ThermoFisher SCIENTIFIC

Top five questions asked about pre-filled syringes

You've assessed dosage, stability, and bioavailability and have determined that your drug dose form will be an injectable. When the time comes to choose your packaging and labeling supplier, here are five important questions to consider.

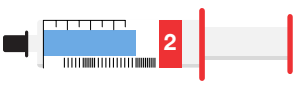
MADE WITH

TECHNOLOGY & TRUST

What are key differences between a fullyautomated vs. manual process?

- Automated solutions are ideal for larger batches, but it is important to understand they take longer to set up due to special equipment engineering requirements. An advantage to automation is it provides the highest job throughput (e.g. 1,800/hour), enabling shorter lead times from product to patient while delivering a lower per-unit cost. Also, packaging and labeling is completed according to exacting, system-enforced precision and quality standards.
- Manual processes are ideally suited for very small batches. They require less up-front job setup when compared to automated solutions, and can be implemented in a shorter timeline from the date you make your supplier selection. It is important to understand that this approach requires increased labor to perform the work and, due to opportunity of human error, requires a higher level of quality oversight.

Is the process for assembly and labeling consistent across all global facilities?

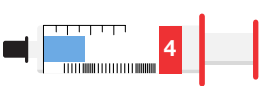


- When running a global trial, every aspect of that study must be executed in a consistent fashion. A quality-focused supplier should ensure standardized, regulatory-compliant procedures are followed regardless of their facility location. As an example, a packaging process in China should be the same as one managed in the United Kingdom.
- Packaging and labeling processes vary between manual and automated systems. It is important to note that automated systems will always be able to perform at higher, more exacting precision standards e.g. label placement within +/-0.5mm accuracy when including dosing graduation. Even so, quality should not be compromised in a manual system and may require increased oversight to ensure standards are met.

How are precision and consistency guaranteed?

- You need assurance that every unit you package is held to a high and consistent standard. To help guide that process, precision / tolerance standards should be established as part of the launch activities so that quality assurance oversight is implemented to ensure compliance.
- An advantage of automated systems is that they can include real-time integrated electronic verification and inspection of each process to reduce the opportunity for human error while optimizing quality.
- To ensure precision and consistency in a manual or semi-automated production process, many suppliers will incorporate the use of in-house created custom-designed tools to facilitate high quality, consistent results.

Is it possible to assemble and label under cold room conditions?



- Many temperature-sensitive products have very stringent "time out of environment" thresholds. When working with refrigerated and/or frozen product, the more process steps that take place at the designated temperature, the greater the chance of maintaining product integrity.
- To help decrease product "time out of environment," facilities can be designed so that the product can be received, packaged and stored at temperature.
- Something that seems simple, like affixing a label, can be complicated in a cold chain environment due to condensation. When possible, labels should be specifically designed to facilitate cold room assembly and subsequent storage.

What kinds of backup systems/ equipment are in place?

- Regardless of the extensive planning that takes place, unforeseen issues can arise due to system failures or catastrophic events. As part of your evaluation ask your supplier to share their business continuity plan to ensure your study will not be unreasonably impacted.
- In the event of a catastrophic event, a viable approach is to work with a supplier that has multiple physical locations that can serve as backup to each other using the same, standardized processes and procedures that have been defined in support of your study.
- When evaluating suppliers with automated systems, you may want to ask what back-up plans have been designed into the system itself, for example multiple lines.

LEARN MORE

No one likes surprises. Asking questions early in the process will help you and your supplier design a solution that will meet your current and future needs.

+1 919 226 3200 ● thermofisher.com/patheon ● pharmaservices@thermofisher.com

patheon

Published 09/21