Donna Matuizek Calls for Stronger Public Awareness Around Medical Quality Systems

Biotech veteran urges communities and professionals to prioritize compliance, patient safety, and everyday accountability

Seattle, Washington Jun 26, 2025 (Issuewire.com) - After more than three decades in the biotech and medical device industry, Donna Matuizek is turning her focus to the public: calling for greater awareness, education, and support regarding medical quality systems and regulatory compliance.

“Most people never think about how safe their medicine is until something goes wrong,” said Matuizek. “But behind every therapy, there’s a system of checks, controls, and people making sure that what reaches you is effective—and safe.”

Matuizek is recognized for her leadership in bringing groundbreaking medical technologies to market. She’s worked on everything from the first FDA-approved HIV blood screening test to *Provenge®*, the first approved cell therapy for prostate cancer. She’s built compliant facilities in record time and helped secure approvals for high-impact treatments.

Yet, she’s clear: “Quality isn’t paperwork. It’s protection.”

The Stakes Are Higher Than You Think

According to the Institute for Safe Medication Practices (ISMP), preventable medication errors harm over 1.5 million people in the U.S. each year. The FDA recalls roughly 4,500 medical devices and drugs annually, many of which are due to process failures that could have been avoided with stronger quality controls.

“People think this is just a ‘big pharma’ issue, but quality happens everywhere—from startup labs to hospital pharmacies,” said Matuizek. “If a process breaks, it puts patients at risk. Everyone from manufacturers to regulators to patients themselves should care.”

The Role of Everyday Advocates

Though regulatory work may seem technical, Matuizek insists that everyone can play a role in supporting safer health outcomes.

“Ask questions. Read the labels. Speak up if something feels off,” she advises. “And if you’re in the industry—even at an entry level—understand why quality systems matter. We don’t cut corners, because we can’t afford the cost of failure.”

In her own career, she has emphasized team education and accountability. While leading quality at Just-Evotec Biologics, the clinical site achieved a 100% manufacturing success rate, and she led the quality requirements and qualified an entire biologics facility during the COVID-19 pandemic in just 18 months.

“It wasn’t about moving fast,” she said. “It was about doing it right, the first time.”

Beyond the Lab

Matuizek brings the same discipline to her personal life. She volunteers regularly by preparing meals for a women's shelter. She's also an avid gardener, marathon runner, and leads a supper club.

"These things keep me grounded," she said. "And they remind me that real quality isn't only in labs. It's in how we show up for people—consistently."

A Call to Action

Donna is encouraging professionals and citizens alike to take small but powerful steps:

- **Stay informed.** Learn how your medications and devices are developed.
- **Ask healthcare providers about safety practices.** Be an active participant in your care.
- **Support organizations that uphold patient safety standards.**
- **For professionals: prioritize training, speak up in audits, and never shortcut the process.**

"If everyone treated quality like their life depended on it—because it might—we'd see real change," Matuizek concluded.

About Donna Matuizek

Donna Matuizek is a Seattle-based biotech and regulatory affairs professional with over 35 years of experience in the field. She has worked at leading companies including Dendreon, Just Biotherapeutics, Magnolia Medical Technologies, and AGC Biologics. She has contributed to multiple FDA approvals and built world-class quality systems for drugs, biologics, and medical devices.

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