

# UNITED WITH CREATIVITY & COMMITMENT

## Broad thinking yields big results

A creative packaging solution yields significant savings for an emerging biopharma company

There are numerous details when considering product packaging that require both creative thinking and feature prioritization. Rather than developing a standard solution for the current need, it's imperative to think broadly and design options that are cost effective, simplify operations and save time and/or resources.

#### The challenge

A small, emerging biopharma company developing an oncology Investigational Medicinal Product (IMP) had been working with Thermo Fisher Scientific to blister-pack capsules in a 12-pack strip. The project was for a single protocol involving a small patient population using three different dosing strategies with a limited amount of drug product.

Over the course of three to four months the requirements changed multiple times, impacting the packaging process, requiring constant repackaging. When this client had a new compound ready for an early Phase I trial, the initial drug product was needed for 10 patients. Within a three to six month window, patient enrollment was forecasted at 100-150. Based on their earlier experiences, the client and Thermo Fisher Scientific team recognized they required a solution that provided greater flexibility to avoid the constant repackaging and associated waste. The Senior Project Manager engaged with representatives from the client as well as internal partners to create a viable and scalable alternative.

#### The solution

During the job initiation meetings, the client identified that most of their product needed to be delivered in factors of three. The Senior Project Manager enlisted the support of the operations and engineering teams at Thermo Fisher Scientific, as well as their labeling colleagues to design a solution. The new idea was to create a blister pack with perforations in strips of three. Depending on the study, materials could be supplied in multiples of 9, 15, 18 and 21 blisters all from one primary manufacturing run. When it came to designing the outer wallet, the team realized that a single larger wallet would provide the flexibility of using one wallet for all dosing configurations. Because of its size, they were able to design a single-panel label that accommodated the six required languages, eliminating the need to print individual booklets – saving the client on cost and time.

API

BIOLOGICS
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SEE

VIRAL VECTOR
EAF
SERVICES
PHA

EARLY & LATE
PHASE DEVELOPMENT

CLINICAL TRIAL SOLUTIONS  COMMERCIAL MANUFACTURING

LOGISTICS

SERVICES

patheon

With a sketch of the proposed approach, the engineering CAD team was able to create a three-dimensional proof-of-concept model. Having a visual sample helped everyone make additional suggestions as well as more informed decisions. The Design, Label and Quality teams worked well together because the end goals and objectives had been clearly communicated by the Senior Project Manager. Additionally, their involvement ensured the solution presented to the client had their full support.

When compared to the more traditional approach, the client recognized the clear advantages to be gained by using the solution presented by the Thermo Fisher Scientific. They vetted the approach with their own internal Quality team, and ultimately it was approved.

### Conclusion

By creating a collaborative, multi-discipline team with clearly identified objectives, the Thermo Fisher Scientific Senior Project Manager was able to deliver a solution that offered clear improvements for this client:

- Adopting perforated blister packs offered the flexibility required to support multiple dosing strategies
- Using one wallet design across all studies reduced storage and costs; only the inside card needed to be changed
- Applying a single-panel label with multiple languages enabled small batch print on-demand runs vs. the more costly booklet production
- Packaging re-work was eliminate delivering time and cost savings
- Design was fully scalable through all phases of the trial

Two years later, this approach is still in use for this client and has been scaled up for other products/protocols. Creating a new method can be risky, but with input and proper testing it can lead to successful outcomes.

