RESOURCES

CMOs and CPOs: Best Practices for Approaching Serialization



As contract manufacturers and packagers for a large share of today's pharmaceutical products, you are critical to the industry's ability to meet upcoming serialization deadlines. Your compliance success hinges on starting early, but you have dependencies on supply chain partners that make it hard to control your own destiny. How can you best prepare for the November 2017 US DSCSA deadline, the European Union FMD 2018 one, and others?

1 - Recognize your two primary tasks

Between now and November 2017 you need to upgrade your lines and achieve data exchange with customers. Without the first, you won't be able to produce and package serialized product, and without the second you won't be able to pass the critical serial number information to upstream and downstream supply chain partners. If you don't successfully address both of these tasks, you will be out of compliance and unable to conduct business as usual – and your customers may be forced to seek other providers.

2 – Start the line conversation now, but be prepared for delays

Because upgrades may cost between $250,000 and $500,000 per line, you will likely want to secure pharmaceutical partner support. Start those conversations now: reach out to each of your partners to discuss their needs, negotiate finances, and agree on a schedule. But expect this process to take time. Most

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pharmaceuticals are focused on upgrading their internal lines first and aren't ready to address external ones. And because there is no established commercial model for shared lines -- which partner should pay for how much of each upgrade? – those negotiations will take even longer. Get discussions going but then turn your attention to lower-hanging fruit.

3 –Take care of communications

While you're waiting for line issue resolution, cross the communications piece off your list. Choosing a solution is a smaller investment, and completely in your control. TraceLink works with 15 of the top 20 pharmaceutical companies in the world. If you choose the TraceLink network as your solution for data exchange, you will be able to easily connect with the pharmaceutical customers that represent the largest part of your business. And if you already share a data exchange platform, they just may prioritize you when they turn their attention to external lines.

Your ability to remain a valued partner to the pharmaceutical community hinges on your readiness for serialization. But being ready on time may also open up opportunities to win business away from competitors who haven't planned ahead, and allow you to turn the regulatory burden into a competitive advantage. Aggressively pursue line upgrades, and make data exchange seamless with as many partners as possible by choosing the industry standard.

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