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.

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