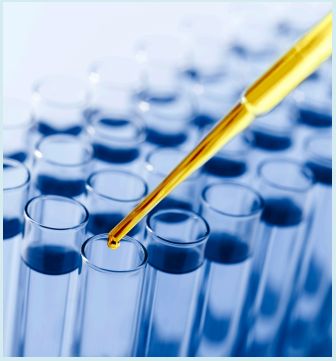
RESOURCES

Why Phase 3 Flexion Therapeutics Seized On Serialization Early



The road to commercialization is lined with compliance hurdles from start to finish. But for clinical-stage companies today, the additional challenge of serialization is unlike anything seen before. Under the U.S. Drug Supply Chain Security Act (DSCSA), even pre-commercial Phase 3s must be ready to devote additional resources to serialization. Because once the November 27 deadline hits, federal law will require it for all manufacturers.

For Flexion Therapeutics, Inc., waiting to address serialization after their FDA approval was not an option. Instead, the early mover shares why Phase 3 companies must address serialization before the time of your FDA filing.

Tomorrow’s approval requires planning today

John Kuczek, Senior Director of Supply Chain, says Flexion’s serialization and commercialization efforts have been happening in parallel from early on. “This is our first commercial product launch and we knew we only had one shot on the goal here with getting our medicine to end patients,” he says. “We have to be risk averse, so we took a stance to implement serialization with product launch.”

As Flexion began to identify its CMO and 3PL trade partners, the Burlington, Mass.-based biopharma began to realize that serialization would need to be tied directly

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to identifying its supply chain. Kuczek's team knew that taking a wait-and-see approach to compliance would be too risky. "When we were on the precipice of Phase 3, and deciding to take our product to commercial, we saw that we would have to have a serialization program while also building a supply chain from the ground up," he says.

"When we started this process, we were told by consultants that serialization would take us six to nine months. But as a small company, we still have to focus on a lot of other things, too. That much time for implementation is huge for us. We don't have the resources to dedicate a team entirely to just serialization while we're also thinking about launching a product, building a supply chain, and building up quality systems," Kuczek says.

In order to ensure they could meet the legal requirements of DSCSA at the time of launch, Kuczek's team planned to give themselves a full year to build out their serialization program, plus additional research time in the beginning.

The road to Flexion's serialization: A brief timeline

Stage	Start Date
Educational process	15 months before PDUFA date
Vendor review	13 months before PDUFA date
Implementation	9 months before PDUFA date

Choosing a proven industry leader for serialization

"I would say we're going to use up every inch of that year that we gave ourselves to do this," says Kuczek. With their commercial launch scheduled this October, Flexion is set to join hundreds of other TraceLink serialization customers who have benefited from early planning.

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In fact, 4 out of 5 companies with FDA-approved drugs since 2016 are already operating on the TraceLink network as a TraceLink partner or customer. And 2 out of 3 clinical or commercial pharmas with medicines approved since 2016 are TraceLink customers today.

“Ultimately, we selected TraceLink as our EPCIS vendor,” Kuczek says, “because we knew we could use them to leverage their capabilities as industry leaders.”



John Kuczek is Senior Director of Supply Chain at Flexion Therapeutics. He is responsible for overseeing Flexion’s trade partners, and for building and implementing Flexion’s commercial supply chain. John has more than 14 years of biopharma experience in GMP laboratory and manufacturing, as well as supply chain planning, execution, and strategy development. He previously worked in executive supply chain roles with Cubist Pharmaceuticals and Biogen.

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