

# What to look for in an audit trail system

**Bulletproof compliance starts with a smart audit trail system. But how do you know what's smart?**

For production companies, keeping track of the activities on assembly lines and packaging lines is key to staying compliant with international standards and regulations. This is especially true for the pharma industry, where the CFR 21-part 11 regulation sets high standards for electronic documentation and signatures. Failure to comply means failure to operate, and that is devastating to business. So choosing the right audit trail system is more important than ever. Read on and find out how to tell the great systems from the not-so-great ones.

## **Centralize critical GxP data by building a smart bridge**

Many audit trail systems are built into the level 1 components of a production line. That means the assembly, labelling, and aggregation devices – along with everything else – each have their individual audit trail system that includes user management and CFR 21-part 11 compliance software.

In theory, that keeps the line in compliance. But in practice, it means a lot of manual work each time an operator needs to log the events from each device.

However, if you choose an audit trail solution that first segregates all the data from each component at level 1, and then exports and centralizes it and makes your full line audit trail accessible to your Enterprise System at level 3, you have essentially built that smart bridge of data between level 1 and level 3. The smart bridge is the key feature in what we can call a smart audit trail system – and it opens up a series of advantages.

## **Advantage 1: Monitor critical parameters and manage users in one system**

Building a smart bridge between the machine components at level 1 and the Enterprise System at level 3 allows you to monitor critical parameters and perform user management much more efficiently.

Critical parameters are defined at the line-level and can include anything from limit values to product-release parameters. When they are synced into the smart audit trail solution, it means you can automatically monitor all your level 1 components at once in one, user-friendly user interface.

Another advantage of the smart audit trail is its user management possibilities. Today, many audit trail solutions operate with user management at the component level.

With a smart audit trail solution, all user logins are managed in the bridge between level 1 and level 3. If a user wants to make a change at the line level, his credentials are checked at the centralized audit trail

level. If the change he wants to make is marked as critical, he is asked to create a digital signature that confirms his actions. That way, we get a digital logbook with digitally signed records in one central system.

As you know, CFR 21-part 11 outlines the regulations for administering electronic records in a medical device company's quality management system. A smart audit trail solution makes it easy to do just that – document and log critical parameters, changes, and user activities.

### Advantage 2: One point of audit

When the FDA comes knocking on the door, nobody wants to feel unprepared. With a smart audit trail solution, there is only one point of audit for everything. The days when you had to collect data from every component on the line are over. With the right audit trail solution, you have easy access to all the necessary data.

### Advantage 3: The digitalized baseline

A digitalized baseline is your ultimate guarantee of full control with your production set-up. It is also where most audit trail solutions fall short. The digitalized baseline for example documents the baseline at the time of delivery the Factory Acceptance Test and at the time a Site Acceptance Test is performed. The two baselines are then compared, and any critical parameters that have changed, are discovered and adjusted.



### CIM TRACKS: Smart audit trail that meets all demands

CIM is a Danish software company that makes end-to-end software solutions for several industries, including pharma. We offer a series of solutions that enable our customers to make business-critical decisions based on solid data. Our smart audit trail software is called TRACKS, and it meets all the demands of an intelligent audit trail system. It keeps our customers in compliance and always ensures full control of users and critical parameters.

- ✔ **One-point audit: TRACKS enables you to consolidate all your data in one place – we call it the one-point audit. Data is easily managed, fully documented, and easy to export to any system you prefer**

- ✓ **Full compliance: TRACKS ensures full compliance with all standards and regulations**
- ✓ **Full integration: TRACKS is unique because it seamlessly integrates level 1 systems with higher levels in the system. With TRACKS, integration is part of the package and you will never have to look in more than one place to find the data and documentation you need**
- ✓ **Integration to Active Directory**



## TRACKS features

TRACKS has a series of features that sets it apart from any other audit trail system:

- ✓ **User Management and Audit Trail parameter logging**
- ✓ **Critical Parameter Monitoring**
- ✓ **Baseline Parameter Report**
- ✓ **Digital Signing of Records**
- ✓ **Interfaces for automatic import and export of data**
- ✓ **User interface for configuration, view and export**
- ✓ **GxP Data Tracking System**

## Get in touch

Please contact us to find out more about how a smart audit trail solution can help your business perform even better. We are eager to tell you about TRACKS – the software that brings you in compliance and gives you full control over your production.

## The company behind TRACKS

CIM makes end-to-end software solutions that enable our customers to make business-critical decisions based on solid data. We create the necessary connections between data acquisition, data analyses, and data presentation so our customers can efficiently and consistently create products of superior quality – and make decisions based on true insights.



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