Perspectives on First Step in Design (Part V)

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.

Q: 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?

Prashanth Rajendran
COO, Pilgrim Software Inc.

Prashanth Rajendran.

The new product development process has changed as the demands for compliance continue to evolve due to an increasing number of regulatory and market standards. In addition, further pressures are applied with reduced research and engineering schedules and new complex applications. To ensure the best "Quality by Design," companies need procedures and training that leverage best practices. These include a thorough understanding of customer needs and technology capabilities; a tighter integration of engineering, manufacturing, quality, regulatory, and marketing departments; a risk-based approach to focus on critical issues; and a culture for continuous learning and evolving the company.

What's the first step? Once it is decided that a design concept is feasible and will be developed, a plan must be established to determine the adequacy of the existing design elements and to develop the appropriate design controls as outlined in 21 CFR 820.30 (a)(1) and (b). The plan and the design controls (policies, processes, and procedures) do not assure the quality of products and services but they provide the best framework for assessing and documenting quality earlier in the development process. With an appropriate plan and design control approach, manufacturers can avoid common inspection problems such as failure to establish procedure for design (the most common design control FDA 483 observation*); no

design and development plans; and risks found but not addressed, etc. The documented plans and controls should be optimized for the organization and product with varying levels of details based on risk. The procedures must ensure compliance, but also contribute to quality and productivity. Keep it simple, succinct, and defendable so volume does not increase unnecessarily due to auditor comments. Streamlined and well-documented design plans and control processes will increase personnel productivity and can yield significant time to market benefits.

**Source: FDA Turbo EIR database 04/05-04/07*

Brian T. Reilly
Product Director, Healthcare Material, NuSil Technology

Brian T. Reilly.

Material choice is a critical step once the initial design for a new device is conceived. Often, a customer with a design idea will have a material in mind based on an existing material or familiar product. Although, important factors to consider in the material-selection process are how the material will be processed and the physical property attributes, we find that our job as the material supplier is to ask the critical questions to accommodate the customer's production needs (e.g., limitations, cure parameters, target elastomeric properties, etc). In many cases, this will be solved with an off-the-shelf material, but what happens when a standard product is not the optimal choice or does not exist? A customized material may need to be developed to fit the parameters of the device. In addition, safety and quality must also be built into the device.

Development of a material with a pre-established regulatory support strategy is highly recommended. The key to new material development is the supplier's willingness to provide global regulatory support for those materials. An intimate relationship with a supplier who can develop a product with quick, seamless responsiveness and has the knowledge of regulatory requirements saves tremendous cost and time down the line.
The material manufacturer should have a documented quality system certified as conforming to ISO 9001 and cGMP 21 CFR Part 820 (current Good Manufacturing Practice). If the device is used as a long-term implant, regulatory support should include a comprehensive masterfile (MAF) submitted by the material manufacturer to the United States Food and Drug Administration (FDA) or other international regulatory authority responsible for regulating the safety and efficacy of healthcare devices and products. Therefore, proper material considerations, regulatory support, and a productive relationship with your supplier will assure a smooth

transition to the next stage in the design process.

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Our perspective is as a component supplier providing functional adhesives, tapes, coatings, and dissolvable films to medical device manufacturers.

Regardless of the end product, the critical first step is an open dialogue with our customer&#151the device manufacturer. It is important to determine where the customer is in their product development process. Is the project at the concept stage, in feasibility, have prototypes been made, or is the product further along in field or clinical trials? Once this is established, we can determine the critical design features of the product and translate these into technical requirements, component properties, and process parameters.
Specifically for adhesive tapes, it is necessary to know the use conditions. What surfaces will be bonded, will the device be used at elevated or low temperatures, will the device be sterilized, and if so, what method and dosage? What biocompatibility testing is required to ensure safety? What are the storage conditions and shelf life requirements? During use, will the device be exposed to biological fluids, moisture, or other reagents?
It is also important to determine the regulatory requirements, since these will dictate the manufacturing environment and controls. A quality system is needed to control and document the product and process development and manufacturing controls. What testing is required and do test methods and processes need to be validated? Product specifications need to be set dependent on process capability and customer needs.
Medical device manufacturers should consider adhesive selection early in the

design process because of the functionality and versatility medical-grade adhesives can provide to help improve their devices or products. Combining two or more properties (hydrophilic/hydrophobic, low fluorescence, biocompatibility, special spectral, porous, breathability, electrically conductive, skin friendly, dissolvable, permanent/removable, long-term wear, etc.) can reduce the number of parts used in a device or product, thus reducing manufacturing costs.

Marco Bafan
Engineering Analyst, Nerac

Marco Bafan.

The design process needs to align with the product's final application, especially when the final product has any physiological interaction with the body. Knowing this helps establish what all the steps in the design process will be and ensures that all regulatory compliance issues will be adhered to. However, the key to the design process is materials selection as most medical devices incorporate materials and manufacturing processes such as injection molding or extrusion. Once the final application of the device and the required materials are determined, all the succeeding steps should be planned out to facilitate device configuration and minimize the potential risks. For instance, in the case of a device that contacts tissue, implementing a predictive analysis tool, such as nonlinear finite element analysis (FEA), can anticipate and avoid some of the devices potential device problems. In the case of a tissue-contact device, local stress at the tissue interface point can be addressed and minimized in advance. In materials selection, all the mechanical or biochemical requirements should be identified as accurately as possible to avoid costly mistakes in the development process. Materials selection can also subsequently help to properly account for cost analysis, assembly requirements, and manufacturing. Taking the appropriate steps at the start of the design process can ultimately accelerate the time to market and significantly avoid costly mistakes. The regulatory nature of the industry places additional pressure on

designers to meet increasingly tight specifications. The designers need to be highly aware of these regulations.

Corey Wesnitzer
Executive VP, General Magnaplate Corp.

Corey Wesnitzer.

Rather than being considered in the early phases of the design process, the coating of devices is too often an afterthought for design engineers.

Typically within the medical industry, engineers are looking to extend the life of equipment by protecting parts from corrosive attack by test specimens and analytical reagents. Protective coatings not only guard metal parts against corrosion, they also provide wear resistance, lubrication, and structural integrity to prevent sticky fluids from clogging up carousels and other critical analysis equipment.

Engineers risk extending product-to-market time by not making the coating of metal parts a primary consideration early in the design process. The most common issues we are presented with are engineers specifying a coating process that cannot be completed properly, or one that is simply not feasible because of the design of the part.

Each type of coating process, whether it's plating, anodizing, or thermal spray, has its own unique properties, but that also brings a unique set of limitations too. For example, electroplating or thermal spray coatings have "line-of sight" issues so what you see is what you can effectively coat. If a surface cannot be seen but needs coating, a more suitable immersion process needs to be considered.

"Air pocketing," on the other hand, is an issue with anodizing and plating so if a critical surface needs to be coated, the engineer needs to ensure there is access to the surface so that air pockets can be removed.

Other factors that affect the type of coating and the success of the process are the choice of base metal, the part configuration, tolerances, and the ability to mask certain areas and to rack parts.

By communicating with the coating engineers at the outset of a design and explaining the properties required, engineers can make informed decisions on recommendations for base metal and part configuration. Process limitations and properties can be discussed and the end result is a much smoother product development cycle.

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