

MEDICAL TECHNOLOGY FIRM ACCESSES FEDERAL LABS THROUGH REGIONAL PARTNERSHIPS

ABOUT TYMPANOGEN LLC. Tympanogen, Inc., was founded in 2014 by a team of engineers and physicians dedicated to simplifying medical procedures and reducing healthcare costs. They develop innovative ear, nose, and throat devices based on a proprietary hydrogel technology. Their flagship product, Perf-Fix™, will transform traditional tympanoplasty procedures into a quick office visit. Perf-Fix can be applied in an office setting within 10 minutes, without general anesthesia, 4 hours in the OR and 6-8 weeks of recovery time. This gel patch encourages regeneration of the full tympanic membrane structure at the same high success rates of traditional tympanoplasty. The product is currently under development, and recently received GAP funding from the Center for Innovative Technology (CIT) in Herndon, Virginia. The company operates out of the Virginia Bio+Tech Park in Richmond, Virginia.

THE CHALLENGE. Tympanogen needed a laboratory with rheology capabilities for gel testing their Class 2 device in preparation for 510(k) Premarket FDA approval. GENEDGE was introduced to Tympanogen through a local economic developer to assist in finding a viable lab facility.

A 510(k) is a premarket submission made to the FDA to demonstrate that a medical device to be marketed is at least as safe and effective and is “substantially equivalent” to a legally marketed device.

MEP CENTER'S ROLE. At the time, GENEDGE, part of the MEP National Network™, was working to connect small Virginia companies with technical needs or hurdles that might possibly be addressed by NASA Langley Research Center (LaRC). Dialogue between Tympanogen and NASA determined that NASA had the rheometers at LaRC to do the work.

"GENEDGE is a valuable resource that connected our small company with NASA LaRC so that our medical device could be tested at their state-of-the-art facilities. The testing results were included in our patent applications to help secure the intellectual property for our device. We found the facilities at LaRC to be excellent and extremely valuable for small companies like ours as they have equipment and expertise that are too expensive for us to invest in ourselves."

-Elaine L. Horn-Ranney, PhD., President & CEO

RESULTS



\$2,000 in cost savings



\$15,000 in plant and equipment



\$1,000 in information systems



\$10,000 in investment saved



\$50,000 in new processes and product development

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