Managing Medical Product Development Effectively: A Systems Engineering Approach

Jennifer Vondran and Richard Moroney, PA Consulting Group



For companies involved in designing and

developing medical devices and diagnostic instruments, adhering to design control principles at every stage is critical. This begins with the identification of user requirements (voice of the customer) and continues through verification and validation testing.

However, user needs, designs, and technical or program risks change rapidly during the product development process. Fluctuations challenge the global, crossfunctional teams that implement design and development programs, forcing them to adapt their work to ensure that quality, performance, and objectives are not compromised.

Medical device and diagnostics companies can improve the management of design and development changes—and achieve their programme and strategic goals faster—by using focused product development functions as the basis for knowledge management.

Smaller Teams Should Stick with Proven Methods

Most medical device and diagnostics companies use some form of systems engineering in their product development process. This is a tried and trusted method, where first-user needs are converted into design inputs and then broken into engineering requirements; these engineering requirements are then broken down further into specific design requirements (the design outputs). Each layer of the development process is matched with a set of verification and validation tests to ensure that the product is built correctly. When a product development team is small, this process usually runs fairly smoothly.

Complex Programs Call for a Different Approach

As product complexity grows, the obligations spread to different groups as more players become responsible for the different layers of development. Managing the interface between the groups becomes a major factor in protecting the integrity of the design. Communication can be complicated by the fact that each team is focused on a different set of requirements.

Consider a component such as a shaft: the user need might be for a flexible shaft, with the engineering requirement specifying a tubing material, outer diameter, and wall thickness, and the component design would specify complete details of the part, such as surface finish and material composition. With each group concentrating on a different aspect of the program, they must ensure that each piece of the puzzle comes back a perfect fit.

Having a single set of neutral product functions can help users, engineers, and designers communicate their needs and requirements to each other much more clearly. So, for the shaft described above, the functions might include "transmit pushing force along the shaft," "maintain an open lumen during flexure," or "allow for product sterilization."

Developing a Knowledge Management Tool to Support Product Development

It's true that developing a set of product functions adds to an already large set of design tables and lists of requirements and specifications that are frequently managed using spreadsheets. But moving this information into a relational database is a natural next step; it connects the different sheets into a much more powerful knowledge management tool. This database can then be used to highlight gaps in complex development projects, clarify conversations about the product (including portfolio-level discussions), and manage the change process, including complicated changes such as a cost reduction effort. It simplifies communication between different groups, such as R&D, marketing, regulatory, and manufacturing, helping the organization achieve its program and strategic goals faster.

The wider the effort, the greater the risk for confusion within product development programs. Companies that focus on communications and tools that enable better flows of information can limit that risk and move toward a faster, smoother outcome.

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