Technology collaboration: When to begin. How to succeed.

Elcam Medical and Eastman Chemical make early collaboration a win-win

Medical device manufacturers are continually challenged to be innovative while operating in a highly regulated environment.

When regulations or market conditions demand a change or create a new opportunity to improve patient safety, a manufacturer often needs to step outside its own comfort zone. Those prepared to draw on the technical experience of other companies—and are able to begin those collaborations early in the product development process—can reduce risk, eliminate false starts and avoid costly delays in bringing effective products to market.

Technology collaboration is particularly valuable when it involves specialized experience with the testing and data required for regulatory compliance. It can involve specialists in many areas, from material suppliers, to molders and mold makers, or others that live and breathe a specific expertise every day.

Two companies who are leaders in their respective fields share how collaborating early in the development process is expanding their opportunities for technical innovation and commercial success.

Made with Eastman Tritan™ copolyester, Elcam Medical designed its new Elcam Tritan™ integrated stopcock to meet new ISO 80396 standard for Intravascular and Hypodermic applications.

Two technology collaborators with a plan

Insight and long-term vision have fueled the successes of Elcam Medical and Eastman Chemical Company. Through years of experience working with hospital and government regulations, both are better prepared to anticipate future needs—then plan ahead for success.

Elcam Medical is a world-class manufacturer of disposable medical devices for the OEM market, with a 35-year history of helping customers connect to safer and more effective fluid management in medical settings—including applications in IV, monitoring, dialysis and nutrition.

Elcam's Validation and Verification process helps it collaborate effectively with OEM customers. Elcam brings this mindset to the table to make collaborations with Eastman efficient and effective.

Eastman Chemical is a leader in medical grade polymer solutions. For more than 65 years Eastman has worked with customers to deliver innovative products and solutions while maintaining a commitment to safety, confidentiality and sustainability.

Eastman's "total solutions" approach to the medical industry now offers world-class technology platforms and even greater insights into technical support in design, processing and secondary operations.

Working together, the companies have discovered many shared values that work in harmony with their specific technical capabilities. Most recently, their ongoing collaborations have resulted in chemical- and lipid-resistant connectors designed to meet ISO 80369 standards—both made with Eastman Tritan™ copolyester.

"The level of technology collaboration between Elcam and Eastman is still the exception rather than the rule,"
according to Eastman's Cedric Perben, EMEA medical application.
"We use it as a model to encourage the rest of the industry to plan ahead and develop trusted relationships with suppliers of materials technology."

Opportunities to collaborate at every project step

Elcam thoroughly understands how to design robust and reliable medical devices. Eastman has specialized and proprietary expertise about its materials. Together, they've been able to innovate and bring safe products to market more quickly.

"Our two companies have been successful at combining medical science and material science," according to Eldad Ohayon, Marketing Director from Elcam: "Based on our individual expertise and shared trust, we engage early in the development process to save time later in the process."

CONCEPT

Early in the concept phase, Elcam considers regulatory issues and fitness for use (FFU) of candidate materials. How will the product be used? What stresses will be applied? What chemicals will it contact? Are there minimum rigidity or toughness requirements? Answers to these questions help inform material selection and avoid costly false starts.

MATERIAL SELECTION

Meanwhile, Eastman continually refines a wealth of data regarding its polymers, such as data to demonstrate biocompatibility or compliance with other regulations. Eastman shares data with Elcam and can provide Product Regulatory Information Sheets and other documents required for premarket 510(k) submissions. Intimate knowledge of material properties also can make processing more efficient—and can help provide consistent quality and reproducibility.

DESIGN

Elcam has a solid history of innovative designs. Eastman provides expertise as well as specialized technology—including mold flow and mechanical simulations. At this critical design stage, it is common for Elcam to also dialog with other stakeholders—including mold designers and tool makers—as part of its validation and verification process.

TRIALING

Trial support validates the material and design choices and helps make any needed adjustments. Eastman uses infrared cameras as a specialized technology to monitor the mold performance and the cooling of the mold and parts. Also the drying capabilities are checked during the trial phase; the dew point was monitored under Statical Process Control (SPC) methodology.

MANUFACTURING

Early collaboration often eliminates any manufacturing issues before the first piece is produced. Unfortunately, many companies wait for the trialing and manufacturing stages to identify problems. Then, they are under a time and budget crunch to troubleshoot and find someone to fix the problem.

TESTING

Eastman continually tests properties of Tritan and other medical-grade polymers using equipment that gives Elcam specialized analyses they may not find on their own. Throughout this technology collaboration, the two companies apply this complementary information to confirm the material's fit for the specific applications and eliminate any disconnect between design and processing. For example:

- They tested how a part will withstand gamma radiation sterilization.
- They reproduced exposure to different chemicals and stresses that can reduce functionality.
- They expedited accelerated aging and other tests required for regulatory compliance and retention of product performance.

This collaboration extends beyond sharing technical expertise

Building on their success with sharing technical expertise, Elcam and Eastman have collaborated on the best way to introduce products to the medical audience. They have joined forces to create the messaging and communication tools to tell their story most effectively, for example during product launches that took place at industry tradeshows like MD&M East and Compamed show where both companies dedicate booth space to showcase the Elcam stopcock and the chemical- and lipid-resistant connectors designed to meet ISO 80369 standards—both made with Eastman Tritan™ copolyester.

Either company would be glad to tell you more about this success story.

Elcam-Medical.com

Eastman.com/medical

EASTMAN

Eastman Chemical Company
Corporate Headquarters
P.O. Box 431
Kingsport, TN 37662-5280 U.S.A.
Telephone:
U.S.A. and Canada, 800-EASTMAN (800-327-8626)
Other Locations, (1) 423-229-2000
Fax: (1) 423-229-1193

Eastman Chemical Latin America
9155 South Dadeland Blvd.
Suite 1116
Miami, FL 33156 U.S.A.
Telephone: (1) 305-671-2800
Fax: (1) 305-671-2805

Eastman Chemical B.V.
Fascinatio Boulevard 602-614
2909 VA Capelle aan den IJssel
The Netherlands
Telephone: (31) 10 2402 111
Fax: (31) 10 2402 100

Eastman (Shanghai) Chemical
Commercial Company, Ltd. Jingan Branch
1206, CITIC Square
No. 1168 Nanjing Road (W)
Shanghai 200041, P.R. China
Telephone: (86) 21 6120-8700
Fax: (86) 21 5213-5255

Eastman Chemical Japan Ltd.
MetLife Aoyama Building 5F
2-11-16 Minami Aoyama
Minato-ku, Tokyo 107-0062 Japan
Telephone: (81) 3-3475-9510
Fax: (81) 3-3475-9515

Eastman Chemical Asia Pacific Pte. Ltd.
#05-04 Winsland House
3 Killiney Road
Singapore 239519
Telephone: (65) 6831-3100
Fax: (65) 6732-4930