

COMPANY BACKGROUNDER

QUALITRU SAMPLING SYSTEMS®: CONSUMER TRAGEDY SPURS SCIENTIFIC INNOVATION AND LEADERSHIP

In early Spring 1985, a Salmonella outbreak in the northern Illinois area that sickened over 1,500 people was traced back to a single processing plant that had performed inadequate pasteurization of 2% milk¹.

In June of that year, a Listeria outbreak sickened 86 people in Southern California. Listeriosis is a devastating bacterial disease that can cause meningitis and sepsis, especially in immunocompromised people. Expectant mothers can transmit the infection to their unborn children, resulting in spontaneous stillborn delivery. In 1985, the majority (58 cases) involved new mothers and their infants. By the time the crisis ended, an estimated 29 people had died, including eight newborns and 13 babies who were stillborn².

In the Listeria outbreak, which is still considered one of the worst food poisoning outbreaks in U.S. history³, the U.S. Centers for Disease Control (CDC) confirmed that most of the affected women had consumed a specific brand of Mexican-style fresh cheese. Because Listeria bacteria can survive over a period of time and the women had consumed the cheese over months, the CDC concluded that the issue was a systemic one related to the company's manufacturing process and not just to select product lots.

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¹ <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000520.htm>

² <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000562.htm>

³ <https://www.foodsafetynews.com/2011/11/a-top-10-list-of-deadliest-foodborne-illness-outbreaks/>

From Tragedy Comes a Vision and a Promise

While consumers were reeling from the cumulative horrors of these dairy-related tragedies, the industry and regulators were taking quick action to establish more stringent standards and greater consumer protections against potential bacterial outbreaks.

Prior to the events of 1985, the dairy industry's regulatory requirements had focused on final product testing; there were no uniform standards for process monitoring to detect potential contaminations that might occur throughout the various stages of milking cows, transporting the milk, pasteurizing and processing it. However, on the heels of the two dairy-related tragedies occurring in rapid succession, both the industry and key regulatory agencies quickly enacted remedies.

One man – Darrell Bigalke, a dairy food safety consultant and entrepreneur who had previously worked in microbiology with Ecolab – played a central role in helping shape the establishment and adoption of these new testing standards in the industry.

Drawing from his extensive knowledge of the dynamics of microbial contamination, Bigalke had focused his new company, Quality Management Inc. (QMI) on the singular mission of promoting aseptic sample testing for the dairy industry, extending far beyond final product testing, which is limited in identifying in-process risks, such as biofilms, and cannot lead to process improvements. Thanks to his work with Ecolab, Bigalke had access to a proprietary patent for a septum that had been invented by Ned Galloway, whose family owns a Wisconsin dairy processing plant. The multi-channel septum allows discrete samples to be drawn aseptically and segregated for analysis, increasing the specificity and sophistication of comprehensive process monitoring rather than limiting assessments only to final product testing.

Bigalke, the dairy industry, and key regulatory bodies all shared the same goal: to initiate process monitoring measures in order to reduce the chances of future contaminations or bacterial outbreaks from ever claiming another life.

Today, the dairy industry's consumer safety record has been consistent and comparable to that of other food categories. And QMI, which began as a modest two-person operation in a suburb outside of Minneapolis, has transformed into QualiTru Sampling Systems Inc., the undisputed global leader in the science of aseptic and representative sampling for milk and other liquid foods.

QualiTru's systems are considered the most trusted method for gathering aseptic and representative milk samples for testing, and are used by thousands of large dairy farms, haulers and food processing plants across the U.S. and in over 30 countries worldwide.

The company offers a line of advanced, cost-effective, easy-to-use systems that enable the dairy and liquid foods industries to perform inline aseptic process sampling to ensure their microbial testing is based on accurate sampling. QualiTru has an unparalleled network of subject matter experts (SMEs) in the dairy and liquid food industries, enabling the company to provide quality in-house expertise for customer training and consultations.

QualiTru's Products: Uniquely Qualified to Verify Quality

QualiTru's products are used to verify product quality across the supply chain, performing inline aseptic sample testing and quality checks in bulk tanks and silos, and for microbiological testing.

The company's unique four-part configurations can be customized to perform representative sampling, whether inline from the milking parlor to truck transport, from raw and pasteurized storage silos, and throughout commercial dairy and liquid food processing operations. This allows these industries to have accurate microbiological and chemical data from the beginning to end, building transparency and confidence in product quality. The company's systems also have proven to be a reliable source to detect and manage mastitis cases on dairy farms⁴, mitigating further contamination that can impact both animal health and milk quality and safety.

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⁴ <https://qualitru.com/case-studies>

QualiTru's products are made in the USA, comply with the 3-A Standard 63-04 (Sanitary Fittings), and are authorized to display the industry standard [3-A symbol](#). 3-A is an organization that reviews and evaluates the effectiveness of sanitary design of dairy processing equipment, which includes an independent audit of manufacturing practices. All QualiTru product materials comply with the U.S. Food and Drug Administration (FDA) requirements, including the FDA's Pasteurization Milk Ordinance (PMO) standards for Grade "A" milk processing, as well as the National Conference on Interstate Milk Shipments (NCIMS) standards.

QualiTru's flagship products include:

- ***TruStream Sanitary Ports*** – These stainless steel ports are designed to work in a variety of locations, such as processing lines, silos, tanks and milk tanker trucks, providing easy access for serial process monitoring to identify potential microbial contamination, as well as line and tank sampling to ensure milk quality at both the dairy farm and the dairy processing plant. TruStream Sanitary Ports are manufactured in the USA in an ISO 9001-certified facility and comply with the 3-A Standard 63-04 (Sanitary Fittings), and are authorized to display the industry standard 3-A symbol. They may be installed at any point throughout the milking or processing workflows as part of a diagnostic function, system quality check, clean-in-place (CIP) cleanliness check, or to collect overall milk quality samples.
- ***TruStream Septa*** – These multi-channel septa are made of food-grade materials and feature either 7- or 12-needle guide channels. TruStream Septa allow aseptic samples to be drawn through a single channel each time, virtually eliminating the risk of cross-contamination during the sampling process.
- ***TruStream Oxygen-Permeable Collection Bags*** provide a sterile fluid path and are equipped with a needle and tubing to easily work in combination with all TruStream Septa. The collection units extend aseptic sampling, while the oxygen permeability allows for the product's incubation. The single-use, disposable collection bags are available in a variety of configurations to accommodate various sample size and volume requirements. QualiTru also offers ***TruMotion*** Collection Bags that are designed to work with peristaltic pumps, creating a continuous flow sampling system that collects a representative sample over an entire process run.

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- **Peristaltic Pumps** – QualiTru offers electric powered peristaltic pumps that draw liquid samples into a TruStream Collection Bag, providing a continuous flow for collecting a representative sample over the entire process run for inline, pen or payment sampling. QualiTru also sells portable peristaltic pumps that are ideal for short duration and troubleshooting applications.

Additionally, the company offers various related consumable items and accessories that may be used during the sampling process.

Embracing Values; Growth and Opportunity Over the Next 40 Years

Despite its growing success as a global entity over these past decades, everyone working at QualiTru today has remained steadfast to Bigalke's original vision and mission: to protect consumers by providing the equipment and expertise for accurate and representative sampling that helps the liquid food industry produce safe, high-quality products.

The world's leader for aseptic sampling equipment and expertise for the dairy and liquid food industries has continued to maintain the original commitments Bigalke declared for his company:

- To collaborate and to prioritize customers' needs
- To take a win-win approach
- To provide the necessary expertise to help customers meet their product quality and business goals
- To partner with high-caliber vendors, customers, universities, and industry professionals to help produce safe, high-quality food products, and
- To continuously anticipate and respond to the changing needs of its customers.

After decades helming the company, Bigalke made the decision to step down from the day-to-day responsibilities in 2019, as the family business began transitioning to the second generation. Now, as the company looks ahead to its 40th anniversary in 2023, the family remains committed to continuing to meet the evolving needs of the dairy and largely liquid food industries and enthusiastic about its future vision.

“QualiTru is uniquely positioned to grow and expand. We have great products, a talented team, and an important mission to help our customers improve food safety and product quality. We are investing in developing the right solutions, putting the right messaging forward into the market, and building the operational structures we need to meet our current and future objectives,” said Barbara Grayes, Vice President of Sales.

In April 2022, QualiTru named Ian G. Davis as Chief Executive Officer of the company. Davis has more than 25 years of senior level management experience, including leadership positions in sales, operations, and information technology in the food, travel and logistics industries in the U.S. and Europe. He began his career working at a dairy in his native British Columbia.

“In the dairy and liquid food industries, sampling and testing are inextricably linked and play a pivotal role in assuring consumer safety as well as steady, efficient production without waste,” said Anne Bigalke, Vice President of Strategic Development. “Because laboratory analysis is only as good as the sample it receives, we see increasing adoption for our aseptic sampling systems, which have been shown to eliminate the risks of contamination that can occur when sampling is done manually. As a result, less product is wasted, and more revenues are preserved for the farmers and processors who are working harder than ever to feed hungry families.”

QualiTru may be changing the world – and making it a safer place for consumers – but at its core, it remains a modest, family-owned operation that partners with respected SMEs and distribution partners to provide the best sampling expertise and guidance to its customers.

From one man’s singular vision and commitment to apply science to stop food poisoning-based tragedies, QualiTru Sampling Systems has grown into a company trusted to provide accurate and representative samples to the dairy and liquid food industry, helping them meet their needs for product quality and safety, public health, and business goals.

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About QualiTru Sampling Systems

Since 1983, [QualiTru](#) (formerly known as QMI) has been the pioneering leader in the science of aseptic and representative sampling. Known for its expertise and commitment to building awareness of aseptic sampling as a critical means of ensuring consumer health and food safety, QualiTru's [innovative sampling technologies](#) are used to help the dairy and liquid food industries produce safe, high-quality products in over 30 countries worldwide.

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