

FDA Warning Letters Surge 59 Percent. One Life Sciences Firm Says the Industry Is Solving the Wrong Problem

Krieger Scientific points to a structural gap in how compliance is managed, not a string of isolated mistakes

DOYLESTOWN, PA, UNITED STATES, July 9, 2026 /EINPresswire.com/ -- The U.S. Food and Drug

“

The FDA recommended outside compliance expertise in 87 percent of the warning letters it reviewed last year. That is not a coincidence. That is a diagnosis.”

Joseph Morwald, Krieger Scientific Founder and CEO

Administration issued 303 drug warning letters in fiscal year 2025, a 59 percent increase over the 190 letters issued the year before. Early data from 2026 shows no slowdown. In April, the agency issued its first ever warning letter specifically citing the inappropriate use of artificial intelligence in a Good Manufacturing Practice setting, signaling that regulatory scrutiny is expanding into territory many life sciences organizations are not prepared to defend.

According to [Krieger Scientific](#), a life sciences compliance and technical solutions firm based in Doylestown,

Pennsylvania, the surge is not the result of isolated mistakes. It is the predictable outcome of a structural problem the industry has tolerated for too long.

"The FDA recommended outside compliance expertise in 87 percent of the warning letters it reviewed last year," said [Joseph Morwald](#), Founder and CEO of Krieger Scientific. "That is not a coincidence. That is a diagnosis. When validation, calibration, and quality functions are managed in silos, by phase, by vendor, by department, with no single point of accountability, organizations lose the ability to catch problems before they become violations."

Morwald, a 35-year veteran of the life sciences industry, founded Krieger Scientific to address that structural gap directly. Most firms in this space are built to handle one or two phases of an asset's lifecycle and stop there. Krieger was built to handle all of them. In practice, that means clients rarely bring Krieger in to manage an entire program at once. They bring Krieger in wherever the need actually is, with the confidence that the same team can step into any phase and contribute immediately, because the full capability already exists behind it.

"Most firms hand a client off as the engagement moves from one phase to the next," Morwald said. "We do not. The model is bespoke to each client. The accountability is not. That consistency is what closes the gaps regulators keep finding."

A Growing Team Behind a Growing Model

Krieger Scientific's growth has outpaced the company's own early projections. The firm recently completed a search for a Head of People and announced the appointment of [Justin Kane](#) to the position on July 6. This is the first in a series of senior leadership hires planned in the coming weeks as Krieger continues to scale its service capabilities to meet client demand.



Krieger Scientific Logo

"We are building a leadership team with the experience to match the complexity of the work our clients are facing," Morwald said. "This industry does not need more vendors. It needs partners who understand the full lifecycle and take ownership of the outcome."

About Krieger Scientific

Krieger Scientific is a full-service compliance and technical solutions firm serving life sciences organizations across the full asset lifecycle. Built around the asset, not the engagement, Krieger was founded by Joseph C. Morwald, a 35-year life sciences industry veteran, and is proudly veteran-owned and operated. The firm offers integrated service capabilities including Commissioning, Qualification, and Validation, Calibration, Owner's Representative, Asset Management, Vendor Managed Services, and Project Management, with national coverage and international partnerships in the United Kingdom, Ireland, and Europe. Learn more at kriegerscientific.com.

Drew Deeter

Krieger Scientific

+1 267-471-1457

[email us here](#)

Visit us on social media:

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/925352156>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.