Medtronic: A CASE STUDY

The benefits of making key decisions early in product design can be substantial. After integrating DfE into the design of a medical product, Medtronic, Inc. reduced chemical use and wastewater loading, resulting in annual savings of $2.1 million dollars. In this case study, learn how the company integrated environmental considerations into product designs to achieve multiple, significant benefits.

Background

Medtronic Inc.(Minneapolis, Minnesota) is a leading manufacturer of cardiac and neurological medical products. As a medical device manufacturer, there is an incentive for the company to optimize initial product designs and associated processes, since changes made later often need government approval. In addition, environmental concerns in medical products can cause delays in getting a product to market due to the need to obtain environmental permits. The company also recognizes that inefficient processes generate large amounts of wastes, which increase manufacturing costs.

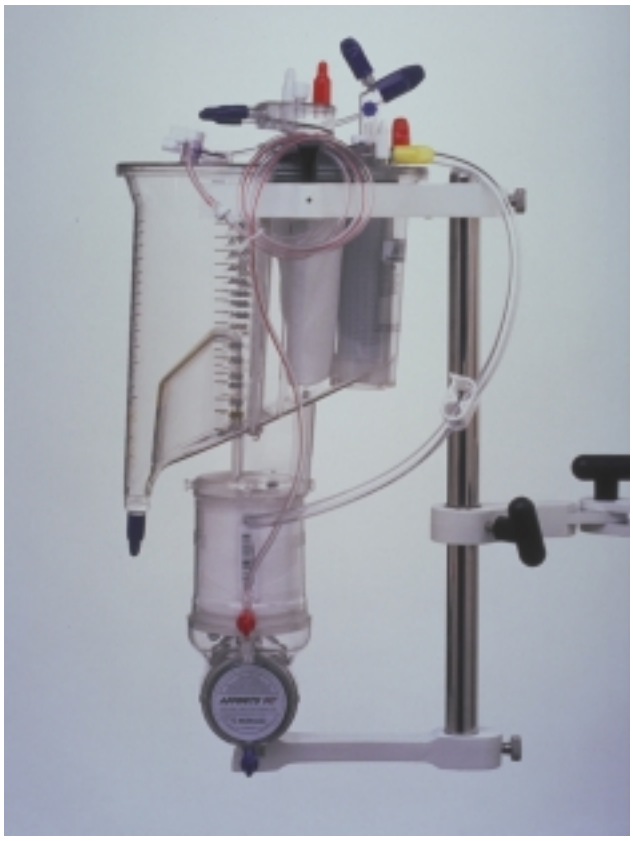
These issues were successfully addressed early on by bringing new perspectives into product design. The new perspectives came from a unique method of integrating DfE into product design developed by environmental personnel. This is a description how environmental personnel became part of the product design team, the challenges, and ultimately the significant results in product improvements including large cost savings.

Results of the Project

Integrating DfE into product design at Medtronic, Inc. has had impressive results:

- a 75-85% reduction in chemical use and wastewater loading for a coating process, with annual savings of $2.1 million
- a planned 30-35% reduction in material use and a 90% reduction in industrial solid waste generation for a battery-manufacturing process, with potential annual savings of over $200,000
- DfE has been built into the system called "Design Control Methodology," which is used to design and develop all products at Perfusion Systems. These system changes which will affect all products developed in that business unit, are expected to yield benefits well into the future.

Find out how these significant results were achieved through the descriptions in the following sections.



The coating process used for this oxygenator manufactured by Medtronic, Inc. was optimized during the design stage, resulting in significant cost savings.

Becoming a Part of the Design Team

Perfusion Systems is part of the Cardiac Surgery Business of Medtronic, Inc. The development of a coating for an oxygenator, a blood-processing product, was targeted for DfE activities.

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During this project, it was recognized that upper-level management support was essential for success. Support from upper level management was solicited and received before the project was initiated. Another key for success was support from "champions" — people who are enthusiastic about the concept and have something to gain from the project.

To identify champions, it was important to consider each department's role in production. For example, the production department's performance is measured on how many products they produce in a certain time period. Therefore, anything that decreases the number of production "bottlenecks" and increases manufacturing cycle times is to their benefit. The research and development department (R&D) is interested in developing a coating process at a marketable cost, and can use environmental improvements in products as selling points to customers.

Because members from any or all of these departments could serve as champions, the rationale for suggested changes were based on covering all of these opportunities. This would establish a broad base of support for the change. For example, part of the production of the oxygenator involves a coating process. After evaluation, it was proposed that the concentration of the coating be decreased, to result in less coating material being used and a reduced wastewater concentration being discharged for an annual savings of $2.1 million. To decrease the manufacturing cycle time, consideration is also being given to reuse of the coating bath rather than making up a fresh bath for each batch of product. Because this proposed change offers opportunities — developing a coating process that meets the product quality criteria, significant cost savings, and environmental improvements — the proposal received broad support.

Thanks to upper management support, the environmental staff was invited to participate as members of the design team. Once on the team, they needed to first carefully listen and learn about the manufacturing process. They added value to the team by applying environmental concepts. For example, a sudden change in the type of coating that would be used would mean collecting and compiling new data rapidly. Opportunities to optimize the coating process for efficient materials use and cost savings would be compiled on a timely basis to keep pace with the rest of the product development process. Since product design is a dynamic process, environmental staff had to become consistent members. By attending the meetings, identifying and investigating specific opportunities to reduce environmental impacts and costs, then presenting the information, they became valuable assets to the team.

Building these relationships at Perfusion Systems, with both upper-level management and champions within departments, was critical to having the opportunity to bring improvements to product design.

Tools and Design Improvements

There were two tools used by the design team to evaluate environmental concerns. One of the tools, called the **Environmental Product Design Evaluation Plan**, consists of yes/no questions, a series of easy-to-read flow charts, and related documentation.

The first question in this tool is "Will hazardous materials be used to produce this product?" If the answer is no, the rest of the questions in the first section can be skipped. If the answer is yes, the quantity and other information about the hazardous material needs to be filled in on the form labeled Table 1. The entire evaluation continues in this pattern as water use, packaging, processing equipment and other potential impacts are reviewed. Through the use of this tool, there is a built-in incentive to minimize environmental impacts, since less impact means less paperwork to be completed.

The project manager, as head of the design team, is responsible for overseeing the completion of the evaluation. Once completed, the evaluation is given to environmental health and safety (EHS) personnel to review

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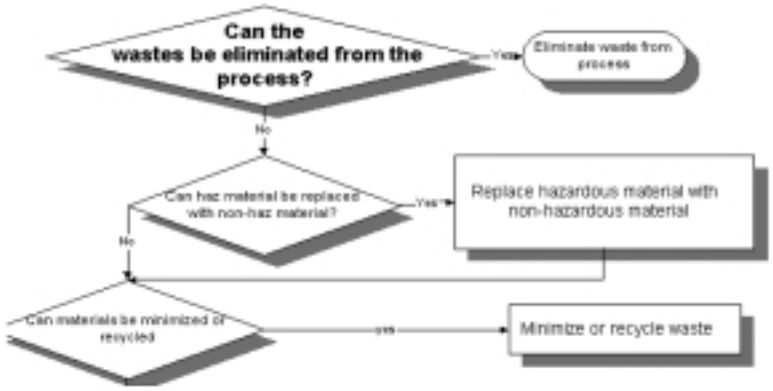
and offer suggestions for improvement. EHS staff then use a series of flow chart questions that ask technical questions such as those illustrated in the figure below to further assess environmental impacts. EHS staff can then suggest alternatives and improvements if needed.

A second tool, the **Materials Productivity Process Overview** is used to identify opportunities to improve the efficiency of materials use and the production operation. This tool also uses flow charts to target where the greatest impact can be made to reduce costs from waste. Alternative materials can also be identified by using the tool.



A partial view of a flow chart borrowed from the Medtronic Corporation Environmental Product Review Plan.

Both of the tools are first used after the product is conceptualized during the second phase of product design when the feasibility is studied and a prototype is developed. They continue to be used during the last two stages when the product is fully developed and manufacturing is established. There was a significant time commitment made by environmental staff during these stages of product design and development. This is because the use of the tools is a dynamic process that involves identifying opportunities as the design evolves, including changes in materials use and improving manufacturing efficiencies.

The earlier potential opportunities are identified, the greater the likelihood they will be used. In many cases, if opportunities are identified during the last two stages, it may be too late to implement them.

Explanation of the Results

In addition to Perfusion Systems, the Medtronic Energy and Component Center (MECC) and a project team reviewing sterilization alternatives used the DfE tools and related methodology to evaluate specific products and processes.

Oxygenator Coating

The development of a new coating for blood processing products was specifically targeted for DfE activities. Initial evaluation indicated that reductions in materials use could occur in a number of stages of the coating process. After further analysis and testing by the R&D department, reduced solution concentrations were incorporated into the coating system design.

Battery Cathode

MECC fabricates cathodes for batteries used in cardiac rhythm management devices. The cathode mix material is used in very small amounts, but is very expensive. After analyzing the cathode mixing and manufacturing process with the DfE tools, designers identified the dispensing process as an area for cost savings. Higher efficiency precision dispensing equipment, like the type used in pharmaceutical operations, was identified as a potential solution.

The waste disposal costs alone of $5,000 per year could not justify the purchase of $300,000-$400,000 for dispensing equipment. However, through the "cost of waste analysis" portion of the **Materials Productivity Process Overview** tool, additional expenses such as labor to change out filters and

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the cost of purchasing additional cathode mix were identified for a potential savings of over $200,000. Plans are underway to purchase new dispensing equipment.

Product Sterilization

The project team also participated in a review of an alternative to the use of ethylene oxide for sterilizing medical devices. An alternative process was explored because ethylene oxide requires special management so that it does not come in contact with employees, is flammable and must be destroyed before it is discharged to the atmosphere. The use of electronic beam sterilization was identified as a viable alternative. This potential change could have company-wide impacts since many products manufactured by Medtronic require sterilization.

In the Future

Medtronic, Inc. plans to continue to expand the use of the Environmental Review and Materials Productivity evaluation methods during product design. The screening part of these methods that identifies which project to target will likely be modified as additional experience is gained.

The success of these initial projects demonstrates that including environmental considerations early during product design can have multiple, significant benefits. Copies of the DfE tools developed and used by the Medtronic, Inc. are available by contacting the Minnesota Office of Environmental Assistance Clearinghouse at 1-800-877-6300 or (651) 215-0232.