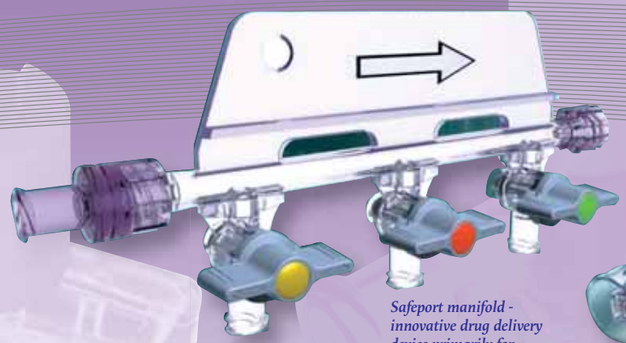
Minimal residual volume luer activated stopcock



Safeport manifold - innovative drug delivery device primarily for anesthesia procedures

Disposable pressure transducer

Slit-septum and cannula line Needleless components for intravenous applications

By **Shelli Zargary**

Validating Innovation at **Elcam Medical**

Ori Ziv, PLM Project Manager, IT Dept.

Mid-sized manufacturer of injection-molded disposable medical devices, Elcam Medical needed a collaborative product data management and process validation solution to comply with regulatory standards. By selecting ENOVIA SmarTeam, the company has improved production efficiency while ensuring product quality.

Elcam Medical is proof that a small company that combines ingenuity with product and process knowledge can succeed in the challenging medical device market. The company capitalizes on its product design and production procedure know-how by executing a smart business methodology supported by ENOVIA SmarTeam PLM. As a result, the company can offer a broad scope of validated medical products and services far beyond the capacity of most companies its size. With ENOVIA SmarTeam, Elcam Medical ensures regulatory compliance and product quality while increasing design and manufacturing process efficiency, saving time and money.

FROM IDEAS TO SOLUTIONS

The world's third largest supplier of disposable stopcocks, valve-like devices used for a variety of clinical applications such as measuring and administering drugs, Elcam Medical today delivers a broad range of fluid management, drug delivery and vital signs monitoring systems and devices to customers and OEM suppliers worldwide. In addition to its many products, Elcam Medical also offers full medical product development services "from Idea to Solution for the End-user", with particular expertise in high-volume precision molding, high-speed assembly and laser applications.

Elcam Medical selected ENOVIA SmarTeam to both organize its validation documentation, working with a comprehensive and easily accessible repository of all its validated product and process data, as well as to enforce these documented, standardized production procedures. This structured access to its knowledge has empowered Elcam Medical engineers to agilely and efficiently reuse validated designs to more rapidly develop more products, as well as to capitalize on its technological and production capacities by selling turnkey services to third parties with ideas for new medical products.

Saving time and preventing errors when building new product structures.

"To strictly comply with FDA (Food and Drug Administration) and ISO (International Organization for Standardization) standards, the medical device industry requires comprehensive tracking of development and manufacturing processes, forcing engineers to employ standardized procedures," explains Ori Ziv, PLM Project Manager in the IT Dept. "ENOVIA SmarTeam facilitates easy, complete implementation of such procedures. In this way, each engineer working on a drawing uses the latest, most accurate version, eliminating data duplication and human error."

LEVERAGING DESIGN REUSE

As a small manufacturer, Elcam Medical also needs the PLM system to enable design reuse to efficiently and concurrently manage its broad product configuration portfolio. According to Ziv Naftalovitz, R&D Leader, "The job of the design engineers is to translate specifications of customer requirements from the marketing department to SolidWorks 3D models. Receiving a new customer request, the engineer looks for relevant existing designs in off-the-shelf products that meet the specifications and copies them into the new product."

Project Leader Danny Moshe explains, "We try to avoid having to carry out a long, expensive validation process for a new product that involves only a small design change; we produce a huge volume of parts and sub-assemblies, therefore our documentation has to be very accurate and we must be very precise in design storage and reuse. ENOVIA SmarTeam has rapidly accelerated searching of design data. Efficient access, finding and reusing validated parts in new designs saves time and assures quality. Design engineers attach drawings to every work order that goes to production, and thanks to the system, production staff can print the correct drawings without involving the engineers."
In addition to tracking of product histories and enabling design reuse, the system facilitates collaboration via secure access to authorized users, with full transparency and measurability of all processes. "The main users are the product design and manufacturing engineers, QA and production planning," says Ori Ziv. "ENOVIA SmarTeam allows transparency in the interface between departments, so that, for example, the production team with one click, sees the right design data they need, and only this data. In the future, the Marketing and Business Development departments will also have access."

With one click, the team sees the right design data they need, and only this data.

THE KEY: A METHODICAL APPROACH

"To comply with FDA regulations, medical device manufacturers must perform process validation for all products, which requires adherence to strict methodologies, involving a very high volume of documentation," says Danny Moshe. "There are four stages in the validation process – Risk Analysis, Installation Qualification, Operational Qualification, and Performance Qualification. All of them must be fully documented. We automatically create process validation templates on top of the ENOVIA SmarTeam platform, saving a lot of time and preventing errors when building new product structures. Then the SmarTeam integration to MS Office enables efficient transfer to MS Word forms." He adds that they use SmarTeam Integration when designing equipment in SolidWorks, entering metadata into the ENOVIA SmarTeam profile cards. This correct data is then automatically featured on the drawing templates, saving a great deal of time and errors.

Moshe explains that the experiments they run during their production processes, involve several lots of tests with statistical information and voluminous documentation. In the future, they plan to use SmarTeam Workflow to automate the procedures.

By organizing the validation documentation, ENOVIA SmarTeam helps Elcam Medical improve knowledge management, moving them towards their future vision of running a paperless office. "ENOVIA SmarTeam protects and enables collaboration around all our valuable corporate knowledge," concludes Lior Izenberg, Elcam Medical Engineering Manager •

For more information:
www.elcam-medical.com

More about Elcam

With over 25 years experience in the medical device field, Elcam Medical develops precision injection-molded disposable medical devices for a variety of clinical applications: IV Therapy; Anesthesia; Patient Monitoring; Cardiology & Radiology and Endoscopy/ Laparoscopy, as well as drug delivery devices such as auto-injectors. Elcam is the premier provider of stopcocks and manifolds to the US and European OEM markets, supplying over 30% of their stopcock needs.