

# Making the grade with the FDA's Title 21 CFR Part 11

CTS gives medical device manufacturers an FDA-compliant leak/ blockage test

## Why 21 CFR Part 11 compliancy matters with Industry 4.0

Just as ERP, MES and OEE significantly improved data collection and analysis in the manufacturing environment to enhance decision-making, Industry 4.0 is taking the utility of data to a whole new level. The emphasis with Industry 4.0 is to integrate more data sources from across the plant and break down the silos that traditionally existed between different process and test stations on the line, and between different areas of the plant.

On the production side, the end goal is to have all the data that is relevant to the line's output collected in a single, central database, correlated by part serial number (or batch, as the case may be). This includes any dataset that documents what happened to a part, batch or end product through each millisecond of its production, test, verification and quality assurance—from machine vision images and related data to scalars and digital process signatures from each process or test cycle.

This results in near real-time insight that is useful to the manufacturer in two ways. First, it delivers a granular data trail that can be used to boost quality, improve yield and reduce unexpected downtime, all of which makes the line more efficient and profitable. Second, it provides proof of compliance to the manufacturer's customers and end users, to demonstrate parts/products were built to spec. When a quality issue does arise, this data trail enables rapid root cause analysis, to quickly trace and correct the cause at source and limit the scope of any corrective actions and/or recalls.

## How this relates to medical device manufacturing

Manufacturing in a host of verticals is undergoing a dramatic digital transformation, driven by the need and desire for this data-driven insight to boost quality, efficiency and accountability.

Modern data analytics platforms and off-the-shelf data collection and management tools have become far less costly and less difficult to implement in recent years. The ease of adding more integrated, standardized and centralized data collection and analysis capability to the production line has raised the stakes for manufacturers. If their competitors are making these Industry 4.0 investments and reaping the benefits, they must too.

Medical device manufacturing is no different. In fact, due to the heavily regulated nature of this industry, Industry 4.0 is having an impact that is more profound and far-reaching.

This extends to what is a crucial quality assurance process for a host of medical devices—leak and blockage testing.

The medical device industry faces several unique challenges that other markets do not. Product failure here impacts patient safety. Because of this, manufacturers are required to conduct thorough medical device testing to ensure products meet strict criteria for health and safety.

With lives literally on the line, what medical device manufacturer does not want to pull more insight from a test station if the result is a faster and more reliable pass/fail determination, along with a depth of data that makes it easier to trace and address root cause if a quality issue does arise?



## The regulatory compliance burden this creates

When a leak test instrument (or any test station) on a medical device production line evolves from delivering a simple, binary pass/fail determination to generating a deeper and more meaningful pool of data, the manufacturer faces an increased regulatory compliance burden.

The U.S. Food and Drug Administration's Title 21 CFR Part 11, as well as the European Medicine Agency's comparable Annex 11, are guidelines for storing and protecting electronic records and applying electronic signatures.

Generally speaking, these guidelines set out the conditions under which regulators consider electronic signatures and electronic records to be trustworthy, reliable and equivalent to traditional handwritten signatures on paper. They define the conditions under which a medical device manufacturer (or a supplier in the supply chain) must operate to meet these requirements if electronic records and signatures are being used in lieu of paper records and handwritten signatures. Medical device manufacturers don't have to use electronic records and digital signatures, but if they do, the requirement to be compliant with these regulations becomes mandatory.

These guidelines extend to the manufacturing, testing, packaging and distribution of medical devices, and include stringent documentation and audit requirements. While 21 CFR Part 11 and EU Annex 11 have existed for more than 20 years, the rise of data-driven manufacturing and quality control processes typical of Industry 4.0 have heightened their importance.

As leak testing instruments have evolved to collect and manage larger and larger volumes of data, how this data is secured, accessed and manipulated falls under the scope of the 21 CFR Part 11 and EU Annex 11.

## What capabilities must a leak/blockage test system have to be compliant?

Cincinnati Test Systems (CTS) has worked extensively with our customers in the medical device industry to answer this question. The results have been distilled into the current release of our **Sentinel Blackbelt Pro**, to ensure it delivers the features and functionality medical device manufacturers need to ensure their leak test is compliant with 21 CFR Part 11 and EU Annex 11.

Blackbelt Pro is CTS' next generation of multi-channel test instrumentation that provides pressure and vacuum leak, flow and ramping testing for medical device manufacturers. It can manage and execute testing of up to four parts (synchronous or asynchronous), all under the control of one Blackbelt Pro instrument.



## Blackbelt Pro features that support 21 CFR Part 11 (and EU Annex 11) compliance

### UNIQUE USER IDS

250 unique user profiles may be stored within the instrument. User authentication requires a unique password for each user. This limits access for specific functions to permitted users only. The administrator can also create unique user roles with security parameters defined for each user.

In addition, Blackbelt Pro helps to enforce good password hygiene and strong policies to prevent a compliance breach.

This corresponds to the 21 CFR Part 11 requirements for an electronic signature that has two distinct identification components—an identification code and password:

*"...electronic signatures to be unique to one individual" by "employing at least two distinct identification components such as an identification code and password" and "maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password."*

And that the system can ensure only authorized access, as stated in 21 CFR Part 11:

*"Use authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand."*

### AUDIT / ACTIVITY LOG

A non-editable Audit Log that is independent of any authorized user and time-stamped is available. This outlines events (logins/executions/edits time and date stamped) performed by all users. Log entries are stored in onboard memory while the system stores all the activity with a built-in autosave function.

This meets the 21 CFR Part 11 requirement for user-independent, time-stamped audit trails.

The administrator can ensure access to the Audit Log is restricted. The data can also be exported to a USB flash drive for review.

### INSTRUMENT EDIT COMMENTS

This may be invoked to force users to enter reasons and comments when any changes are made to the instrument. This delivers an added degree of transparency with additional documentation to ensure all user actions are above board and defensible.

### PDF REPORT GENERATION

All reports, such as Test Result Data, Program Configuration, Instrument Setup, Audit/Activity Log, may be exported as a non-editable PDF. This ensures data security, while at the same time, making that data accessible and usable across the organization.

### DATA RETENTION AND SECURITY

All data is retained for easy retrieval and examination for as long as required under 21 CFR Part 11 guidelines. If storage capacity in the leak test instrument is reached, it can be securely exported via text or PDF.

In addition, other than exportation (subject to their individually defined roles), users have no direct access to the data (ability to modify) stored within the leak test instrument.

## ADMINISTRATOR CONFIGURABLE

The administrator function of Blackbelt Pro allows the highest authorized user to assign and manage capabilities to other users regarding:

- Password expiration days
- Max login attempts
- Inactivity timeout and expiration

This meets the 21 CFR Part 11 requirement that "password issuances are periodically checked, recalled or revisited." In addition, testing process sequences, as defined by the type of test being performed, are strictly controlled and can only be modified by an authorized administrator.

In addition, Blackbelt Pro allows for customizable login banner messaging. While this capability is not specifically required under either 21 CFR Part 11 or its EU counterpart, it does provide an administrator with added versatility to provide targeted messaging to individual users when they log in. This helps to ensure that anyone with authorized access to the leak test instrument remains informed about terms and restrictions of their user privileges.

## Conclusion

The need and desire to collect and analyze greater and more granular volumes of process and test station data from the production line has long been a holy grail for manufacturers in many verticals. As the technology to do so has become more powerful and intelligent, and less costly and complex to deploy, manufacturers find themselves in something of an arms race with their competition.

This includes competitors in the medical device manufacturing industry. But any investments in such data collection and analysis capability in this domain must abide by the regulatory requirements laid out by The U.S. Food and Drug Administration's Title 21 CFR Part 11 and European Medicine Agency's Annex 11.

With the latest iteration of our Blackbelt Pro leak test instrument, CTS has listened and responded to the needs of our medical device manufacturing customers to ensure they can make the most of their leak test data with the confidence that they are fully compliant with current regulations.

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