First Step in Design

The idea has been thought up, the "napkin sketch" has been made, and the project is ready to move forward. So what's the first "real" step in the design process? This was the question for the participants in this month's Perspectives feature. Ideally, you will be able to take away a tip or two before embarking on your next project.

Once the general idea for a new device is formulated, what aspect should first be addressed in the design process and why is this the critical first step?

Craig Berky

VP of Research & Development, Interphex Medical LLC

When we have an opportunity to begin a new project as engineers, our inclination is to log onto the computer and start-up our favorite CAD program with our design notebook at our side starting the first sketch, leaving the paperwork behind for someone else (hopefully quality) to worry about. Unfortunately we have learned over the years that this is not a practical way to begin developing anything, especially medical devices.

After reviewing the proposed concepts, ideas, and sometimes prototypes, our first step is defining the scope of the project. We do this by initiating a Design Plan and populating a Project Plan. These are the first steps to define the scope of work to be performed. In several instances, our customers may have a preliminary Design Specification that we will use as Design Inputs to begin defining the boundaries of our design. The Design Inputs are a pseudo contract that defines the attributes of the devices; for instance, the device must be able to be activated in either hand and the required force to pull the trigger must be less than 15 lbs. We will then begin a draft our Failure Modes and Effects Analysis (FMEA). By identifying potential failure modes up front, we are able to design systems or mechanisms that provide a fail-safe mode rather than identifying a failure mode that may result in severe patient harm with no feasible way to prevent the occurrence. Now we have initiated a structured approach to begin designing medical devices and our engineer is back to doing what he or she enjoys most: designing.

Ron Celander

Director of Engineering, E-Switch INC.

As the electronic industry drives towards smaller, more compact devices, the switch industry has been forced to follow in this same direction. This push for smaller switches with enhanced features has given new challenges to engineering teams. So once a market need has been identified, the first approach for a new switch design is to fully identify the required features and given size constraints applicable

to the application. Such items would include the mechanical, electrical, and environmental requirements as well as any processing or manufacturing issues from the end user that would need to be addressed. This then allows the engineer to evaluate the most important areas where they will need to concentrate their efforts. For example, the material selection process for the switch will have to take into account the type of soldering process the switch will have to withstand. Or, if the new switch design needs to incorporate illumination, there are limitations on LED package sizes and how to effectively connect the LED terminations through the switch device.

Once the functionality for the switch is established, the engineer can then effectively begin the design process. Working within the given parameters on size, he can identify any design concern areas such as minimum wall thickness, ribs and support features, minimum bend radii, etc. With a clean precise definition on the product requirements, it allows the engineering team to efficiently design a product and minimize development costs. The last thing you want is to have engineering working on a new switch design for several weeks and then tell them that the product needs to be a double pole switch instead of the single pole version they have spent countless hours on. This only leads to frustration as well as large over runs in development time and money.

Jack Stritch

VP, Buisness Development, Freetech Plastics Inc

To ponder the question as to what's the first step from the perspective of design, I say, "Consider the chicken." The experience of good design happens when the human comes in contact with the object and, because of this interaction, creates the possibility of doing something fun, or interesting, or great. Whether that interaction is visual or tactile, the color, texture, smell, sheen, and feel of the material all contribute to the experience and are why material selection is the first step. It's where the rubber meets, nay, crosses the road.

I participate in the world of plastics, and my assessment is that material selection is key to design-the elementary element. There is something wonderful that happens in human/object interaction, specifically an amorphous structure. I think back to high school when, in a moment of boredom (or deep thought, but I suspect it was the former), I rested a Chuck Taylor Converse All-Star on my knee and doodled a little doodle on the side of my rubber sole. The feeling of rolling my Bic over the rubber, in circles and squiggles, is as silky sensual and seductive now as it was in 9th grade. Exterior comes first. The more pleasurable the interaction experience, perhaps the better the design.

Some could argue that we are all individuals and differ in such a manner as to have different experiences when in contact with the same object. Perhaps with the possible exception of the bathroom mirror, I believe this to be not exactly false, but not entirely accurate. If it were the case that we are all special and unique individuals (as our grandparents would assert), why then do my glasses look basically the same as yours, only mine are plastic and yours are metal? The design distinction is the critical point-the material. Metal, leather, glass, wood, polycarbonate-the material used in the product in many cases IS the product. Sit in the "wood" chair or drink out of the "plastic" cup.

The chicken came first.

Peter Resca

Director of Engineering, Astrodyne Corp.

Product design and development is never simple. Each project has unique requirements and objectives to consider. Creativity, imagination and a working knowledge of the design tradeoffs are required to arrive at an optimal solution.

When designing medical devices, one should first consider the electronics, since electronics typically influence a particular solution or enhancement. Electronics impact product functionality, efficiency, and utility. For instance, the selection of components such as microcontrollers or advanced sensors may facilitate the processing of new or existing information in greater detail.

Another reason to first consider the electronics is because that portion of the design is often the least flexible. The molding (housing) is commonly custom designed for an application, dictating the optimum form factor or most appealing design.

Material selection is also an important and often critical cost driver that is impacted by a wide range of options. For instance, careful consideration of project parameters such as temperature and component isolation may persuade a designer to use costlier materials. However, since several solutions may be available, this is not necessarily a primary consideration.

Recently the power options have expanded. With rapid turnaround times, companies can deliver modified power solutions based on standard platforms that meet medical requirements. Also, economically priced custom power supplies with increased efficiencies and features are available, even at relatively low volumes. Traditionally designers have considered power sources at the end of the design cycle. Having recognized this oversight, power manufacturers anticipate this common practice. Consequently, the value proposition offered by power supply manufacturers provides medical device OEMs with shorter design cycles and easier system certification.

John Zeller

Engineering Manager, Guill Tool & Engineering Co.

Today, when a new medical tubing device is formulated, the first aspect addressed

in the advanced design process is the multilayer or multi-lumen tubing requirements.

With the accelerating array of new medical technologies being introduced, the demands on medical extrusion require ever greater performance in ever smaller and smaller applications. The increased sophistication of the latest medical devices now require extrusion tooling to produce tubing with multiple layers and multiple lumens. These new specifications may call for anywhere up to eight lumens, some with wire inside, some with braids, and some with different lining materials.

And there seems to be no end in sight for the complexities that users demand. Right now, the sky's the limit on multi layer needs. For example, sheet manufacturing requirements may go up to 10 layers.

More performance in less space, along with rising costs of and shifts in materials used, have increased the demands on extruders for a continually increasing level of product and process innovation in all types of tubing and all other related medical applications.

Tighter tolerances are a key requirement for a host of new medical extrusions. Many of our customer OEMs note that the tolerance requirements are getting even tighter. In terms of percentage of wall, the previous tolerance goal was 90%, but today, we don't blink at 95%. In fact, we have customers that are running 99% to 99.5% tolerances on their walls.

As wall thicknesses decrease due to the new smaller size requirements of tubing and other medical extrusions, it becomes difficult to retain all the desired properties using a single material, and increasingly, the solution has been co-extrusion. By combining two materials, with each material containing specific benefits, it's now possible to create a thin-wall tube that will maintain the rigidity of a thicker-wall tube.

Larry Carlberg

Service Bureau Manager, Laser Design Inc./GKS Inspection Services

In today's marketplace, a part must be manufactured economically to move forward with the design process in the majority of cases. However, approaching product design from a fiscal standpoint should not disregard other important considerations that ultimately play a role in the success of a new product. The primary consideration is what is the critical first step?

Designers, engineers, managers, and manufacturers all have a vested interest in the new product, and all can argue that their perspective is worthy of the first-step consideration. Considering molding as the first step will make sure that the impact of time and cost for tooling changes will not be overlooked. The success of most new products can be traced to beating the competition with the introduction of the new design. This strategy is not new, but is well tested and worth repeating.

How do you integrate molding considerations prior to the final design of the product? The answer often lies with the method chosen by the R&D group that introduced the new product concept in general terms. More than likely, a prototype model was developed to convey styling designs, provide feel and function tests, and satisfy some engineering requirements. This valuable introductory model has some of the design features built in, but no molding considerations. A simple, fast, and effective means to capture the prototype design in a computer model for developing molds is by reverse engineering a CAD model with 3D laser scanning. This method delivers a generic CAD model used by designers to integrate the mold design of the product before or in parallel development with electronic components, material consideration, and marketing aspects.

The result is a shortened time to market from concept to successful finished product.

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