

FTLA Snapshot

Edition 2.0 | Webinar date: September 23, 2025



What is FTLA?

The First-Time Launch Alliance (FTLA) is a peer-driven forum helping emerging biopharma companies navigate the defining milestone of bringing their first product to market.

Through candid discussions and shared lessons, FTLA highlights the cross-functional decisions—spanning strategy, operations, supply chain, and market access—that make or break launch success.

Each *FTLA Snapshot* captures insights from these conversations and turns them into practical guidance. This second edition continues that mission, focusing on outsourcing as one of the most critical choices for FTL leaders.



Outsourcing: Smart Move or Risky Bet?

Outsourcing is an unavoidable reality for emerging biotechs, but whether it creates value or risk depends on how it's done. In this FTLA discussion, the panel shared candid sponsor and provider perspectives on the outsourcing spectrum: deciding to keep in-house, navigating RFPs, building partnerships beyond the contract, and recognizing the risks that never fully transfer.

They underscored that outsourcing success goes beyond the contract and that it's about alignment, communication, and accountability on both sides.

Panelists



Andrew DeMarco
Biotech Journey Advisor
(Sage Advisors)



Christopher Armstrong
VP, General Manager
(McKesson)



Scott Sutton
Senior Director, Supply Chain
(MorphoSys)

FTLA Membership Opportunity

FTLA is now inviting nominations for members to serve a six-month rotating seat on the FTLA Executive Committee. This is a chance to help shape the dialogue, guide future topics, and support FTLA to deliver value for all members.

If you are interested, please share **why you'd like to serve and what makes you a strong, inaugural candidate** for this leadership role to **James Zenevitch** (JZEN@nnit.com)

Quick facts about FTLA



Launched May 2025

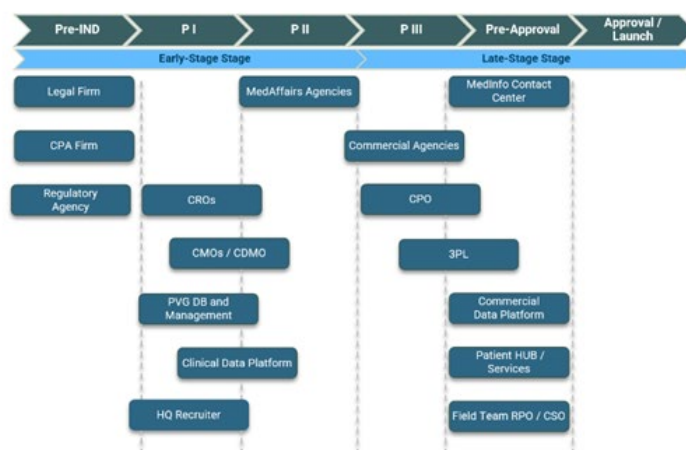


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November 4, 2025: Attend our first in-person FTLA Summit in Boston, MA
[Register here](#)

Outsourcing: Smart Move or Risky Bet?



Best Practices & Lessons Learned

Outsourcing by the Numbers

Emerging biopharma now drives 63% of clinical trial starts, which is up by 56% since 2019. With limited resources, CRO outsourcing has become the default for trial execution.

Nearly 9 in 10 drug developers use FSP or FSOs. FSPs add people into sponsor organizations while FSOs run entire projects. Both offer scale, but accountability blurs without clear roles.

Contract manufacturers project 13.8% annual growth in bioprocessing outsourcing. Capacity is shifting rapidly to CDMOs, making vendor alignment critical.

Only 20-30% of stakeholders are fully aligned on goals, assumptions, and constraints at the start of a relationship. Most failures aren't technical—they stem from hidden misalignment.

Sources:
ContractPharma, CRO Industry Trends for 2025

FierceBiotech, Market Insights: What's Driving the Shift Toward FSP Models (2024)

ContractPharma / BioPlan Associates, Post-COVID Trends in Biopharma Contract Manufacturing (2024)

FTLA Quick Tip

Prior to developing requirements and your RFP, perform a structured situation analysis with everyone instrumental to success.

Case for outsourcing: What's the driving need internally and externally?

Critical outcomes: What does success look like at one, three, and five years, and who benefits?

Barriers to success: What could go wrong at each stage (pre-deal, due diligence, start up, year 1, year 2+)?

Decision criteria: Before making your selection decision, define, rank and agree on what matters most

Outsourcing can be a launch enabler or a costly detour. Success depends less on contracts and more on alignment, trust, and transparency between sponsors and your partners. Our FTLA panel shared practical guidance on decision criteria, RFPs, partnerships and accountability.

Here are the key messages:

Deciding What to Outsource

Emerging biotechs rarely have the infrastructure for every function. Scott pointed to equipment-heavy processes like GMP manufacturing and packaging as clear candidates for outsourcing, while functions tied to core scientific or strategic strengths should remain internal.

The risk is in outsourcing by default. Vendors often package ancillary services around their core offerings, which can sound efficient but may dilute focus or create capability mismatches. Chris added that too many sponsors arrive at the vendor's door without clarity about their own competencies—assuming the provider will define strategy for them—and that almost always leads to friction.

Procurement and Preparation

RFPs and RFIs are the standard way to start a vendor relationship, but they're far from perfect. Chris explained that an RFP tells him what the sponsor thinks they need, but it doesn't show how the team operations, whether expectations are realistic, or whether the partnership will work day to day.

Scott emphasized that sponsors often stumble before the RFP even goes out. Technical teams aren't involved early enough and requirements are vague or overly technical, leaving vendors to guess. Both panelists agreed that when vendor options are limited or timelines are compressed, formal RFPs may add unnecessary steps, but the discipline of documenting requirements and vetting claims should never be skipped.

Building and Managing Partnerships

Scott likened vendor relationships to managing internal teams: just because work is outsourced, doesn't mean accountability leaves the sponsor. He stressed the need for frequent interaction and for treating vendors like an extension of the company. Chris noted that onboarding is the most fragile stage. Without resourcing on both sides, early assignment of project managers, or clear account ownership, problems show up quickly and can linger.

Both panelists underlined transparency as the currency of trust. When sponsors hide uncertainties or vendors gloss over limitations, alignment ravel. Instead, both sides must embrace open dialogue and collaborative problem solving.

Warning Signs and Course Correction

Problems rarely appear out of nowhere—they show up as small signals. Scott highlighted slow response times or incomplete answers as early indicators that a vendor may not be on top of their commitments. Chris cautioned that lack of transparency is a deeper warning sign, often pointing to systemic issues rather than individual failings.

Both urged leaders to distinguish between personality conflicts and real misalignment, and to use candid communication to surface root causes before they compound. Most importantly, they agreed that cultural alignment and shared patient focus are the ultimate safeguards.

Partnerships framed purely as transactions are fragile, but those built on shared mission can absorb setbacks and recover.

AI: Helpful but Limited

An audience question prompted discussion of AI in vendor management. Both Scott and Chris saw promise in using AI to streamline data-heavy processes, such as analyzing proposals or monitoring performance metric. However, both cautioned against overreliance. Scott compared it to early supply chain technologies: they improved efficiency, but human oversight was still needed to validate outputs and catch risks the system can't see.

Chris stressed that no algorithm can replicate the trust, judgement, and relationship building that make partnerships succeed: good news for us humans.

Key Takeaways

- 01 Define your core before you outsource:** Map your internal strengths and gaps. Own your strategy first, then outsource to fill true capability gaps and not the other way around.
- 02 Prepare before you procure:** Use RFPs as a tool, not a crutch. Clarify needs with technical experts early, simplify requirements, and supplement documents with real conversations to test cultural fit and chemistry.
- 03 Invest in the partnership, not just the contract:** Treat outsourcing as a team extension. Resource onboarding internally, assign clear ownership, and set a cadence of interaction that mirrors internal team management.
- 04 Catch small problems before they grow:** Watch for red flags and address them directly. Build a culture of feedback and prioritize mission alignment as much as technical execution.
- 05 Use AI as a tool, not as a substitute:** Let AI streamline admin work, but keep leadership judgement, accountability, and trust firmly human. Efficiency helps, but relationships drive outcomes.

Final Thoughts

At the FTLA, we believe that outsourcing isn't just an option; it's a strategic necessity for today's emerging biotechs. With limited people and capital, and with competition intensifying for patients, mindshare, and market access, there is no room for trial-and-error approaches.

Outsourcing, whether for studies, manufacturing, logistics, or commercialization support, must be deliberate. It requires clear-eyed decisions about what to keep internal, disciplined preparation before engaging vendors, and an ongoing commitment to partnership and accountability. Done right, outsourcing enables agility and speed without sacrificing alignment. Done poorly, it drains scarce resources and creates risks that no contract can fix.

The lessons captured here reflect the lived experience of leaders who have navigated this reality from both sides of the table. We hope they give you practical guidance to strengthen your own outsourcing strategies as you move from science to strategy to success. If you have follow-on questions or insights, please join and post them on our [FTLA LinkedIn](#) Group!



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About First-Time Launch Alliance (FTLA)

The FTLA brings together biopharma leaders and innovators who are dedicated to the successful first-time launch (or subsequent launches) of commercial biopharma products. Operated by FTL leadership with strategic direction provided by the executive committee, the FTLA creates a vibrant, expert-driven community that shares knowledge, drives innovation, and elevates execution—so that every launch is set up for success and every patient benefits from new therapies.

[Visit the FTLA website](#)

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