klöckner pentaplast
white paper

DESIGN OPTIMIZATION AND RAPID PROTOTYPING SOLUTIONS FOR BLISTER PACK DESIGN, DEVELOPMENT, AND TESTING

a four-part series of white papers

INTRODUCTION

Previous papers in this series have shown how new tools for accelerated stability assessment and digital modeling allow packaging engineers to perform sophisticated "virtual prototyping" that streamlines the process of designing and evaluating blister packaging for pharmaceuticals. With those tools, engineers can now predict packaging performance with a degree of detail and certainty that could not be achieved previously.

This final paper will discuss how the information and designs generated by that process can feed a rapid prototype production facility like Klöckner Pentaplast's (kp) Blister Technology Center, where engineers design and build the tools that form the blisters and use state-of-the-art blister machines to produce prototypes for testing. This rapid production model allows pharmaceutical packaging development to move from design to prototype production to stability testing in very short time frames. That speed to production also means that multiple iterations for design and material adjustments can take place with unprecedented rapidity. What once could have taken months of design, testing, and feedback can now in many cases be accomplished in weeks.

PAPER IV:
RAPID PROTOTYPE PRODUCTION FOR BLISTER PACK STABILITY TESTING

DESIGNING THE TOOLS

The first step in moving from virtual modeling to the production of physical prototypes is to design the tools that will form the film into blisters. The thermoforming process will vary in some details depending on the product application and the machinery being used, but by and large a thermoforming production line for blister packs involves the following steps:

1. A plastic laminate film is passed over a "forming tool" or mold in the shape of a blister card.
2. The machine subjects the film to pressure (either air pressure, or possibly physical pressure from a "plug" that is designed for the task) which conforms the film to the mold.

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3. The blisters are then separated from the mold and filled with doses of the product.
4. A second application, typically a foil with heat seal coating or a laminate with child resistant features, is pressed into place by a "seal tool" to seal the blisters.
5. The production line then performs any finishing steps that are needed (perforation or trimming, for example) and outputs finished blister cards.

Working from the refined models of the desired cavity shape, engineers use industry-standard 3-D Computer-Aided Design (CAD) software to design the forming tool and the seal tool for the production line. At this stage, the design engineers can begin to take into account not just the required shape of the blister itself, but also any requirements imposed by the manufacturing process and materials limitations. For example, certain card geometries and compositions may require stiffening ribs to reinforce and support the card. Blister molds will typically require vacuum holes to allow for air to be vented as the blister is formed so that the film can reach the desired shape. And seal tools must be designed to account for stretching and thinning of the film during thermoforming. All of these things can be implemented and accounted for at the tool design phase of blister development.

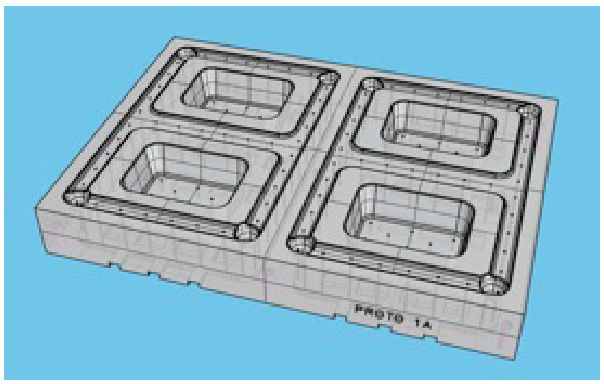

Figure 1: 3-D CAD model of a forming tool for a blister pack

COMPUTER-AIDED MANUFACTURING (CAM)

In the next step, the 3-D CAD design of the forming tool and seal tool are passed to computer-aided manufacturing software. This software automates the process of turning the 3-D model of the tools into the machine instruction codes that drive the actual fabrication. The CAM software analyzes the shape and constructs a fabrication process for achieving it. That process will involve hundreds of small steps, each of which must be properly described with the CNC (computer numerical control) codes that are appropriate for the milling machinery being used. In most cases, all of the steps and the codes describing them can be auto-generated by the software. However, each of the fabrication processes can also be directly specified or edited in the software by the engineers, allowing them to refine the process in whatever ways are necessary.

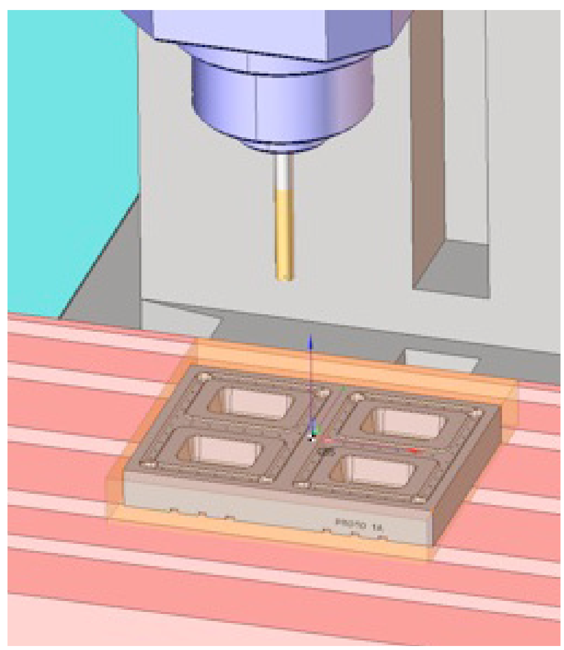

Figure 2: Digital dry run of form tool machining process

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Once a provisional machining process is arrived at, the CAM software can generate digital dry runs of milling and lathing. The dry run is animated on the computer screen with 3-D wireframe models. This digital modeling of the manufacturing process allows the engineers to further fine-tune the fabrication before it is actually run, eliminating costly and time-consuming mistakes, and allowing for streamlining and optimization.

When the process is refined and finalized, the CNC instructions are sent to the mill. A block of raw material, typically aluminum, is fitted to the mill, and the proper machining tools are set up, and the fabrication proceeds automatically. The process will typically involve rough passes to bring the raw aluminum block into approximate shape, then a series of finishing passes with finer tools to achieve a high-precision finish. The fabrication process for the tools can be completed in a matter of hours.

With tools in hand, the engineers are ready to start producing prototypes.

BLISTER PRODUCTION AND TESTING

The use of Finite Element Analysis (FEA) software, outlined in Paper 3 of this series, is one of the two most significant recent developments in blister prototyping. The other is the arrival of state-of-the-art blister machines that can be set up in a matter of minutes and produce runs of thousands of prototypes in hours. For the cost of luxury automobile, and with a size that is similar as well, these machines make it possible for a cutting edge facility like kp's Blister Technology Center to serve as a one stop shop for rapid prototyping.

The presence of design, tool fabrication, and blister production all under one roof means that the time lag between iterations of a design can be reduced considerably. Testing for shelf-life, marketing and labeling, and other user acceptance considerations can now proceed in a tight feedback loop with requests for design refinements and newly-revised prototypes—all of which speeds progress toward the final design.

With customer approval, the prototype production line can then serve to produce runs of thousands of samples—for stability testing, for child-resistance testing, or for any other requirements.

Figure 3: Uhlmann B 1240 blister machine produces testable quality blisters rapidly.

SERIES CONCLUSION

New developments in chemical stability assessment, digital prototyping, and rapid prototype production are now revolutionizing the process of moving pharmaceuticals quickly through package design to stability testing and user testing. A state of the art prototyping facility can serve as a one stop shop for

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designing and producing high quality prototypes with a speed that was never achievable before. The result is greater control over design parameters, a faster arrival at optimal designs, rapid movement through prototype iterations, and a greatly accelerated time to market for pharmaceutical manufacturers looking for an edge in the marketplace.

The presence of all of this expertise under one roof has another benefit as well. With the growing dispersal of drug and packaging production to low-cost zones around the world, blister design engineers can provide essential technical expertise, training, and support for implementation of a global production strategy. The experience of producing prototypes and samples means that engineers can help establish standards, practices, techniques, and training to ensure quality in a globally dispersed production environment.

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