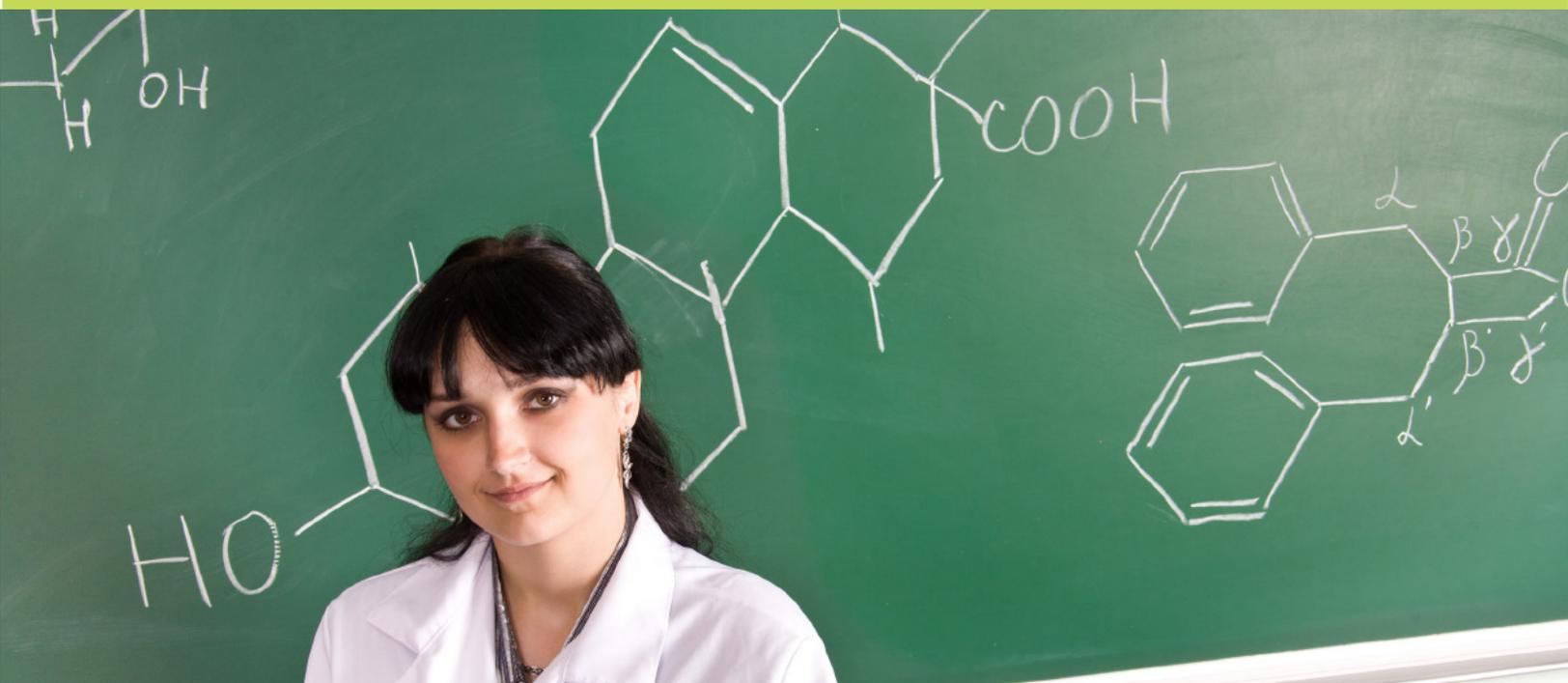


A Chemsultants International Case Study



A medical device company seeks expert recommendations on their process for manufacturing blood sensor strip laminates

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MISSION

To Make Recommendations to Improve a Life-Saving Process

TERUMO CARDIOVASCULAR SYSTEMS

Located in Ann Arbor, MI, Terumo Cardiovascular Systems is a group who develops, manufactures, and distributes medical devices for cardiac and vascular surgery. Their emphasis is on cardiopulmonary bypass, intra-operative monitoring, and vascular grafting. Each year, millions of patients around the world benefit from the use of Terumo CV Group Products. The parent company, Terumo Corporation, is a global medical device manufacturer, which focuses on cardiac and vascular specialties, hospital products, and home health care. Terumo has more than 11,000 associates in 82 sales offices and 17 production facilities around the world.

CHALLENGE

Terumo approached Chemsultants looking for expertise and knowledge in adhesives to evaluate a peel adhesion method that was being developed in their lab. They were seeking recommendations of their current process to manufacture blood sensor strip laminates.

THE PROCESS

The Chemsultants scientist studied the Terumo process, including materials, testing, quality, etc. offsite by reviewing materials provided by Terumo. His next step was to visit the company and study the entire process first-hand. By traveling to Ann Arbor, he was able to observe the lab, the materials being used, a large amount of data and properties. He examined the raws, the testing techniques, every action, material, and piece of equipment that was being utilized in the lab. After taking copious notes, he returned to Chemsultants and authored a lengthy report that included many potential process and testing improvements.

METHODS

Sample preparation was essential. The samples were pre-cut to a 0.2 inch width before arriving at Chemsultants. The specific film and polycarbonate were also laminated with the appropriate adhesive component and coating thickness prior to delivery. Stainless steel panels were used as a mounting surface to aid in the preparation of the samples. These panels were an 18 gauge (.043 in.) 304 grade with a bright annealed finish, which were obtained from ChemInstruments. The panels were used only as a rigid surface to support the polycarbonate film and meet PSTC specifications.

PEEL ADHESION

Peel Adhesion was tested according to a modified ASTM D 3330 method. The modification included the dwell time, pull speed, and substrate. Chemsultants is A2LA accredited to the standard method. Peel adhesion testing was performed on a ChemInstruments PA-1000 Adhesion Tester with the EZ Lab software program. Pre-laminated samples 0.2 inches wide were applied to a stainless steel substrate with a double-sided tape. The film was then peeled from the polycarbonate film at a 180° angle at 6 in./min. The data was averaged and a data stream graph was saved. All tests were conducted at $73 \pm 3^\circ\text{F}$ and $50 \pm 5\%$ relative humidity.



RESULT

This outstanding response from the Senior Engineer II at Terumo Cardiovascular Systems outlines the ongoing result of this partnership. On the following page, you will see a letter from a Senior Engineer at Terumo.



February 19, 2013

Our Production Chemistry Team at Terumo Cardiovascular Systems manufactures disposable products that are used during cardiac surgery. Our product requires lamination of various layers using adhesive technology. We were interested in improving our lamination processes and testing methods and Chemsultants agreed to help.

Chemsultants provided the services of a very knowledgeable consultant, Mike Hilston. After doing some homework on written materials that we had provided, Mike visited our facility for one day. After viewing our processes, he provided a report that included 21 potential process and testing improvements. These ideas were novel to us; there was little chance that we would have discovered them without Mike's help. We are in the process of evaluating these improvements for inclusion in our production and testing processes.

In addition to these suggestions, Chemsultants has a plethora of available benchtop instruments that are designed for adhesive testing, sample preparation and semi-automated lamination. During Mike's visit, he invited us to visit his laboratory in Mentor, Ohio. During our visit to Chemsultants, we were able to see the capabilities of this equipment and to try this testing equipment on our product. The Cheminstruments (which is a division of Chemsultants) equipment is well-suited to our production scale and testing requirements.

After Mike's visit we sent him samples of one of our substrates for Fourier Transform Infrared (FTIR) Spectroscopy analysis. The results of this surface analysis gave us some valuable information on the suitability of this substrate for use in our process. During our tour of Chemsultants, we were able to see the instrument firsthand, as well as other capabilities, equipment and expertise contained in the Chemsultants facility in Mentor.

The science of chemistry is vast; it is difficult to have expertise and knowledge in all areas that are required to engineer a robust product. Chemsultants has been and will continue to be a valuable resource and partner in our continuing efforts to improve our engineering process. At Terumo Cardiovascular Systems, our actions and decisions help save one thousand lives every day. We made the right decision in choosing to learn what action Chemsultants recommended.

Murray Rosenthal, Ph.D.
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UPDATE

After the visit to Chemsultants in Mentor and seeing the ChemInstruments testing equipment operational, the professionals from Terumo Cardiovascular Systems purchased a PA-1000 peel adhesion machine for their own use!

For more information

Please contact our Laboratory Services Group at:

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