The 9 Year Supply Chain Gap

Prevention over Remediation

The Cost of Decisions Made Without Supply Chain Input in Drug Development

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Based on industry research, calculations, and operating experience.

Executive Summary

Many regulatory setbacks and commercial underperformance in drug development can be traced back to a set of recurring decisions, made in preclinical development and early Phase 1. Many of these decisions either affect supply chain directly or are later inherited. In early-stage biotech, supply chain as a function is typically established in late Phase 2 or Phase 3. In larger organizations, it is rarely involved before Phase 2 or 3. This means 4 to 9 years of decisions are made before supply chain is onboarded.

As many novel treatments are developed for patients who have exhausted all other options, a delay in approval, a supply disruption, or a cost structure that makes treatment unaffordable or inaccessible is not just a setback or inconvenience. It is life altering. Reliable, affordable, and consistent supply is not a back-office concern. It is part of the treatment.

The evidence is consistent across multiple independent sources:

- A study at the University of Michigan found that 10% of clinical trial failures are attributed to commercial viability or poor strategic planning, not the science.[1]
- An analysis of FDA Complete Response Letters found that 74% issued between 2020 and 2024 cited quality or manufacturing deficiencies.[2]
- A Deloitte analysis of 284 drug launches found that one-third missed analyst forecasts in their first year, with manufacturing delays and supply chain disruptions explicitly cited as causes.[3]
- An industry survey by STAEDEAN of 130 pharma professionals found that 62% cite compliance and validation as the primary barrier to switching suppliers.[4]
- The Tufts Center for the Study of Drug Development found that a single day of development delay costs an average of $800,000 in lost sales.[5] A CMC-related CRL, with a typical delay of 8 to 18 months, represents between $192 million and $432 million in lost sales.[6]
- Across all New Drug Application (NDA) submissions, approximately 1 in 17 programs end due to quality or manufacturing deficiencies that are, in many cases, preventable.

There are many other sources that explore these setbacks, but do not link them to a root cause. The pattern appears due to a structural gap, not by accident.

The gap is structural, driven by how early development is organized. These decisions determine whether a drug is approved, can be manufactured reliably, meets quality standards consistently, at a cost the market will accept and the organization can sustain, without triggering a setback that costs months and hundreds of millions to resolve. In many cases, these constraints cannot be fully reversed once established.

Prevention is more effective than remediation. The evidence points to a structural issue: supply chain input is introduced after the decisions it should inform have already been made. For early-stage organizations, this may not yet exist as a formal function. For larger ones, it exists but is rarely engaged at these stages. In both cases, the gap is the same: supply chain is not present as a strategic input when the decisions that determine regulatory and commercial outcomes are being made. Introduced early, this input materially changes the risk profile of a program. Introduced late, it inherits problems it could have prevented.

These outcomes are not primarily execution failures. They are the result of decisions made without supply chain input at the point of decision. The issue is not ownership. It is timing. Supply chain is not present as an input when decisions with long-term commercial consequences are made.

1. Delay, Loss and Program Failure: The Most Common Causes

Five recurring failure categories can be observed. Each represents a different decision point. In each case, the decision is made on scientific and regulatory criteria alone, without commercial supply chain considerations or input. The consequences are documented, recurring, and quantifiable. For programs serving patients with no other treatment options, the consequences extend beyond the commercial. In each case, the decision owner is clear. What is missing is supply chain input at the point of decision.

1. Components and Bill of Materials
2. Manufacturing Network and CDMOs
3. Supply Network and Reliability
4. Technology Transfer
5. Post-Approval Changes

1.1 Components and Bill of Materials

Components are selected during formulation and process development for technical fit. The commercial implications of those selections are rarely evaluated at the same time.

Speed is critical at this stage. That pressure creates gaps between R&D and commercial requirements that can lead to reliability and quality constraints later in the product lifecycle:

- Custom single-use assemblies account for up to 70% of single-use supplier SKUs and tie customers to a single supplier for the duration of the product's commercial lifecycle.[7]
- Lack of standardization creates a quasi-monopoly supplier position with low leverage for the end user.[7]
- In one case study, standardization delivered savings of more than EUR 1 million per monoclonal antibody process per year.[7]
- 34% of pharma companies take more than five months to qualify a new supplier under normal conditions.[4] 62% cite compliance and validation as the primary barrier to switching.[4]

The Gilead Sunlenca CRL is a documented example of component selection failure. Glass particles from incompatible commercial vials were found in clinical batches because the container closure system selected for clinical development was not compatible with the proposed commercial container.[2]

1.2 Manufacturing Network and CDMOs

Various analyses of the FDA Complete Response Letter (CRL) database found that the most common cause for a CRL is a quality or manufacturing deficiency:

- 74% of 202 CRLs issued between 2020 and 2024 cited quality or manufacturing deficiencies.[2] In a separate analysis, 50% of CRLs cited CMC or supply chain deficiencies.[6]

- Up to 40% of CMC-related CRLs are attributable to issues at CDMO sites specifically.[6]
- More than half of facility-related CRL deficiencies arose because the FDA could not complete pre-approval inspections of third-party manufacturers.[8]

FDA enforcement data shows a sustained increase in regulatory scrutiny across the global manufacturing network. FDA Form 483, Inspectional Observations, reached 561 observations in 2024, with partial data in 2025 already exceeding 600 at the time of the research.[9] cGMP warning letters rose from 84 in 2019 to 105 in 2024, with partial 2025 totals estimated at approximately 120.[9] This reflects a manufacturing environment where manufacturing and CDMO quality track records are increasingly consequential in selection decisions.

Of the products that receive a CMC-related CRL, 8% stop development entirely.[6] Across all NDA submissions, where approximately 74% receive a CRL citing quality or manufacturing deficiencies, this translates to roughly 1 in 17 (6%) programs ending due to preventable CMC-related causes. The remaining programs that continue often face an 8 to 18 month delay before eventual approval, leading to revenue loss, delayed launch, poor speed to market, and potential market share erosion.[6]

Industry guidance, drawing on BCG and ISR benchmarking, advises sponsors to initiate CDMO engagement ahead of the intended start date for biologics and sterile programs, allowing time for technical alignment, quality review and contracting, since slot scheduling and availability often has a lead time of 6 to 8 months.[9] Sponsors that delay engagement risk selecting partners based on near-term availability rather than long-term strategic fit. Across the biologics development programs I have supported, this pattern is consistently observed.

Below are four cases that demonstrate how the manufacturing network led to a CRL:

- **Novartis / inclisiran:** CRL issued December 2020 due to unresolved inspection findings at a third-party contract manufacturing site. US launch delayed following a $9.7 billion acquisition of The Medicines Company.[10]
- **Daiichi Sankyo / patritumab deruxtecan:** CRL issued June 2024 due to inspection findings at a third-party manufacturer. No efficacy or safety concerns raised.[11]
- **Checkpoint Therapeutics / cosibelimab:** CRL issued December 2023 following inspection findings at a multi-sponsor CMO. Company disclosed lack of redundant supply.[12]
- **Aeglea BioTherapeutics / pegzilarginase:** Refusal to File issued June 2022, citing CMC issues before full review had begun. Filing halted, additional spend required.[13]

1.3 Supply Network and Reliability

Supply reliability risk is established during development and reinforced through commercial scale-up. Without supply chain input at the right stage, it is not identified until it becomes an operational problem.

Drug shortages are not rare events. Between 2013 and 2017, 62% were caused by manufacturing or quality issues.[14] When a shortage occurs, the consequences are lasting: affected products lose an average of 10.8% of market share during a shortage, and that share is not fully recovered.[15]

For complex therapies, the consequences are more severe. Manufacturing cannot simply be replicated by an alternative supplier. In biologics, qualifying a replacement manufacturer requires demonstrating analytical comparability, which carries substantial regulatory

timelines and costs. For cell and gene therapies, supply base constraints have already translated directly into patient access failure. Slot shortages for CAR-T therapies have created waiting lists at major treatment centers exceeding available manufacturing capacity, with clinical directors at leading cancer centers identifying shortages of commercial-grade GMP viral vector as the root cause.[16]

The supply base decisions that determine this exposure are made in early development. By the time a shortage occurs, the options available to resolve it are defined by choices that were made years earlier, without supply chain as a strategic input.

1.4 Technology Transfer

Technology transfers typically take place in Phase 3, when the commercial manufacturing site needs to be ready ahead of launch. By this stage, the CDMO selection, which determines where the transfer goes, was already made in preclinical or Phase 1. Supply chain is only beginning to form at Phase 3. The questions that should shape the transfer, commercial slot access, equipment alignment, capacity headroom, and site readiness at the receiving facility, are supply chain questions. They are rarely asked at the right time.

Selecting the wrong partner, or transferring without adequate supply chain input, has major implications for a program:

- Industry estimates put the cost of a single technology transfer at more than $5 million.[17] Costs are driven by analytical method transfer, comparability studies, stability testing, batch manufacturing at the new site, and regulatory documentation.
- Transfers related to sterile products can take 18 to 30 months.[18]
- Transferring to an external site adds an average of 5.8 months compared to an internal transfer.[18]
- At a 2025 industry roundtable, Dr. Uwe Hanenberg, Head of Product Implementation at Recipharm, reported that approximately 50% of all technology transfers experience quality problems.[19]

1.5 Post-Approval Changes

Post-approval manufacturing changes are frequently the downstream consequence of decisions made earlier in development: a supplier never dual-sourced, a component never qualified at commercial scale, a CDMO whose capacity was assumed rather than verified. When the change is forced, the regulatory burden is substantial.

- A post-approval manufacturing change requires simultaneous regulatory reviews across all launched countries, a maximum of approximately 140 countries.[20]
- Based on biosimilar development data, when analytical comparability cannot be demonstrated, a pharmacokinetic bridging study needs to occur, which can cost $9 million to $13 million and can take 6 to 12 months.[21]
- In extreme cases, a full clinical bridging study can be required, which can cost between $20 million and $28 million, over 1 to 3 years.[21]
- In a review of 12 approved advanced therapy medicinal products (ATMPs), comparability inadequacies were identified in 50% of them.[22]

These are not theoretical risks. They are not random quality failures or isolated operational mistakes. They share a common structural explanation: supply chain decisions being made at a stage of development when supply chain expertise is not present as a strategic input.

2. The Supply Chain Gap: Decisions Before the Function Exists

Supply chain management covers every decision from supplier selection through to product delivery. It is responsible for cost structure, supply reliability, regulatory standing, and ensuring that a product reaches the patient consistently and at a sustainable price. It is not a back-office function. The five failure categories in Section 1 are not isolated quality failures. They fall squarely within the scope of supply chain responsibilities. Understanding why requires two things: a clear definition of what supply chain owns, and an honest look at when that ownership typically begins in drug development. This definition is not intended to shift decision ownership, but to clarify where supply chain expertise is required as an input to those decisions.

2.1 Supply Chain Responsibilities

The Chartered Institute of Procurement and Supply, the global professional body for procurement and supply chain management, defines procurement's mandate as:

- Market analysis, sourcing, negotiation, and contracting
- Supplier relationship management and prequalification
- Risk mitigation and identification of critical materials
- The make-or-buy decision.[23]

Supply chain management's mandate extends from primary suppliers through to the point of sale, with responsibility for predicting and satisfying end customer demand back through to suppliers.[24]

Each of the five failure categories in Section 1 falls within that mandate. Component and BOM selection involves critical materials identification and direct procurement. CDMO selection is a supplier selection and prequalification decision. Supply network risk is a risk mitigation failure. Technology transfer planning involves contractor management and supply route analysis. Post-approval change is the consequence of inadequate supply route analysis in development.

The connection between each failure category and the supply chain mandate is not incidental. Component specifications determine whether a resilient, multi-source supply network is possible. CDMO selection decisions determine supplier quality and regulatory standing. Supply base decisions determine whether a program can withstand disruption. Technology transfer decisions determine whether commercial supply is feasible on the required timeline. Post-approval change is the direct consequence of all of the above being made without adequate supply chain input. These are not edge cases within the responsibilities. They are the responsibilities.

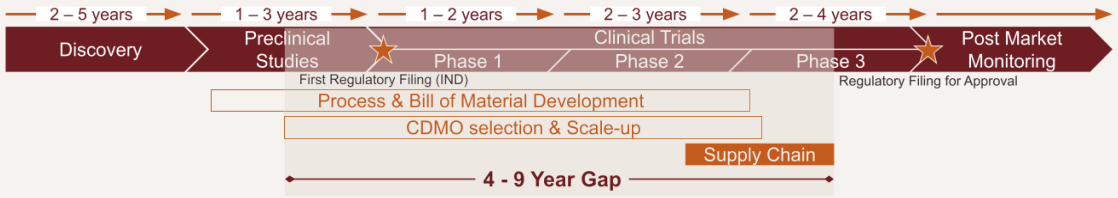
2.2 The 9 Year Gap

Supply chain is not absent from early-stage development by accident. It is absent because the organizational priorities of early development do not include it, and the frameworks used to guide early-stage companies do not flag it as a gap. The evidence from multiple independent frameworks is consistent:

- Industry frameworks describe CMC as a preclinical IND-preparatory activity, positioned alongside pharmacology and toxicology.[25]
- Silicon Valley Bank's startup lifecycle guide identifies the Series A priority as establishing a sales function to grow and expand the customer base. Supply chain is not mentioned.[26]
- In a Deloitte cohort analysis of 20 early-stage biotech companies, five dimensions of successful scaling were identified. Supply chain is not a standalone dimension in any of them.[27]
- Most emerging companies operate with a lean staff focused on research, clinical development, and intellectual property protection.[28]
- Industry experts recommend incorporating supply chain strategy two to three years before market launch.[29] Even this recommendation places supply chain at late Phase 2 or Phase 3, after the critical decisions are locked.
- Based on my own conversations with life sciences recruitment organizations, supply chain and procurement roles are rarely listed as early-stage priorities, with most mandates appearing at late Phase 2 or later.

The diagram below maps where supply chain decisions are being made against where supply chain organizational capability as a commercially-focused function typically exists. From preclinical development through to late Phase 2 or Phase 3, that gap spans 4 to 9 years.

FIGURE 1: The 9 Year Gap



Timeline showing supply chain decisions made during preclinical through to Phase 3, against the supply chain function being onboarded at late Phase 2 to Phase 3. This creates a gap spanning 4 to 9 years.

2.3 The Cost of the Gap

Bluebird Bio's withdrawal of Zynteglo from the European market, after failing to secure reimbursement coverage for a gene therapy whose manufacturing cost made viable pricing impossible, is a documented example of structural cost locking in commercial failure.[30] The drug worked clinically, but failed due to the high cost of production. For patients with no alternative treatment, that outcome is not a market access statistic.

The financial consequences of the timing gap accumulate in two places. The first is immediate: regulatory delays, technology transfer rework, and comparability bridging studies. These are one-time costs, bounded and attributable to specific events. The second

is structural: the COGS baseline locked in by early manufacturing decisions, which sits in the P&L for the entire commercial life of the product. These costs are the downstream expression of earlier decisions that constrained what was possible.

Asset at risk

A peer-reviewed analysis published in the Journal of the American Medical Association (JAMA) Network Open found that the mean capitalized cost of bringing a drug to approval is $879 million per program, with a range of $379 million to $1.76 billion depending on therapeutic area.[31] Taken together with the earlier findings, these figures indicate that approximately 1 in 17 (6%) programs end due to preventable CMC-related causes, representing a complete loss of the capitalized investment.

Delay costs

The Tufts Center for the Study of Drug Development found that a single day of development delay costs an average of $800,000 in lost sales, based on a peer-reviewed analysis of 645 drugs.[5] This is an average across a broad sample. Oncology programs average $840,000 per day. Cardiovascular programs average $1.4 million per day. Smaller or earlier-stage programs will be materially lower.

Against that benchmark, the failure events documented in Section 1 carry the following illustrative costs:

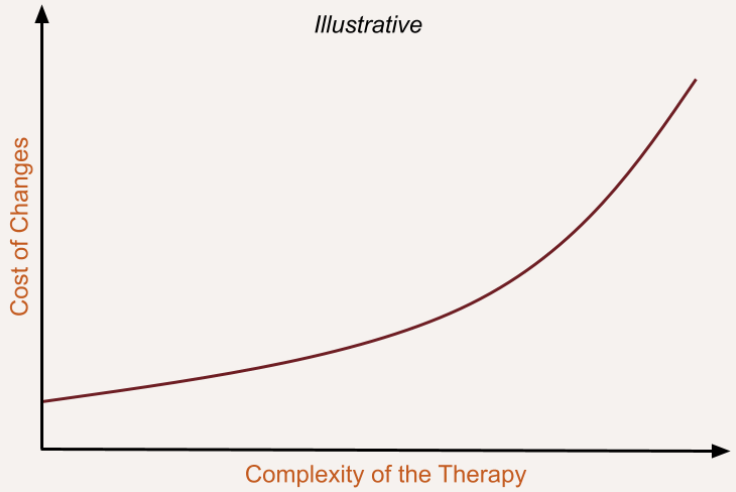
- A CMC-related CRL, with a typical delay of 8 to 18 months, represents between $192 million and $432 million in lost sales.
- A technology transfer to an external site, which adds an average of 5.8 months compared to an internal transfer, represents approximately $139 million in lost sales.
- A forced post-approval supplier change carries a combined qualification and regulatory burden. Even minor regulatory changes require a minimum 30-day review.[32] More substantive manufacturing changes follow individual timetables set by the competent authority, with procedures suspended during clock stops when additional information is required. Against the Tufts CSDD benchmark, even a 30-day regulatory delay represents approximately $24 million in lost sales.

These are illustrative calculations using Tufts CSDD inputs, not cited benchmarks. They illustrate what is at stake when decisions made in preclinical development surface as problems in Phase 3 or post-approval.

COGS opportunity

Early manufacturing decisions do not only create one-time setbacks. They lock in the cost structure for the commercial life of the product. The cost of optimizing that structure increases with the complexity and uniqueness of the therapy, as illustrated in Figure 2 below. At the simpler end of the spectrum, post-approval network optimization is possible but carries regulatory cost and timeline risk as documented in Section 1.5. At the high complexity end, the window to optimize is effectively closed once early clinical decisions are made.

FIGURE 2: Cost of Late Supply Chain Optimization by Therapy Complexity



Illustrative curve showing the relationship between therapy complexity (x-axis) and the cost of making a change (y-axis). At the simpler end of the spectrum we would find small molecules and on the right therapies like CGT, radioligand therapies, etc.

BCG's analysis of leading generic and biosimilar manufacturers found that procurement and contract manufacturing spend accounts for 40 to 65% of total COGS, with a savings potential of up to 30% through better procurement and network management.[33] Based on this benchmark, a program with $500 million peak annual sales and 40% COGS, that savings potential represents approximately $60 million per year. While this benchmark is for biosimilars and generics, this principle also applies to specialty and complex biologics.

For autologous cell therapies, COGS is not a post-approval optimization problem. It is determined by decisions made before the first patient is dosed. Three independent sources confirm the structural challenge:

- Cytiva's process economics modeling found that material costs are fixed per dose regardless of volume, because each patient's treatment is manufactured individually. There is no batch scale-up lever and no bulk purchasing advantage. Labor dominates at 53% of COGS at early clinical scale.[34]
- Spink and Steinsapir's peer-reviewed model, based on publicly available Yescarta and Kite SEC data, found labor at 71% of manufacturing costs in a base case, with a per-dose cost of $58,200. Critically, capacity utilization decisions made before commercial launch can double per-dose costs: at 40% utilization, the base case cost rises to $106,000 per dose. A 10-fold volume increase delivers only 22% COGS reduction. Even in the best-case optimized scenario, per-dose cost remains above $21,000. At these per-dose costs, every supply chain decision in early development carries commercial consequences that compound across the commercial life of the program.[35]
- McKinsey identifies manufacturing cost reduction as the primary lever required to make these therapies viable for larger indications, linking COGS directly to whether these treatments can achieve broad commercial adoption.[36]

The implication is consistent across the spectrum. Whether the program is a generic, a biologic, or an advanced therapy, the cost structure is substantially determined by supply chain decisions made before supply chain exists as a function. The later those decisions are revisited, the more they cost to change.

3. Bridging the Gap: Supply Chain as a Foundational Function for Prevention

The decisions documented in Sections 1 and 2 are not abstract commercial risks. For patients dependent on novel therapies with no alternatives, a delayed approval, a supply disruption, or a cost structure that makes treatment inaccessible is a clinical consequence, not a business one.

Supply chain is typically thought of as a commercially oriented function, engaged for launch readiness and beyond. That framing is too narrow and too late. The decisions that determine whether a launch succeeds, whether a drug is approved on schedule, manufactured reliably, and priced at a level the market will accept, are made years earlier. Supply chain input at those earlier stages is not a structural change. It is a timing correction.

Early supply chain involvement does not require a full team. It requires a strategy, a framework, and active oversight at the right decision points. The strategy defines the network and identifies critical supply paths. The framework enables the decisions that follow. Together, they form the foundation of the future supply chain function. This does not change decision ownership. It ensures that decisions are informed by supply chain considerations at the point they are made.

Supply chain oversight for each of the five risk categories would look as follows:

- **Components and BOM:** Assessment against commercial network standards before specifications are locked. The question is not only whether a component works, but also about lead times, delivery reliability, and whether a commercial-scale, multi-source supply exists for it. Where that is not possible, the risk should be identified and managed proactively. This includes specification review to create resilience by design and to avoid over-specifying components, which limits sourcing flexibility post-filing.
- **CDMO selection:** Supply chain input before the contract is signed. A structured evaluation of inspection history, capacity headroom, regulatory compliance track record, and a reliability assessment alongside technical capability.
- **Dual-source strategy where required:** Designed in from the start, not retrofitted post-approval. The time to identify the second source is before the first is qualified.
- **Technology transfer planning:** Supply route analysis alongside the science plan. Commercial site readiness, slot access, and equipment alignment determine whether the transfer timeline is realistic.
- **COGS modeling:** Introduced as a commercial viability input during Phase 2 portfolio decisions. The cost structure of a program is substantially set before Phase 3. That assessment belongs earlier, allowing for a more complete COGS optimization strategy and plan.

The goal is not to add process, but to avoid locking in constraints that are significantly more costly to resolve later.

4. Conclusion

These decisions are not operational. They are strategic. They determine whether a drug is approved, can be manufactured reliably, at a cost the market will accept, without triggering a setback that costs months and hundreds of millions to resolve.

Earlier supply chain input does not guarantee these outcomes, much like any other function involved earlier. It reduces the probability of failure because these areas fall within core supply chain expertise. The goal is to mitigate risk where possible. Where mitigation is not possible, the risk should be an active, informed decision, not an oversight. For example, choosing an inexperienced CDMO may be the right call. But it should be a conscious one, with a clear understanding of the implications and a plan in place to manage them, whether that means agreeing upfront investment in capability, defining clear milestones, or building contingency into the transfer and scale-up plan.

Every program makes these decisions. Most make them without supply chain input being present at the point of decision. The gap that this creates, and what it costs, has been documented in the sections above. Bridging it begins with an internal assessment of current activities, timelines, and stage gates, and then mapping where processes, partnerships, or materials are being decided without supply chain input. Those are the moments that carry the most risk, and where supply chain input has the highest impact.

The gap is not a lack of capability. It is a misalignment between when decisions are made and when the function designed to inform them is engaged.

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