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Partnering for Success

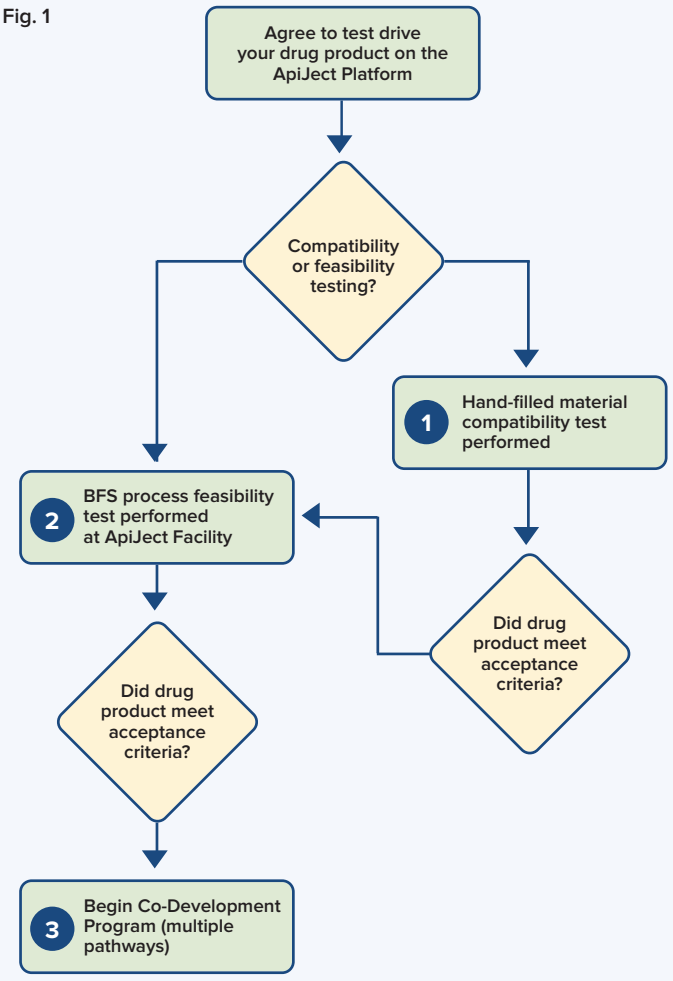
How to Get Started with ApiJect

It has never been easier to assess whether Blow-Fill-Seal (BFS) and the Prefilled ApiJect Injector* is the right packaging and delivery solution for your injectable drug product. Before entering a co-development program, you need to consider whether your drug or vaccine product is 1) stable and compatible with an LDPE primary packaging container, and 2) feasible for ApiJect's temperature managed BFS aseptic filling process. ApiJect can answer these questions using a low-cost low-risk process, while also highlighting foreseeable technical hurdles that will impact your critical fill-finish decisions.

Assessment Before Committing to Co-Development

There are two entry points when initially considering your drug product for an ApiJect device. ApiJect's Pharma Services Team will help you in assessing the right entry point for your drug, considering factors such as product availability, existing data, and risk tolerance. *(See Fig. 1)*

Fig. 1



1 Compatibility Assessment

The drug product is filled by hand into an empty LDPE container provided by ApiJect, and then assessed for chemical stability, typically over 1-3 months.

This process can be done by the pharma partner with support from ApiJect personnel. If the result is acceptable, then the feasibility assessment can be performed.

2 Feasibility Assessment

Feasibility Assessment is the key decision point before proceeding with co-development of a combination device. The drug product is filled and sealed in LDPE containers via ApiJect's proprietary temperature-managed BFS aseptic filling process. This is done at ApiJect's Florida facility.

Once filled, sponsors typically conduct 3 months of stability testing and leachables assessment. Where appropriate, ApiJect can collaborate to conduct device performance testing.

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3 Co-Development Program

Co-development programs typically fall under a device development program or a repackaging initiative. A comprehensive device development program typically spans from conceptual design to full-scale development, ensuring seamless integration of the device with the drug product.

A repackaging initiative is usually done for marketed products that are looking to transfer from glass vials or prefilled syringe to an ApiJect delivery solution.

This may entail re-packaging into the first generation 0.3-1.0 mL ApiJect device, or a new device for > 1.0 mL injection.

Common Questions and Answers

Do I need to conduct both an LDPE Compatibility Assessment and a BFS Feasibility Assessment?

No. BFS Feasibility Assessment will provide the relevant LDPE material compatibility data. However, if conducting LDPE Compatibility first, a Feasibility Assessment of the BFS process is required prior to moving forward with a co-development program.

What types of drug products/ vaccines have you supported, or think are compatible with your BFS process?

ApiJect's temperature managed BFS process has shown to be suitable for a variety of small molecules, biologics, emulsions, suspensions, mRNA vaccines, and peptides.

Who does the device functionality testing?

Device functionality testing is carried out by our team in Durham, NC. If appropriate, ApiJect can provide real world feedback via our Field Research Network of community healthcare workers.

How do I know whether I should consider conducting a Compatibility Assessment before undertaking to a Feasibility Assessment?

Consider the following:

- Do you have less than 8L of a product available for testing?
- Are you concerned about the product's chemical stability if it is exposed to 55°C for approximately 5-10 seconds?
- Is your data supporting stability of the product in LDPE lacking?

If you answered "Yes" to any of the above questions, then a Compatibility Assessment may be the appropriate first step.

Who performs the analytical testing?

Analytical testing results are compared to the current closure system, typically determined by the client's analytical methods or by a third-party lab to evaluate the compatibility of the drug product or vaccine with the temperature controlled BFS process and chemical stability within the LDPE containers.