FIRST-TIME LAUNCH ALLIANCE

FTLA Snapshot

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First-Time Launch Challenges in Europe: Commonalities & Differences

When launching in Europe for the first time or following the US launch, substantial challenges are encountered. Although the primary stages to launching a medicine in the European market are comparable to the US and much work can be leveraged, there are significant distinctions that require prompt and meticulous attention to ensure a smooth and controlled success.

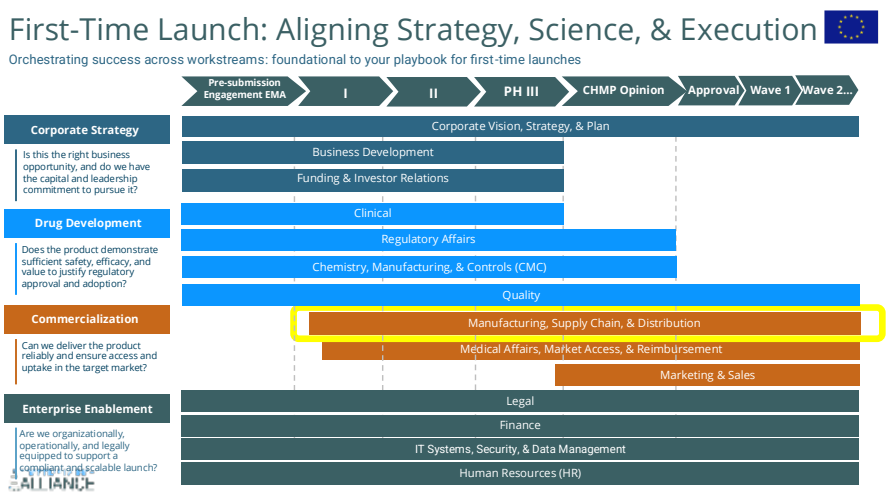
Our panel of experts who have supported numerous biopharma companies during their internationals FTL experience came together to discuss FTL challenges, focusing on the supply chain—one area that stands out when preparing to go to Europe.

Panelists

Jenny Miller
Formerly Chinook Tx & SeaGen
(Seattle, WA)

George Clothier
Dynavax
(Berkeley, CA)

Christoph Krähenbühl
NNIT
(United Kingdom)



What is FTLA?

Our second FTLA Snapshot continues the conversation we began with our first newsletter—this time focusing on the challenges and opportunities of **First-Time launches in Europe**. Drawing on our recent panel discussion with experienced supply chain and commercialization leaders, we've captured not just the facts, but the nuances: regional differences, market access complexities, regulatory readiness, and the operational pivots that can make or break a launch across the EU.

The FTLA Snapshot is designed to move beyond theory and into practice. Each edition shares **real-world insights from peers who've been there**, highlighting the decisions, lessons, and frameworks that help emerging biopharma companies navigate their first launch successfully.

First-time launches (FTLs) remain defining moments for emerging biopharma companies. Success hinges not only on scientific and regulatory achievements but on **cross-functional orchestration—strategy, operations, supply chain, market access, and enabling functions all working in lockstep**.
We hope this second edition sparks fresh thinking and provides practical guidance as you prepare for your own launch—whether in Europe or beyond

Quick facts about FTLA

- Launched **May 2025**
- **290+ members** across **230+ organizations** and growing daily
- **November 4, 2025**: Attend our first in-person FTLA Summit in Boston, MA
  Register here

Best Practices & Lessons Learned

Partnering Smartly

Don't go solo: Use experienced, specialized partners for regulatory advice, VAT/tax, company structure, etc.

Leverage local experts: In-country resources help with language, culture, regulatory bureaucracy, and speed

Plan for scalability: Choose partners with capability to support future markets beyond the EU/UK

Utilize strategic advisors to provide market insights, country specifics, and your compliance roadmaps

Regulatory Preparation

Start early: Understand blue box, labeling, and national number requirements upfront

Map both levels: Account for EU-centralized requirements and market-specific national rules

Factor in both GMP and GDP: Recognize the distinct responsibilities of QP (manufacturing and batch release) and RP (distribution compliance)

SC Execution

Design for success: Supply chain should be "invisible" in a successful launch

Validate entire route: This includes air, sea, road, and interim storage. Factor in cross-border leg specifics (e.g. ferry from UK/Ireland)

Consider future compliance from Day 1: Even if not required in Europe, features like aggregation can help with global alignment later

Your FTL in Europe Supply Chain: Overall Takeaway

Entering the EU/UK pharmaceutical market is a **multi-layered orchestration** of regulatory compliance, partner management, and logistical execution.

Success hinges on **early preparation, deep knowledge** of national differences, **smart partner selection,** and **future-proofing systems** for global expansion—all while ensuring the supply chain remains a smooth, invisible enabler rather than a launch bottleneck

Looking back at our lively panel discussion, we explored:

- How US launch experience translates (or doesn't) to Europe
- The biggest similarities and differences between US and EU launches
- Key decisions and lessons learned from leaders who've been there

From timing to supply chain to regulatory roles, our panel highlighted the factors that can make or break a European launch. Here's a look at the themes they shared and the practical steps that came up most often:

When to Go to Europe and Where First

George shared how Dynavax approached its EU launch by starting in Germany. With a manufacturing site already in place, they considered pricing and market access, but ultimately opted for an external distribution partner even with a local footprint.

Jenny reminded us that "Europe" isn't just the EU. The UK and Switzerland each have their own regulatory paths, challenges, and opportunities—like the UK's post-Brexit approach.

A recurring theme: build for the future from day one. Even if full track-and-trace compliance isn't required in Europe yet, putting systems in place early can make global alignment far easier—especially if Europe is your springboard for broader expansion.

Supply Chain is a Key Focus Area

Strategic timing: Coordinating US and EU launches takes careful planning. EMA filing timeliness, using US dossiers to prepare centralized EMA submissions, and engaging with both FDA and EMA in parallel can reduce launch gaps, but it's a heavy lift and regulators may ask very different questions.

Supply chain: Supply chain complexity in Europe should never be underestimated. It interacts with other critical choices:

- Company structure: Set it up right from the start. Decisions about tax, IP protection, and overall strategy are hard to reverse and carry long-term implications. This is a specialized area we'll explore more in-depth in a future session.
- Market access, pricing, and target markets: Strategies vary—some companies target individual countries while others focus on the "EU Big 5": France, Spain, Germany, Netherlands, and Austria. The UK is now outside this group.
- Country-specific requirements: Despite centralized approvals, every country has unique regulatory and local requirements—from artwork and serialization specifics to pricing timelines and additional registration steps—requiring dedicated local coordination.

Execution approach: Launching in multiple countries simultaneously works best with a strong global infrastructure supported by specialized local teams on the ground. Language, time-zone presence, and an understanding of local bureaucracy are key enablers.

Packaging, Labeling, and Distribution

- While US upstream manufacturing can sometimes be leveraged for EU launches, EU-based packaging and labeling are often preferable. Local regulations require elements such as Braille, BlueBox pictograms, national coding, and multi-market cluster packs.
- Identifying and contracting a European 3PL before market authorization approval is a crucial step. They should be able to support you not only at launch, but also for future expansion beyond the EU and will be an integral part of your supply chain.
- EU serialization introduces additional complexity, including onboarding with European Medicines Verification Organization (EMVO) and each National Medicines Verification Organization (NMVO). Teams and senior management need to understand that EU processes differ significantly from US ones and bring extra costs (e.g. EMVO/NVMO fees). Even though US and EU serialized packs share GS1 data matrix standards, operational and process requirements differ greatly.
- On top of that, the EU market places a stronger emphasis on environmental efficiencies and reducing packaging waste. Distribution flows will also need more robust shipping validation (air, truck, ferry). Upstream processes may feel familiar, but implementing and operating your downstream EU supply chain is more complex and resource intensive.

Understanding the EU framework vs. the US

The EU system layers centralized, EU-wide requirements on top of national level regulations, creating complexity and country-specific variation. A few EU-specific roles to know:

- **Qualified Person (QP):** Personally liable for ensuring accurate information, adherence to processes, and sign-off on documentation—a centralized role in EU pharmaceutical legislation
- **Information Officer (IO):** A national level role, such as Germany's "Informationsbeauftragter", defined in country-specific law
- **Responsible Person (RP):** Another EU-specific role that must be factored into operations and planning

Understanding these distinct regulatory positions early will help you build a compliant and efficient EU operation.

Key Takeaways

01 **Plan across the whole system:** Entering the EU/UK market isn't just a regulatory exercise; it's coordination across manufacturing, packaging, logistics, compliance, and multiple regulatory bodies at once

02 **Master the two-tier rulebook:** EU-wide legislation and centralized approvals co-exist with country-specific requirements (artwork, packaging, product information)—build processes and teams that can handle both.

03 **Local presence speeds success:** Time-zone alignment, language skills, and cultural familiarity—whether from your own team or trusted partners—make day-to-day problem-solving faster and smoother.

04 **Think long-term and global:** Set up systems, partners, and data flows now that will scale for future compliance needs worldwide. Decide early what you'll do once and outsource vs. what you'll keep in-house and master over time.

05 **Don't assume a copy/paste from the US:** US launch experience provides a head start, but not a template. Don't let the commonalities mask the differences. Communicate internally that Europe's patchwork requires new strategies, partners, and a different execution model.

Final Thoughts

At the FTLA, we believe that a successful first launch isn't just about approval—it's about building an organization that can execute with clarity, collaboration, and confidence.

Breaking into Europe isn't just about copying your US playbook; it's about understanding the market's unique layers, planning ahead for compliance, and making deliberate choices on structure, timing, and partners. By taking these lessons into account early, first-time launchers can move faster, avoid costly missteps, and set up themselves up for global success.

The lessons captured here are shaped by the real experiences of cross-functional leaders working through the complexity of first-time launches. We hope this gives you a structure to work from and a shared language to bring your teams together as you move from science to strategy to success.

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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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