## An Interview with

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Life Sciences companies have increasingly reached out to Tenthpin with a common challenge: their custom-built Quality Management Solutions no longer serve them well.

These solutions, once designed to give flexibility, have grown into bottlenecks: difficult to maintain, expensive to validate, and misaligned with modern SAP Clean Core principles.

In this interview, Jim Williams, Partner & Member of the Executive Board, USA, at Tenthpin, shares insights shaped by many proactive customer conversations and requirements. Drawing on these real-world discussions, he explains why organizations are reconsidering their "make or buy" strategies and how standardized, intelligent solutions can create a more scalable, compliant, and innovation-ready future.

### Why is the "make or buy" question so critical when it comes to Quality Management Solutions in Life Sciences?

In the past, many Life Sciences companies relied on custom-built Quality Management Solutions. These offered flexibility and control, which felt right at the time. But over the years, these bespoke solutions have turned into technical debt. What do I mean by that? They've become difficult to maintain, costly to update, and misaligned with SAP Clean Core principles.

As companies grow and regulatory demands increase, organizations face a crossroads: continue investing in complex customizations or adopt standardized Quality Management Solutions designed to work seamlessly with SAP Clean Core.

### What hidden costs do companies face when they "make" their own Quality Management Solutions?

The upfront development costs are only part of the story. Over time, hidden costs pile up: ongoing maintenance, complex validation cycles, and challenges in keeping up with SAP upgrades. Quality data often ends up siloed in separate systems, requiring manual transfers prone to error.

All of this consumes IT resources and burdens quality teams. Ultimately, what I've found is that custom-built solutions carry a significantly higher Total Cost of Ownership compared to standard Quality Management Solution platforms that align with SAP Clean Core.

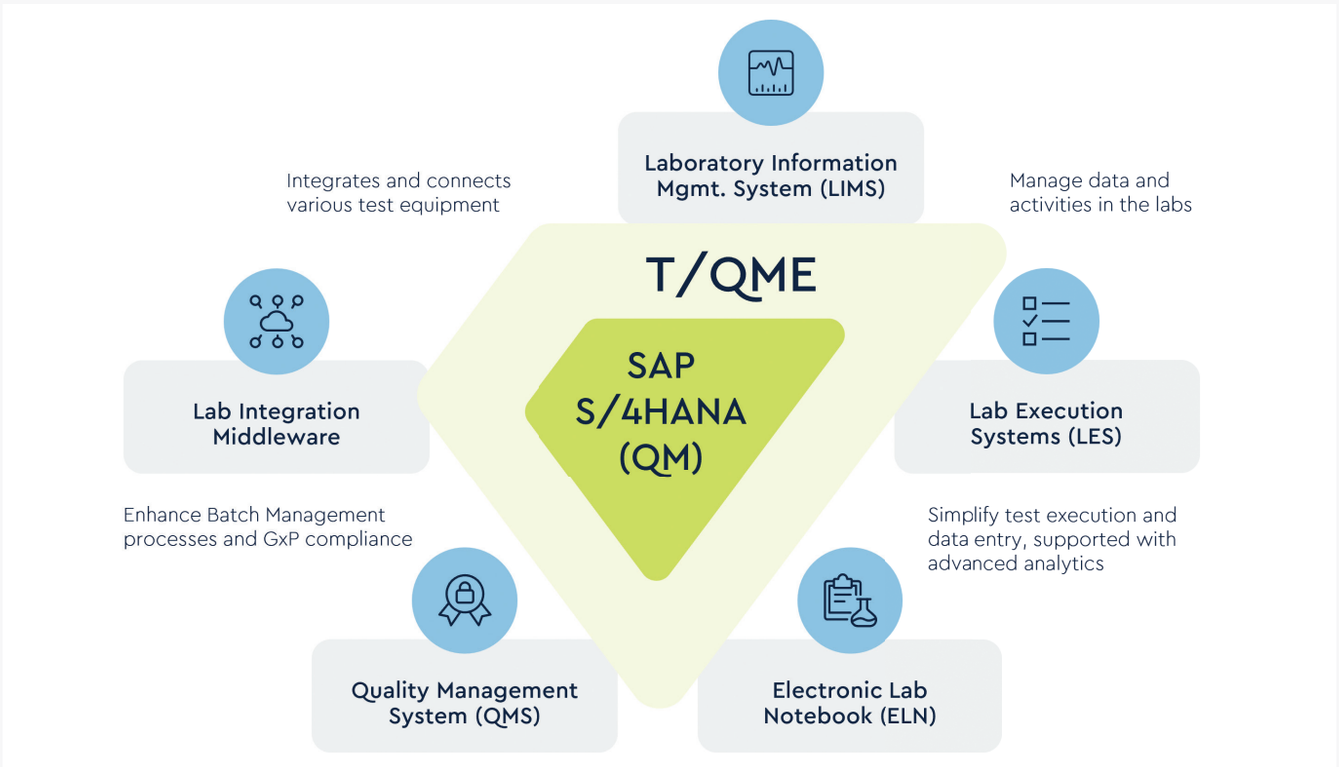
### How does SAP Clean Core change the equation for Life Sciences companies?

SAP Clean Core is about creating a simplified, standardized ERP environment that supports continuous innovation. For Life Sciences companies, it means faster and simpler upgrades, smoother compliance and verification, reliable integration with tailored solutions, and stronger global process consistency.

Perhaps most importantly, it establishes a solid foundation for advanced data analytics and AI. With a clean and reliable SAP environment, companies gain the agility to respond quickly to market or regulatory changes while safeguarding compliance. This is obviously critical.

### From a Total Cost of Ownership perspective, how do standard solutions compare to custom ones?

Standard Quality Management Solutions typically require lower upfront investment and carry far fewer maintenance burdens,




since vendors provide regular updates. They also reduce reliance on internal development teams and mitigate risks associated with compliance and security.

In contrast, custom solutions accumulate technical debt over time, driving up costs and delaying innovation. When viewed over the full lifecycle, standard solutions consistently deliver lower TCO and stronger scalability. That's not just my opinion, but a fact.

## How does aligning Quality Management Solutions with SAP Clean Core impact Quality Assurance (QA)?

Custom systems often make QA a bottleneck. Data becomes fragmented across tools, and every small change triggers heavy validation. Standard Quality Management Solutions built on SAP Clean Core principles simplify QA dramatically. They offer built-in workflows, automated documentation, and audit trails, all of which reduce manual work while ensuring compliance.

More importantly, they break down data silos, enabling faster batch release and better decision-making through real-time visibility into quality processes.

## What role does Tenthpin's T/QME solution play in this landscape?

Simply put, Tenthpin Quality Management Evolved (T/QME) was designed specifically for Life Sciences. It incorporates industry best practices, minimizes validation and compliance efforts, and supports SAP Clean Core integrity. Our solution also helps organizations free up IT resources, reduce Total Cost of Ownership, and accelerate innovation.

T/QME also ensures smooth upgrades in SAP S/4HANA environments, so Life Sciences companies can always benefit from the latest features without disrupting their quality processes. It really is the best choice.

What is your advice to Life Sciences companies facing this make-or-buy decision today?

In my view, Life Sciences organizations need to take a long-term perspective. While custom solutions may seem appealing for their flexibility, they ultimately create barriers to compliance, scalability, and innovation.

Standardized Quality Management Solutions, particularly those aligned with SAP Clean Core, deliver the best of both worlds: efficient integration, reduced costs, and future readiness. For companies looking to optimize their quality landscape, this is the moment to act and to embrace a strategy that ensures both compliance and agility.