Building an Audit Trail Through Live Traceability™

Audit trails are integral to regulatory compliance in industries ranging from medical device manufacturing to automotive production. But what's the best way to build an audit trail that stands up to scrutiny? **It starts with live traceability.**

Live Traceability is the ability for any engineer at any time to see the most up to date and complete up and downstream information for any requirement, no matter what stage of development it is in or how many siloed tools and teams it spans.

Why Live Traceability is Necessary

Among other purposes, an audit trail helps strengthen product development controls and in turn curb the risk of recalls. **In 2019, there were 50 medical devices recalled by the FDA—the most since 2014.**[1]

The top three reasons for recalls throughout the 2010s were device design flaws, software issues, and defective production processes.[2] **Audit trails document how such problems emerged.**

But too often, audit trails are assembled after the fact, without live traceability. **Information may be pulled from numerous discrete documents,** such as spreadsheets with hundreds of outdated entries.

In contrast, live traceability happens along the way, adding supporting context for data relationships and contributing to better decision-making and future planning.

The Live Traceability Difference

For example, a medical device takes 18 to 24 months to come to market.[3] In that time, many changes will be made to its software, design, and functionality.

Those modifications should be compiled in one secure place. Live traceability ensures that they are, by mapping out relationships and dependencies in real time and making them exportable, too.

All of this traceability data answers questions about who built what, when, and for what purpose. Accordingly, it's easier to demonstrate that a product meets all specifications and complies with applicable mandates.

Live traceability lets organizations manage growing complexity as well. Between 2017 and 2018, software-related complications drove up U.S. automobile recalls, underscoring the need to live-trace complex development processes.[4]

Implementing Live Traceability can improve your processes and reduce risk across the development lifecycle. To learn more, we're offering a no-cost, guided diagnostic to set you on the right path. **Click here to get started.**

SOURCES

1 https://www.beckershospitalreview.com/supply-chain/number-of-medical-device-recalls-in-2019-highest-in-4-years.html

2 https://www.medtechintelligence.com/feature_article/trends-in-medical-device-recalls/

3 https://www.manufacturing.net/home/article/13056367/improve-medical-device-timetomarket

4 https://www.recallmasters.com/2018-recalls/