The Pursuit of Quality

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An Inside Look at FDA Enforcement, Remediation, and Patient Safety

A conversation with former FDA leader **Sean Boyd** and QualityHub's **Junior Villagomez** on what companies get wrong — and how to build systems that actually protect patients

Sean Boyd
Vice President at QualityHub, (former FDA, retired USPHS Flag Officer)

Junior Villagomez
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What happens when someone who spent 31 years inside the FDA steps into the consulting world and starts helping companies on the other side of the table? What does that reveal about how companies approach compliance, quality systems, and patient safety?

And where are companies falling short?

> **Sean Boyd,** former Director in the FDA's Center for Devices and Radiological Health (CDRH), is now Vice President at QualityHub, a MedTech consulting firm that supports companies through some of their most difficult regulatory moments. During his tenure at the FDA, Boyd served as a U.S. Public Health Service Flag Officer, overseeing device review programs across the total product lifecycle — from premarket submissions to postmarket surveillance and enforcement.

In other words, his role bridged policy, enforcement, and systemic oversight at the highest levels.

> In this exclusive MLV interview, Boyd was joined by **Junior Villagomez,** a veteran in the MedTech space who has spent more than a decade helping device manufacturers dig out from FDA-483 inspectional observation forms, warning letters, and consent decrees, and build quality systems that prevent those problems in the first place.

As a duo, they've seen both sides: the agency's perspective and the company's. Together, they unpacked how manufacturers approach quality, what it takes to manage change under pressure, and how strong systems support the people who rely on their products.

Experience as a Driver: Understanding the Client Perspective

Before discussing case studies or inspection models, we talked about the nature of QualityHub's work: when clients call, what those first conversations sound like, and what drives value in a crowded quality space.

Understanding the kinds of situations in which clients find themselves was key.

They explained to me that some companies reach out after receiving a 483 or when facing a consent decree. Others are trying to proactively prepare for an FDA inspection or product launch. Whatever the context, the engagement starts with listening.

> ***"We really try to convey the knowledge and experience and the accomplishments in our track record of work that we've done in the past through these major… consent-decree-type projects and warning letters," Villagomez said. "We have a proven process and a recipe, but we also tailor our approach based on the client's unique needs, quality system maturity, internal resourcing, et cetera."***

That customization isn't guesswork.

The team draws on established frameworks and matches their personnel to the issue at hand — a strategy rooted in both repetition and precision.

> ***"There's math behind the way we set up our audits — duration, number of auditors, how we're going to audit design controls versus how we're going to audit complaints, those types of important things," Villagomez explained.***

The Role of Resilience and Adaptability in Remediation

When we discussed remediation, we began by defining what it entails.

In the MedTech space, remediation is a focused effort to identify, correct, and prevent systemic failures in a company's Quality Management System. It can follow any number of regulatory outcomes: a 483, a warning letter, a consent decree, or even internal signals that something's gone wrong.

Fundamentally, they said, remediation is about rebuilding trust. Trust with regulators, with leadership, and with the public.

> ***"It gets really tough and it gets really strenuous, stressful," Villagomez said. "It's almost like you're going to war. Right? And battle is not easy. It's a long process with a lot of challenges and changes in direction that requires a high level of commitment, fortitude, and perseverance."***

The way through is resilience, structure, and a willingness to adapt.

> ***"You have to keep moving forward, stay positive and look for ways in which to continuously improve," Villagomez said. "Also, think outside the box… you're going to hit walls, and you may have to shift a little to do something different to overcome a challenge."***

Boyd echoed this point and brought in a broader systems view.

> ***"Any of these large projects that we're engaged on is effectively a change management effort that's oftentimes going on corporate-wide," he said. "One of the critical pieces… is the investment in people and culture. That's really critical to successfully implementing a change management plan of any type."***

Seeing the Big Picture: Regulatory and Industry Expertise in Practice

Quality consulting is a crowded space.

What sets QualityHub apart is the depth and balance of its team — a network that includes former FDA staff and seasoned industry professionals who've led global quality and regulatory functions.

> ***"We use a strong mix of both ex-FDA folks… and also industry professionals," Villagomez explained. "They understand the big picture… not just from a quality and compliance standpoint, but they understand the linkages between the other departments — R&D, production, marketing, sales."***

This enables QualityHub to see problems before they compound and it helps ensure their solutions fit the operational and business realities of the clients they serve.

> ***"If there's a problem with how [a company is] triaging complaints for MDR reportability," Villagomez said, "we're bringing in a subject matter expert that lives, eats, and breathes complaint handling... cradle to grave."***

It's a specialty-based model. Like medicine, the right diagnosis depends on the right kind of expertise.

Preparing for QMSR: Aligning Systems Before the Deadline

One of the key regulatory shifts on the horizon is the replacement of the FDA's current, decades-old Quality System Regulation, 21 CFR Part 820, with the new Quality Management System Regulation (QMSR), which aligns more closely with international quality systems standard ISO 13485:2016.

I asked Boyd and Villagomez for their perspective — how significant is this change, and what should companies be doing now?

> ***"My thinking has evolved... particularly since I left FDA," Boyd said. "Initially, my thinking was, it was very minimal change for industry... but I think there's still work for companies to do to understand the crosswalk."***

Part of that work involves mapping FDA requirements against ISO standards and identifying where new systems, language, or training may be needed. But it also involves preparing for a new inspection approach — one that FDA has not yet revealed.

> ***"One of the big questions in my mind is, what is that new inspection model going to look like?" Boyd said. "It's going to be published in a compliance program that will be released before February 2, 2026. And I think that's what everybody's waiting to see right now."***

The advice from both leaders was clear:
Don't wait — prepare now.

Inspection Readiness: The Role of Observation and Context

We further spent time discussing inspection readiness — both from the regulator's perspective and the company's. Boyd offered insight into how observations are viewed inside the agency.

> ***"Inspection observations are just that — they're observations," Boyd said. "They may or may not be indicative of a real problem... That's the responsibility of a compliance officer through subsequent review of findings and the supporting objective evidence."***

But industry often treats them with significant weight, and rightfully so.

> ***"Seeing the level of effort that industry puts into not only a violation that's written into a warning letter, but an FDA-483 observation... that's been eye-opening to me," Boyd noted.***

Part of the challenge for companies is not just responding — it's telling the story behind the response. Not fiction, but a clear narrative that connects the issue to the action plan and the corrective path forward.

Adapting to Change:
AI, eQMS, and the Next Phase of Quality Systems

Curious to hear their views on emerging technologies, I asked Boyd and Villagomez how AI and digital systems are impacting their work and industry more broadly.

Villagomez broke it into two streams: product and process.

> ***"You've got to look at it as two buckets — product and process," he said. "For product, people are starting to look at, 'OK, how do I embed AI into my product?' But there's also an eQMS perspective, and that also includes R&D and operations."***

Boyd pointed out that the FDA is beginning to incorporate AI and algorithmic tools in its own internal review and analysis processes.

And that's a shift that manufacturers should anticipate.

> ***"The interesting thing will be as FDA begins using it more… how should industry adapt its own submission preparation?" Boyd said. "Knowing that FDA is going to use some algorithm or use AI to help in evaluating that information… how can industry best adapt to partner with the agency but also stay ahead of the technology that will be used to aid reviewers in their work?"***

So, Where are Companies Falling Short?

Boyd and Villagomez didn't point to a lack of knowledge or technical capability. Instead, they described patterns of misalignment between leadership and teams, between strategy and systems, and between stated values and actual practice.

Too often, companies treat remediation as a documentation exercise rather than a culture shift.

The most successful organizations, they said, are the ones that bring their people with them — that make quality a shared priority, not a delegated task.

The Bottom Line:
Patient Safety and Product Quality

Throughout our conversation, one theme kept resurfacing: Patient safety and product quality are not talking points. Rather, they are the baseline for every decision and they're the filter through which every recommendation must pass.

That mindset, Boyd explained, is what initially drew him to QualityHub.

> ***"The things that drew me here... one was the mission," he said. "Our core purpose as an organization is to keep our focus there and serve our clients and their customers who are patients."***

Villagomez shared a personal story that brought this point home. He recalled being in the OR during a family member's procedure, personally reviewing the device's recall and complaint history.

> ***"Our loved ones and ourselves one day will be in front of one of those devices," he said. "And we want to make sure that it's not going to fail."***

That commitment is grounded, personal, and unwavering. It is the foundation of their work

About Sean Boyd

Vice President at QualityHub,
(former FDA, retired USPHS Flag Officer)

Sean Boyd is a former FDA senior leader with over 30 years of experience in medical device regulation and quality systems. As Vice President at QualityHub, he helps MedTech and pharma companies navigate complex regulatory landscapes, accelerate market entry, and ensure patient-focused innovation. Previously, he led regulatory programs at the FDA's CDRH, shaping policies that balanced innovation with safety.

About Junior Villagomez

Senior Vice President, Business Operations at QualityHub

Junior Villagomez is a regulatory and quality systems expert with over 10 years of experience guiding medical device companies through FDA compliance challenges. At QualityHub, he specializes in remediation strategy, helping clients address 483s, warning letters, and consent decrees with tailored, risk-based solutions. Junior combines technical precision with a practical approach to building resilient quality systems that support both compliance and business goals.

About QualityHub

QualityHub is a life sciences consultancy that helps companies within the MedTech, pharmaceutical, and other FDA-regulated spaces strengthen their quality systems, respond to regulatory actions, and improve patient-safety outcomes. With deep regulatory expertise and a global network of former FDA and industry leaders, they specialize in audits, remediation, inspection readiness, compliance strategy, corrective and preventive action (CAPA), and much more.

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