



*With its unrivaled e-liquid manufacturing facility, eLiquiTech will help the vapor industry comply with FDA regulations, however strict they turn out to be.*

By Timothy S. Donahue

**W**hen the U.S. Food and Drug Administration (FDA) releases its e-cigarette industry regulations, many companies will realize that their e-liquid manufacturing operations fall short of the new standards. They will either have to bring their processes up to snuff or find a third party to supply them with compliant liquids.



Enter eLiquiTech, a division of Tobacco Technology Inc. (TTI), the most advanced e-liquid manufacturing center in the United States and possibly the world. This month, the firm will begin production at its new 22,000-square-foot, state-of-the-art facility in Maryland. Though eLiquiTech has been producing e-liquids for some time, the new facility is unprecedented in its scope, according to internal sales manager Jeremy Cassels-Smith Davis.

Because the FDA in its rule-making has commingled vapor products with tobacco products, vapor companies will want a supplier that understands both the tobacco and the vapor industries. They need a company that can produce large quantities of e-liquid in a single facility and is able to adapt to this evolving industry.

Setting eLiquiTech apart from other manufacturers are the new facility's process controls, which are designed specifically to meet or exceed future FDA requirements. The building can adapt to various regulatory scenarios, according to Tom Cravotta, eLiquiTech's president. No one definitively knows what final regulations

will be enacted, he says. ELiquiTech, however, has prepared for any foreseeable possibility.

"This company has had the vision to prepare for this regulation," says Cravotta. "The claim of 'clean room' facilities has been mentioned frequently in the e-cigarette/vapor industry. What we have is not simply a clean room," he says. "The FDA is going to require verification that you actually meet the prescribed requirements."

Indeed, the FDA is going to require documentation, according to FDA ombudsman Ella Yeargin. "The FDA will require documentation from vapor manufacturers that they comply with regulation once they are implemented," she told a gathering of vapor executives in Washington, D.C., recently.

Literally built from the ground up, the new facility's architectural and system designs include features to allow for non-biologic pharma-grade product processing. "Features include a central facility corridor, which acts as a ventilation plenum integrated into the clean room HEPA-HVAC systems, maintaining positive clean room barometric pressure. Separate pedestrian and freight airlocks equipped with 'fast doors' buffer air movement between the clean rooms and central corridor, maintaining clean room air quality as required," Cravotta says.

All of the facility's technology is geared toward e-liquid compounding and nicotine dilution under pharmaceutical-grade processes, says George Cassels-Smith, CEO of eLiquiTech. "This building has been on the drawing board for over three years.

From the beginning we wanted to have the ability to leapfrog the industry and provide an FDA-compliant e-liquid when those standards are finalized,” he says. “Right now, probably 90 percent of e-liquids being produced will not comply with the FDA’s deeming proposal. We plan to change that statistic. Our process controls generate over 400 quality data points per batch.”

### A peek inside

From the outside, the eLiquiTech building looks straightforward and unassuming. However, once you step inside, it reveals some of its secrets. From the central facility corridor, you can observe most of the operation. Windows allow visitors to peer inside the compounding rooms where numerous brightly polished tanks are ready to be filled. What seems to be miles of stainless steel pipe run along the walls, carrying e-liquid ingredients to their prescribed destinations.

A dedicated nicotine dilution room capable of blending up to 2,100 liters per batch is on-site, according to Cravotta. “We needed our building to be able to handle the processes and safety procedures that are required when dealing with pure nicotine, he says. “There need to be protections for not only the product but also for the workers exposed to these materials.” Stainless steel pipes carry the nicotine solution to the e-liquid mixing tanks seamlessly and automatically. The nicotine room also has its own safety protocols, as well as committed drainage and air handling systems. All the machinery has clean-in-place systems, which means the system cleans itself between batches.

In the main compounding area, automated compounding cells have the capacity to produce from 20 to 1,500 liters of e-liquid per batch. Two separate 6,000-gallon stainless steel vessels store propylene glycol (PG) and vegetable glycerin (VG) that is pumped to the mixing tanks by way of the stainless steel pipes



Photos: Timothy Donahue

Five e-liquid compounding cells can produce between 20 and 1500 liters of product without ever being touched by human hands.

high on the walls. The PG/VG vessels are large enough to hold a full tanker-truck load, which reduces the quantity of lot numbers in the process.

The entire e-liquid compounding process is controlled by a custom-designed Rockwell automation system. This allows the whole process to be operator-controlled from a tablet-style computer. The Rockwell system is ANSI/ISA 88 compliant and is used to implement and monitor automated batch process controls (ISA 88 is a design philosophy for describing batch equipment, process management systems and process data acquisition). “For FDA compliance, you have to be able to show that every system is doing exactly what it is supposed to be doing. Every valve, every pump must be certified,” says Cravotta.

In another clean room across from the e-liquid compounding room sits the Genesis, the fastest fully automated high-speed filling machine for cartomizers on the market. Capable of filling 150 or



The world’s fastest cartomizer filling machine, Genesis, is housed in a clean room large enough to operate up to five machines.



The entire e-liquid compounding process is controlled by a custom-designed Rockwell automation system, which allows the whole process to be operator-controlled from a tablet-style computer.

more cartomizers a minute, eLiquiTech's Genesis is the only one of its kind in the U.S. TTI has partnered with Technical Development Corp., a subsidiary of International Tobacco Machinery, and Miami, Florida-based C&C Industries in the creation of the new high-speed filling machine for cartomizers.

The first cartomizer suite is large enough to house five Genesis machines, according to Cassels-Smith. It could also be arranged for packaging so a product can be completely produced and ready for shipping under the required environmental conditions. "This is an industry first," he says.

### Beyond being different

More than just a manufacturer, the company is a one-stop shop capable of performing all aspects of e-liquids production, from flavor development/product conception to product packaging all under one roof, according to Cassels-Smith. "We want to become the premier provider of e-liquid development and supply," he says. "As the leaders in flavoring tobacco products, we felt we were in the right position to lead the e-liquid category."

TTI is one of the tobacco industry's oldest flavor houses, and eLiquiTech is the result of a more than \$7 million investment. Its tobacco ties give eLiquiTech a unique perspective to predict the evolution of the vapor industry. "We have anticipated future industry regulatory requirements because we have been operating under stringent regulations for quite some time," he says. "Being a tobacco flavoring company, we possess the expertise to understand what a combustible cigarette tastes like. However, people also want a flavoring that may not be associated with a tobacco flavor," says Cassels-Smith.

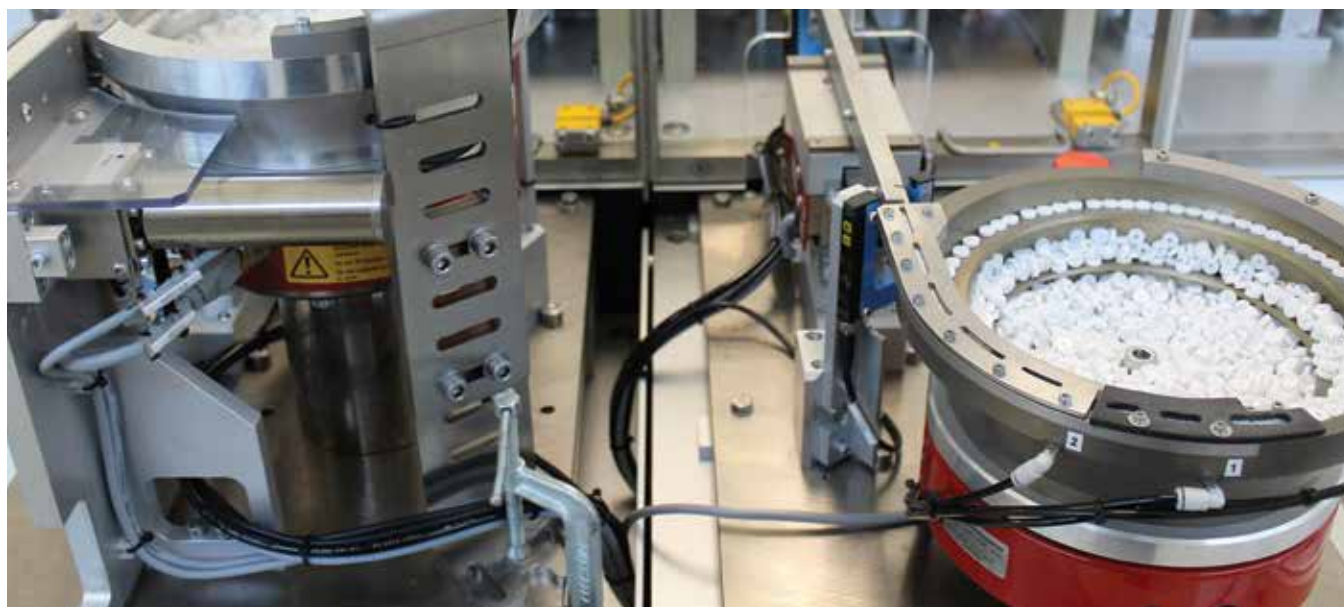
As a cutting-edge flavoring company, TTI has excelled at creating flavors for other tobacco products (OTPs). The first generation of flavored tobacco products were stand-alone flavors, such as orange or peach, according to Cassels-Smith. Then they evolved into fusion flavors, a layered blend of various flavor sensations.

"We have been at the forefront of innovation and development of the fusion flavors for the last dozen years. However, TTI and eLiquiTech believe that the product that tastes like a traditional cigarette is the product with longevity," he says. "We are concerned that the FDA may only allow tobacco-style flavors. The FDA is frowning upon on a lot of the fruit-type flavor profiles."

All raw materials entering the eLiquiTech facility undergo vigorous quality control testing in its onsite laboratory, according to Davis. "All e-liquids are vaped by our in-house evaluation panel prior to being sampled to the customer, and everything we use is USP grade: nicotine, PG and VG," she says. "We control the entire pedigree of the product until the finished product leaves our facility."

Cassels-Smith says accommodating smaller companies is also an important aspect of eLiquiTech's philosophy. "We do not turn our back on any responsible tobacco product manufacturer," he says. "We started with these small companies that we stayed with for numerous years. We want to be available for small companies. We need to be sure they have a spot at the table."

TR



The Genesis is capable of filling 150 or more cartomizers a minute, eLiquiTech's Genesis is the only one of its kind in the U.S.