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## Blister pack design considerations

A detailed approach to drug packaging design provides time and cost-efficiencies for a growing biopharma company

**Clinical trial primary packaging projects that require blister packs involve numerous variables that can impact cost and timelines. For a sponsor that has limited experience, engaging the services of an experienced packaging supplier is essential. Determining the best approach requires detailed information gathering, and a design strategy that ensures the solution meets requirements, and is delivered on-time and within budget.**

### The challenge

A growing biopharmaceutical company needed a solution for a blister packaging project. Although they had performed in-house blistering operations in the past, that service was not available to support this particular study.

The clinical trial team wanted to re-purpose the materials they already had in their warehouse. Beyond that, and because this team had not executed a similar project in the past, they had a limited understanding of the details required to have their packaging supplier generate a detailed estimate and project plan. They needed someone that could guide them through the process, and turned to the Thermo Fisher Scientific to provide the experience required to define a solution.

## The Solution

### Defining the blistering process

Blister tools need to be designed and produced for the appropriate blister tooling and package configuration. Because they were starting at the ground level, the Packaging Project Manager requested drug samples or, at minimum, technical drawings. Failure to get samples or tablet/capsule technical drawings of anticipated deliverables can cause significant time delays and potential increased costs if discrepancies are discovered once the project reaches the production room.

The team evaluated Thermoform vs. Coldform blistering options. Although most commercial products use Thermoform materials where you can see the drug in the blister, the film is more breathable and, as a result, it isn't ideal for light or humid sensitive product. A disadvantage is the blister film can have a longer lead-time (13 to 14 weeks). By contrast, Coldform materials have a shorter lead-time when compared to Thermoform (e.g. 3 weeks). Because the product is fully sealed in foil, it is more suitable for products where stability data is a primary concern.

The next issue that needed to be considered was whether to utilize a slit/chop vs. punch format for the blister tooling. The slit/chop feature allows flexibility to create blister strips of varying sizes. Although perforated blister strips also provide flexibility on blister strip size, it requires a special perforation tool that can potentially add an extra month to the project lead time.

Having considered Coldform vs. Thermoform and also the required format, the Project Manager recommended Coldform with slit/chop tooling. This design would provide the greatest product protection and overall flexibility. The approach proved extremely beneficial when the sponsor made a late-stage decision to change the blister strip size. The Project Manager also suggested that they start with this approach for the smaller earlier-phase studies. By doing so, the tooling costs could be applied over the entire study, reducing overall costs.

### Preparing for production

When the Thermo Fisher Scientific team reviewed the blister materials the sponsor intended to provide, they discovered they were the incorrect web width and the outer roll diameter was too big for the blistering machine. As a result, the sponsor had the blister materials cut to the required specifications in advance. This proactive Blister tools need to be designed and produced for the appropriate blister tooling and package configuration.

Evaluation prevented the inevitable unexpected 'surprise' at production time which would have introduced a multi-week delay and cost increase above the project estimate.

Drug overages were something the sponsor had not considered, but are essential to ensure project success. For example, start-up and in-process inspections are performed during the production process to ensure the quality of the final product. The Project Manager provided guidance to the sponsor so that an appropriate product overage was included in the budget. As a result, there was no unplanned stoppage in production which would have required another job setup with associated study delays.

### Proactive future planning

Because the sponsor performed secondary packaging operations in-house, working with Thermo Fisher Scientific helped address issues that might have arisen later in the process. For example, when designing the blister card, it's important to consider blister strip size and if blister strips will be used in multiple studies. Large Coldform blister strips could result in larger blister cards that are less convenient for patients to handle. By engaging in collaborative, fully-transparent design discussions the team was able to ensure the best possible end-to-end solution.

### Conclusion

Leveraging Thermo Fisher and the expertise of the Senior Packaging Project Manager the sponsor was able to save time and money across their study. The consultative project management approach resulted in a solution that:

- Accelerated timelines by selecting materials and tooling that had shorter lead-times
- Improved product protection by using an approach better suited to drugs with limited stability data
- Increased flexibility by choosing a production technique that is easily changed without requiring additional tooling
- Eliminated delays by ensuring sufficient overage was on hand to support full production runs
- Delivered cost-efficiencies by making upfront investments that could be applied across all phases of the study

The packaging design job was a collaborative effort with the sponsor and several Thermo Fisher Scientific teams. Sharing detailed information in a timely way shortened the setup time, minimized issues and resulted in a quality deliverable. Throughout the process, the sponsor gained knowledge and insight that will benefit future projects as well.