



RESOURCES

Home
Resources
Resource Center

Poll: 4 of 5 Phase 3s Are Preparing for Serialization Before FDA Approval



Even though Phase 3 companies may not have a product on the market this November when the manufacturer serialization deadline for the Drug Supply Chain Security Act (DSCSA) takes effect, a large number of them are preparing anyway. That's the finding based on poll results from our recent [DSCSA Journey: A Day in the Life of a Serial Number](#) webinar.

On May 2, webinar attendees from 24 virtual pharmaceutical companies gathered to understand the journey of a serial number as it travels through the pharmaceutical supply chain. According to poll responses, most of your peers are already in the active stages of researching and deploying their serialization infrastructure, even though many won't have product on the market for at least 12 months. How does your approach compare with your peers?

Here are the top poll findings:

1. 4 of 5 are preparing now—before their drug product has launched.

Serialization goes beyond printing and labeling, so whether you're [Clinical-Stage Pharmas: What Do You Need to Know About Serialization?](#) an orphan drug or the next blockbuster, planning in parallel with commercialization will minimize the risk that you won't be able to ship once your approval arrives.

Respondents indicate a strong preference for doing just that, with many jumping in even before filing an NDA. Of the 82% preparing for DSCSA before FDA approval, 56% are still more than 12 months away from launch. Another 11% are at least 6 months out. The rest of the respondents still in Phase 3 (33%) expect to commercialize in the next six months. Just 18% of respondents currently have a drug on the market.

2. 9 out of 10 companies are currently researching, designing, or actively deploying serialization.

While half of the respondents are still in the learning or research stages, the other half are further along in their plans. Today, 43% of respondents are designing their serialization program, and 7% are actively deploying serialization in the U.S.

CMO line and software upgrades can take 12 months or more, and lead times are getting longer. Once you've identified your CMO and 3PL partners, you'll want to discuss scheduling logistics, line equipment needs, your specific technical requirements, and meeting data exchange demands as soon as possible.

3. 55% will aggregate in the next 12 months.

While DSCSA doesn't require aggregation, more than half plan to do so anyway within the next year. Virtual companies looking to avoid the higher cost of another project later will often choose to aggregate at the same time they implement serialization. Polls indicate that just 10% are considering the option of adding aggregation later. The remaining 35% of respondents are still learning about aggregation before they make a decision.

Your decision will impact packaging processes, distribution operations, CMO conversations, and more, so whether or not your company aggregates—and on which lines—is a determination you will need to make.

If your Phase 3 or virtual company has invested years of work and millions of dollars on a product, the last thing you want is to be held up by compliance

following your long-awaited FDA approval. [Watch our on-demand webinar](#) to see what it takes to manage DSCSA compliance throughout the life of a serial number, including:

- Journey through an end-to-end serialized workflow.
- See the benefits of partner onboarding in a network environment.
- Learn how to leverage your network for operational efficiency.

Blog Serial Number Manager Phase 3 / Commercialization Serialization United States

Subscribe to Agile Supply Chain Insights

Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

More Serialization and Compliance Resources



Four Reasons Why Pharma Companies Need a Serialization Intelligence Solution

Pharmaceutical companies need real-time visibility into operations, people, and systems across serialization infrastructures. See the reasons why.

[View More](#)



Serialized Operations: Challenges and Opportunities

How do your serialized operations compare with more 100+ pharmaceutical companies? Get the results of TraceLink's serialization program assessment.

[View More](#)



From Reactive to Proactive: Take Control of Your Serialized Operations and Achieve Operational Excellence with Self-Service Analytics

Learn about the unprecedented rise in supply chain disruptions and what it will take for pharma manufacturers to get products moving again.

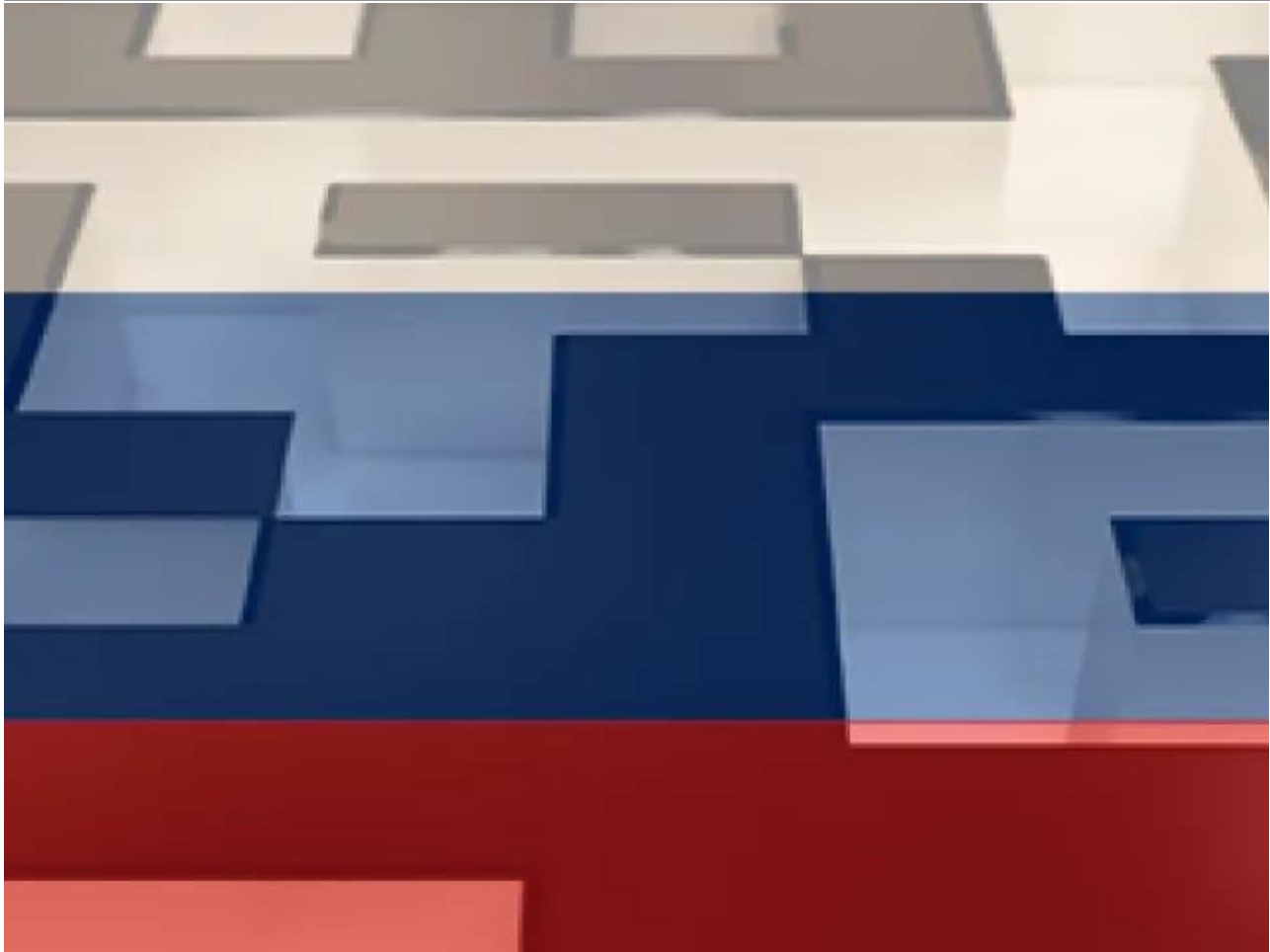
[View More](#)



Solving the COVID-19 Pharma Supply Chain Struggle

See exclusive research on COVID-19's impact on pharmaceutical supply chain agility, visibility, and resilience. Get actionable insights.

[View More](#)



Poll: Russia Crypto Codes Create Unique Operational Challenges Manufacturers Must Address Now

Companies are moving forward with Russia compliance and crypto code strategies. Are you behind?

[View More](#)



94% Recommend Product Track with End-to-End Administration Services

See how pharmacies continue to realize significant time and cost savings with TraceLink service.

[View More](#)