I run a contract packaging company, and I get all kinds of questions from new customers. Most questions are specific to the job, but two are fairly common.

“What is your normal lead time?”

Is that a trick question? Allow me to pose it a little differently: “From the time I get you all my materials and signed approvals, how long will it take to package my product?”

If your project is very large or entails a lengthy campaign, ask for the expected run rate of the product. You may also want to know the specific type of equipment to be used. For example, if your product will be packaged in a blister, ask how many blisters the machine forms per cycle. At what cycle speed has that format been qualified? With this information, it’s fairly simple to calculate how many hours, days, or weeks your job might take. I also recommend you compare this information with the data you gathered during your capabilities audit.

There are a few other aspects to keep in mind, too.

Approvals. Waiting for you, the customer, to approve printed material proofs is a common source of delays. In fact, proof approvals often take longer, in calendar days, than actual production. They are also a major cause of missed target dates.

Product on site. It’s a good idea to discuss production windows and how they relate to our receipt of your bulk tablets or capsules, especially if they’re to be delivered by a third party. Most contract packagers prefer to schedule a production slot only after the bulk product is in house and all approvals are documented. Rule #1 in contract packaging: If we don’t have it, we can’t pack it.

Tooling. If your blister packaging job requires custom tooling, ask about the issue as soon as possible, because that could extend the lead time and cause delays due to approvals. We also need to price the tooling. To get the best pricing on a job, match the number of blisters per cycle (format size) to the run size and line speed. Larger runs are more likely to call for larger tooling formats to overcome speed constraints.

“Can you take care of my track-and-trace responsibilities?”

My response to this question is a question: What responsibilities are you asking about? I’m not sure that I understand yet what the different responsibilities are or whose they are. In fact, I don’t think the FDA really knows. Here is what I am prepared to do:

• Place a machine-readable, matrix code on each individually dispensable package of drug product. The code will represent a secure, randomly generated, unique identification number that will follow that unit to its final destination. An automated system will record the new package and its new identification number.

• Place that uniquely identified package into a shipper carton of the size and design you prefer, along with the number of sibling packages that you assign to the shipper. The system will “take attendance” in the shipper by reading the unique identification numbers and assigning them to their new container. The shipper will be closed and labeled with both human- and machine-readable documentation that will allow it to be tracked to a pallet that meets your shipping specification.

• Give each pallet of product its own equally informative label that will relate to a data package assembled for your entire batch.

• Assemble an electronic data package for your batch that contains the previously assigned identity of the product you shipped to me and that records its chain of custody from my dock to your truck. That data package will be compatible with industry systems and will present the identification of each individual package, the shipper, its siblings, and the pallet identification. I will provide that data package to you in whatever industry-compatible format you select.

I know what you’re thinking: “That was the easy part!” And you’re right. But the rest of track and trace is up to you.

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