

Excellis Q&A: Why Phase 3 Manufacturers Shouldn't Delay Serialization

If you're a clinical-stage company still waiting for FDA approval, the compliance hurdles you face are comprehensive—especially with the **Drug Supply Chain Security Act (DSCSA)** serialization deadline for manufacturers coming in November. Getting ready for both commercialization and serialization at the same time requires a significant investment in staff, infrastructure, and support.

To navigate the industry sea change, many Phase 3s are turning to Excellis Health Solutions—a U.S.-based consulting group and TraceLink Certified Partner with decades of experience supporting the extended pharmaceutical supply chain. A full third of Excellis customers are virtual Phase 3-type companies that have either just launched or about to launch within the next 12 months, and are simultaneously preparing for both DSCSA compliance and commercialization. In a recent conversation with Excellis CEO Greg Cathcart, we discussed his company's philosophy behind phase 3 planning, the technical challenges of DSCSA, and how to avoid bottlenecks during implementation.

Are most Phase 3 companies aware of DSCSA requirements, including serialization?

To be honest, DSCSA is catching a lot of clinical-stage companies by surprise. Most are focused on their clinical processes and programs, and have not yet been

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affected by new regulations for their commercial products. We've been working with private equity groups that have funded these companies—educating them on what Phase 3s need to be aware of—so that we can help their funded partners prepare for DSCSA and other commercial issues.

Are these Phase 3 pharmas starting their serialization planning before they get FDA approval?

Most companies start their planning efforts prior to launch, and then launch the final product-labeling phase when they get the PDUFA letter from the FDA. During that time, we'll get to work on building their DSCSA strategy, implementation of their T3 and serialization solutions, and integration with their CPOs and 3PLs. You can't launch until final labeling is approved, but you have the foundation in place to prepare for the PDUFA date. This way, you can make sure when you get the okay from the FDA on the PDUFA note, or they give you the date, you're ready to launch.

How do Phase 3 companies work with CMOs/CPOs and 3PLs?

Once you get a product approved, you'll be performing business processes as a virtual manufacturer. Without facilities, the product is manufactured and packaged by a CMO or CPO, and picked, packed, and shipped by a 3PL 99% of the time. Connecting to trading partners is much harder than connecting to your own site, so don't underestimate the effort it requires. More importantly, make sure your trading partners are as prepared as you need them to be. Many times, we see they're not ready—especially the smaller specialty packagers.

How can Phase 3s address the technical challenges of serialization?

Phase 3 and virtual companies understand the immense challenges but they don't have the technology infrastructure or IT team to know how to set up and manage data exchanges, how to get their file formats correct, and all the other complex details. That's why many of them look to a skilled solution partner for help.

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Do you recommend aggregation for Phase 3 companies?

I would absolutely suggest implementing aggregation at the onset. There are other things to worry about, like launching your second, your third, and your fourth product. The last thing you want is to have to revisit aggregation at a future point in time.

Most Phase 3 products are biologic, anti-cancer-type drugs that are high-dollar, low-volume products. In the grand scheme of things, serialization is not going to be that expensive. Don't try to cut the minimal expense at the risk of having issues a year from now.

Why do you think Phase 3 companies are taking such a proactive approach to serialization?

The virtual and Phase 3-type companies are focused on their product launch, and recognize that help with compliance is needed. For them, it's about being ready and being prepared. When a Phase 3 has $50 million of private equity money in it—maybe they've already gone public and raised another $200 million—are they going to put all that at risk? No.

What's your advice to companies that might not be ready by the November deadline?

The real message is don't stop working. Make sure you have a strong plan, so even if you're not live and the FDA walks in your building, you can show them a plan, and the fact that you're on your way to completion.

Once companies achieve compliance, are they done?

Compliance needs to be an ongoing focus. You can be out of compliance 30 days later if your software isn't updated. Our message is simple: work with a partner who will help you stay consistent on software releases so you get all the newest functionality to meet the changes in the regulations on an ongoing basis.

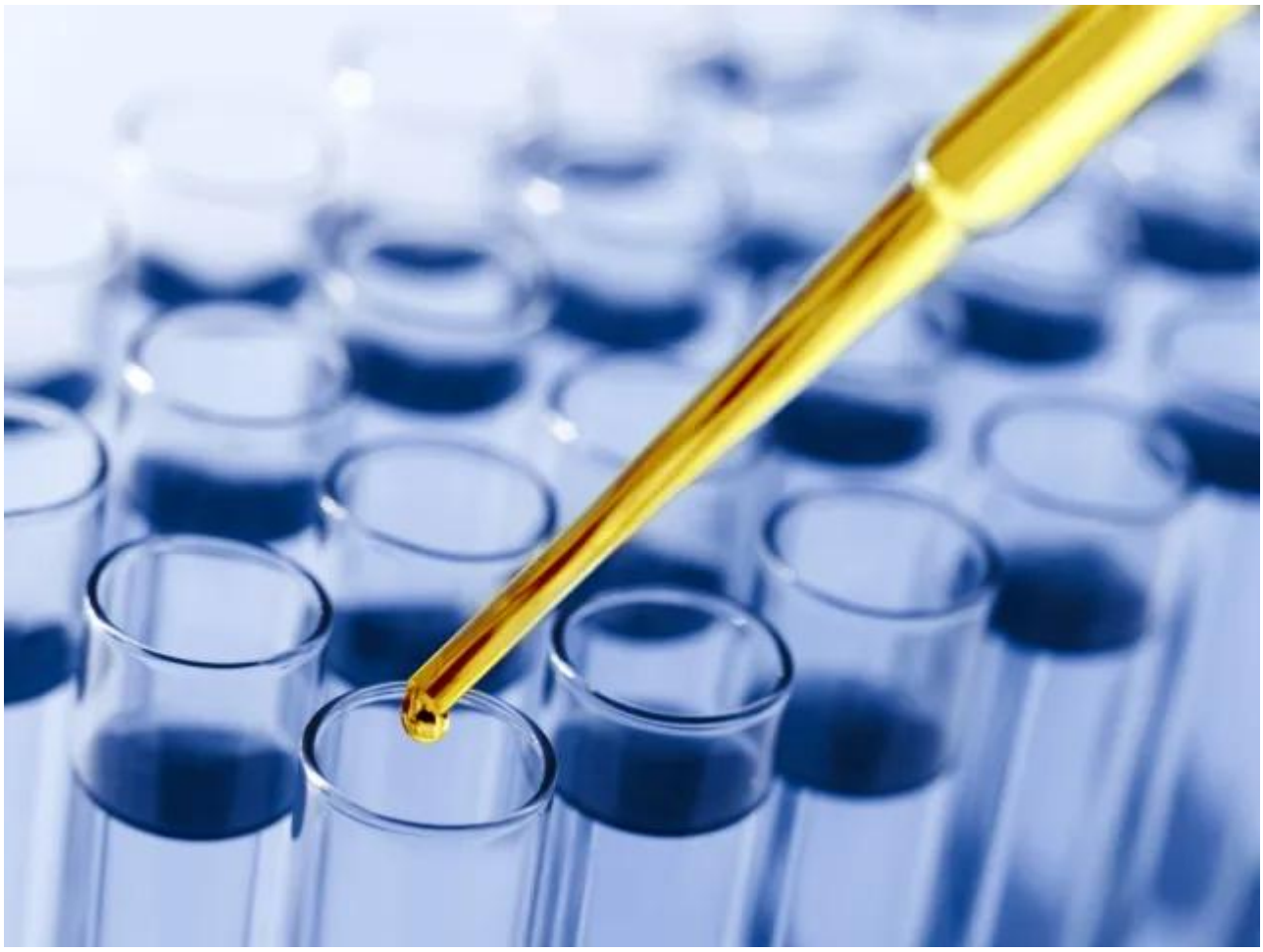
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Greg Cathcart is the CEO of Excellis Health Solutions. He is responsible for the company's strategic direction and growth, as well as cultivating emerging markets. He is a recognized industry leader through his work with HDA, NACDS, PDA, and is a founding member of Global Track and Trace (GTT). In 2010, AMR Research recognized Greg as one of the top ten influencers in the pharmaceutical supply chain industry. Recently, Greg was nominated for CEO of the Year by the Philadelphia Alliance for Capital and Technologies 2017 Enterprise Awards.

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