice, decisions made during cell line development directly influence process performance, analytical product quality attributes, and scalability. When those connections are not accounted for early, they tend to surface later as inefficiencies or rework.

Asimov is a life sciences tools company that has developed an AI-native synthetic biology platform integrating cells, genetic tools, computational models, and processes. Rather than relying on standardized expression constructs, Asimov develops molecule-specific vector designs, optimizing parameters such as codon usage, signal peptides, and overall architecture. The company's computational models are built on large volumes of proprietary experimental data generated in Asimov's labs, creating a feedback loop that continuously refines future designs. The result is a more controlled and informed approach to generating high-performance cell lines, particularly for molecules that fall outside conventional formats.

LOTTE Biologics is a contract development and manufacturing organization with capabilities spanning process development and large-scale GMP biologics manufacturing. Its core strength lies in translating upstream outputs into robust, scalable processes that can be executed reliably in a manufacturing environment. This includes upstream and downstream process development, analytical readiness, and technology transfer into GMP production. LOTTE's approach emphasizes both speed and control, leveraging established development frameworks while applying process expertise to ensure that scale-up and manufacturing proceed without disruption.

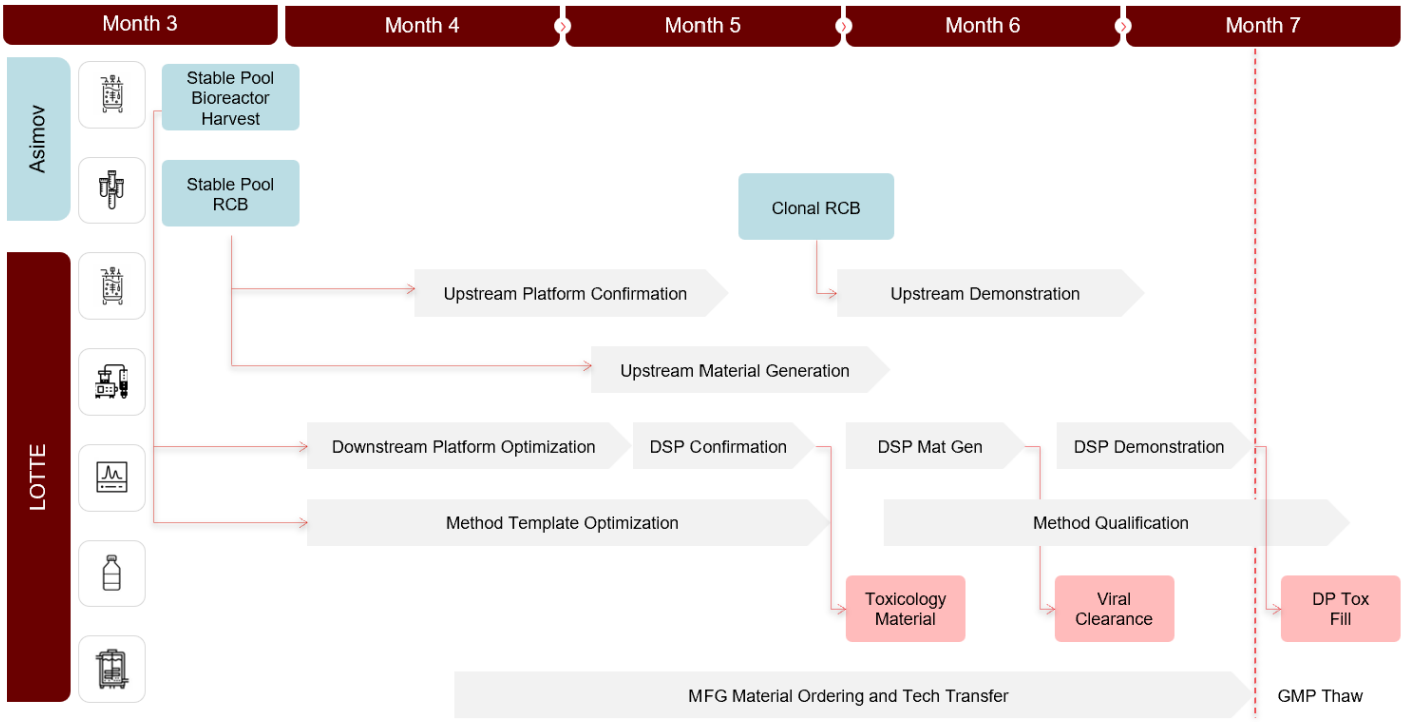
Individually, each organization addresses a different part of the development challenge: Asimov focuses on shaping the biological system to improve expression and consistency at the source, while LOTTE focuses on converting that system into a manufacturable process under real-world conditions. The following case study underscores the value of aligning core competencies like these into a complementary, cohesive framework that can operate agilely while improving on the foundational science underpinning today's more complex and challenging molecules.

## CASE STUDY:
## Accelerating IND Readiness for a Complex Antibody Through Integrated Development

A recent program involving a non-standard antibody with dual binding characteristics demonstrates the impact of this integrated approach. While not a traditional bispecific molecule, the antibody presented unique challenges related to expression, consistency, and downstream processing. The client required an accelerated path to IND while maintaining confidence in manufacturability and long-term scalability.

Achieving this objective required more than simply compressing timelines: the program was designed around a series of coordinated acceleration and derisking strategies that enabled development activities to proceed in parallel while generating critical process knowledge earlier than would traditionally be possible.

## FROM DNA TO DRUG SUBSTANCE, THE PROGRAM WAS COMPLETED IN APPROXIMATELY 8.5 MONTHS, AND THE PRODUCT WAS SUPPLIED FOR CLINICAL USE



## EARLY MATERIAL GENERATION ENABLES PARALLEL DEVELOPMENT

One of the most significant acceleration mechanisms was the generation and transfer of early-look material from stable pools before final clone selection. Using its CHO Edge platform, Asimov generated molecule-specific vector sequences and rapidly established stable pools capable of producing representative material early in development.

Traditionally, downstream process development, analytical method development, and manufacturability assessments must wait until lead clones have been selected and sufficient material becomes available. In this program, early-look material enabled LOTTE Biologics to begin evaluating process compatibility, downstream purification strategies, analytical methods, and scalability weeks earlier than would normally be possible.

Early access to representative material was particularly valuable for analytical development, where teams first assessed whether platform methods were suitable for the molecule, determined which assays required redevelopment or optimization, and initiated the comprehensive validation activities required before IND lot release.

Because analytical method development and phase appropriate validation often represent a significant portion of the overall development timeline, advancing this work in parallel with process development eliminated a major potential bottleneck. Simultaneously, early process evaluation identified manufacturing challenges before they evolved into schedule risks, enabling multiple technical workstreams to progress concurrently.

## REMOVING BOTTLENECKS THROUGH PARALLEL EXECUTION

Additional timeline compression was achieved through several coordinated development activities. Bulk pool batch analysis was conducted while at-risk research cell banks were prepared and transferred in parallel.

Early clone banking was initiated ahead of Ambr15 harvest, ensuring critical materials would be available when needed rather than becoming downstream bottlenecks.

The program also leveraged stable pools to generate toxicology material before final clone selection. This pool-to-tox strategy enabled the client to advance key preclinical activities without waiting for fully characterized production clones, eliminating a significant source of delay that often impacts accelerated development programs. Collectively, these approaches transformed what are traditionally sequential development stages into concurrent activities, substantially reducing overall program duration.

## ACCELERATING SCALE-UP THROUGH EARLY PROCESS UNDERSTANDING

LOTTE Biologics leveraged the early-look material generated by Asimov to begin establishing process understanding well before formal technology transfer activities. Using the upstream process framework defined during cell line development, LOTTE evaluated manufacturability and scalability while simultaneously developing and optimizing a platform-based upstream and downstream process strategy.

Because process development began with representative material generated early in the program, knowledge gained during pool-to-tox manufacturing could be directly applied to tox-to-GMP scale-up activities. Early scale-up work significantly reduced the process design space by identifying operating conditions and confirming process performance well before GMP manufacturing.

As a result, later development activities could concentrate on confirmation runs instead of iterative process optimization, shortening the overall development timeline and increasing confidence during scale-up.

Combined with LOTTE Biologics' prior experience working with Asimov-derived cell lines, which provided a strong understanding of expected growth characteristics and process behavior, this approach enabled efficient scale-up to 1,100 L without extensive process redevelopment.

## BUILDING ANALYTICAL AND MANUFACTURING READINESS EARLIER

Analytical readiness progressed in parallel with process development throughout the program. Early material generated by both organizations enabled LOTTE Biologics to begin analytical method development and qualification activities substantially earlier than what would occur in a traditional workflow. Moreover, templated analytical methods provided an initial assessment of process performance and product quality attributes, allowing analytical understanding to evolve alongside process development. These methods also simplified eventual transfer into GMP quality control laboratories and reduced the burden associated with later-stage analytical qualification.

Additional risk reduction was achieved using platform raw materials and established supply chains; because materials and consumables were defined early, procurement activities could begin sooner, minimizing supply-related timeline risks while limiting the need for extensive supplier and material qualification activities. By deploying an integrated quality framework spanning both organizations LOTTE and Asimov were able to align documentation, traceability, deviation management, and GMP readiness activities across the program.

## RESULTS: FROM TRANSFECTION TO DRUG SUBSTANCE BULK FILL IN 8.5 MONTHS

Through a combination of early material generation, parallel execution, accelerated analytical readiness, platform-based scale-up strategies, and integrated quality oversight, the program successfully progressed from transfection to drug substance bulk fill in approximately 8.5 months.

Importantly, this timeline was achieved for a molecule that fell outside the boundaries of a conventional platform antibody. Despite its complexity, the program advanced to approximately 1,100 L manufacturing scale with minimal process optimization, reflecting the value of establishing process understanding early rather than relying on extensive late-stage redevelopment.

While this approach is not exclusive to any single organization, it requires development partners that are willing to work collaboratively, share data early, and coordinate activities across organizational boundaries. By generating process knowledge sooner, reducing technology transfer risk, and enabling multiple development workstreams to proceed in parallel, the Asimov–LOTTE Biologics partnership demonstrates how customer-centric collaboration and thoughtful integration can transform traditional sources of delay into opportunities to accelerate development without compromising manufacturability or product quality.

## CONCLUSION:
## The Value of Coordinated Expertise

As biologic modalities continue to diversify, development success increasingly depends on the ability to connect specialized expertise across the development lifecycle. Whether capabilities reside within a single organization or across multiple partners, the critical factor is the degree of alignment between biological design, process development, analytics, and manufacturing execution.

Models that employ these strategies will become particularly relevant as pipelines continue to diversify. Development bottlenecks are increasingly shifting beyond cell line generation and into downstream processing, analytics, and manufacturing scalability. Success, therefore, depends not only on excellence within individual functions but also on the ability to coordinate decisions across the entire development lifecycle, where early design choices directly influence manufacturability and process performance.

The collaboration between LOTTE Biologics and Asimov illustrates this approach in practice: by combining advanced cell line engineering with process development and manufacturing expertise and aligning those capabilities through deliberate orchestration, the partnership demonstrates how organizations can address molecular complexity without sacrificing speed, scalability, or technical depth.

## OUR COMBINED CAPABILITIES

### DS Bulk Fill in 8.5 Months

Integrated, risk-adjusted approach enables a robust tech transfer between Asimov and LOTTE Biologics at manufacturing scale

### High-Titer, Scalable Cell Lines

Predictable, high-titer results with fewer surprises at scale. Producing titers at 8-12 g/L before process development across modalities

### Enable Multiple Modalities

Able to support the development and manufacturing of diverse modalities including monoclonal antibodies, bi-specifics, ADCs, fusion proteins and others

### End-to-End Manufacturing

Expert scale up and manufacturing for every step. Offering various scale manufacturing, from tox runs to full scale GMP manufacturing

## ABOUT LOTTE BIOLOGICS

LOTTE Biologics is a global contract development and manufacturing organization with sites in the U.S. and South Korea delivering integrated biologics and bioconjugate services across the full product lifecycle.

Our capabilities encompass phase-appropriate drug substance manufacturing for mammalian-cell-based biologics, including monoclonal antibodies, fusion proteins, and multi-specific modalities, as well as fully integrated bioconjugate manufacturing supported by strategic investment in onsite conjugation facilities.

## ABOUT ASIMOV

Asimov is a life sciences tools company that has developed an AI-native synthetic biology platform integrating cells, genetic tools, computational models, and processes.

Through a combination of products, services, and collaborations, Asimov advances therapeutic design and manufacture across modalities, including biologics, cell and gene therapies, and RNA.