DPT Thought Leadership
Issue 4

KEY STEPS TO CONSIDER WHEN WORKING WITH A CDMO TO IDENTIFY OPTIMAL PACKAGING OPTIONS

INTRODUCTION

There are many factors to take into consideration when selecting or designing a packaging component. Steps involved during the initial stage of the process are extremely important in ensuring that the most optimal packaging is identified. Working with a contract development and manufacturing organization (CDMO) early in the process helps eliminate packaging problems that may arise after the development stage.

RATIONALE

A service provider should begin the process by evaluating the chemical background to identify potential compatibility issues. Subsequent steps include review and evaluation of container/closure requirements and evaluation of container/closure form, fit and function. Then, the container/closure should be analyzed to ensure compatibility with the product. The next step in the packaging development process is to create container/closure specifications and assist in documentation preparation for regulatory submissions. At this point, the CDMO should provide packaging instructions or production modules. Engineering studies should be conducted to analyze packaging capabilities and identify critical parameters to be used in packaging validations. If something unforeseen occurs that requires modification, the CDMO should begin analysis and troubleshooting as soon as possible.

A CDMO with extensive experience in providing packaging services will then determine compliance with regulatory requirements, the product's presentation to the end user, proper use and adherence, and the most efficient way to avoid delays in getting the product to market.

SOLUTION

A CDMO that focuses on specific formulation types can provide valuable insight into selecting the right packaging options. This is based on their knowledge of specific formulations, as well as their understanding of physical properties that work well with a particular type of packaging. A strong relationship with the packaging component vendor is also essential for timely delivery and product specifications.

An experienced CDMO can evaluate a company's preferred delivery system and discover it may not work for that type of formulation. At that point, the CDMO should suggest alternatives or modifications that make it compatible with the formulation or packaging equipment.

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Involvement in the early stages of development provides the CDMO with the advantage of knowing how the product was engineered and the most efficient way to achieve a robust and repeatable process. An experienced CDMO should also be knowledgeable about packaging for a wide range of product types, such as those that are sensitive to oxygen, moisture, light, temperature, or other environmental factors.

Essential packaging services a CDMO should offer include:

I. Pharmaceutical Packaging Services

- Identification and sourcing of relevant packaging options
- Design input to initial concepts
- Packaging specification development
- Formulation and package compatibility assessment
- Proof-of-concept demonstration
- Packaging equipment sourcing, design and engineering services
- Ballpark commercialization estimates
- Turnkey sourcing services for unique and specialized drug packaging

II. Primary Container Evaluation

- Volume delivery verification per actuation and doses per container
- Spray pattern evaluation
- Dosage repeatability

III. Container Closure Compatibility Testing

- Thermal analysis
- Light transmission
- Water vapor permeation
- Non-volatile residue
- Heavy metals
- Extractables and leachables

CONCLUSION

Whether a company is developing a new pharmaceutical product or improving an existing drug delivery system, there are numerous factors to consider when outsourcing packaging services. An experienced CDMO that is involved early in the process is the best resource to identify the most optimal specialty, unique or custom packaging solutions.

ABOUT DPT LABORATORIES:

DPT is a contract development and manufacturing organization (CDMO) providing companies the best solutions to their sterile and non-sterile pharmaceutical development and manufacturing needs through innovation, technology, and service. Specializing in semi-solid and liquid dosage forms, DPT has a reputation for quality, unmatched technical expertise, extensive manufacturing capabilities, and an exemplary regulatory compliance record. With five cGMP facilities in San Antonio, Texas, and Lakewood, New Jersey, DPT offers full-service outsourcing solutions, including stand-alone development, site transfers, state-of-the-art manufacturing, packaging, and worldwide distribution. For more information, call 210-476-8100 or visit www.DPTLABS.com.

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