Technical Note

March 2019

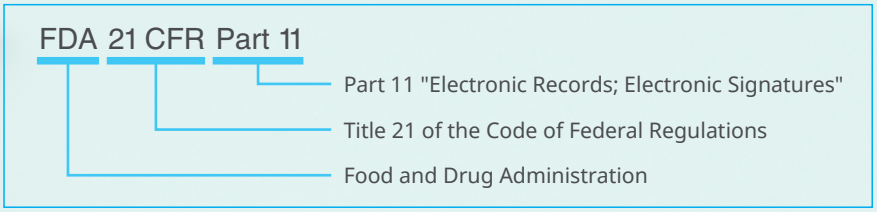
Anritsu
envision : ensure

21 CFR Part 11 Data Management are the basis of Data Integrity

Accurate and complete data management and tracking is of critical importance in pharmaceutical production. The United States FDA regulation **21 CFR Part 11** addresses how pharmaceutical manufactures are required to collect electronic records and signatures.

• What is "FDA 21 CFR Part 11"?

FDA 21 CFR Part 11 regulates electronic record keeping for pharmaceutical and medical product manufacturers. It requires that electronic records be generally trustworthy, reliable, and generally equivalent to paper records and handwritten signatures.
Additional requirements for this regulation include that "data shall not be easily falsified" and "history of all changes to records shall be captured". If you satisfy all the requirements, this will give the electronic records and signatures equivalent legal weight of paper records and signatures.



• Why is data management necessary?

To ensure that pharmaceutical products are safe in the digital age, it is critical to properly record all manufacturing parameters during production runs.
The data requires strict management to prevent falsification and assure trust in the data's integrity.

• How can data reliability be secured?

Even if data is managed properly, it is very difficult to prove that the data is reliable. For this purpose, each country has developed guidelines for securing data reliability. If users manage data in compliance with the guidelines, they can demonstrate data integrity and use it as evidence that their drugs have been manufactured in accordance with the applicable local standards.

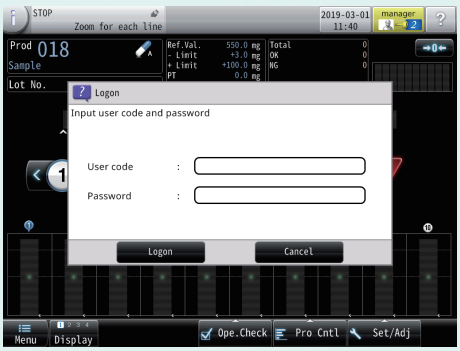
• Anritsu's compliance with Part 11

Anritsu satisfies Part 11 with the following functions:
- User authorization
- Audit trail
- Data output to USB and data encryption/decryption

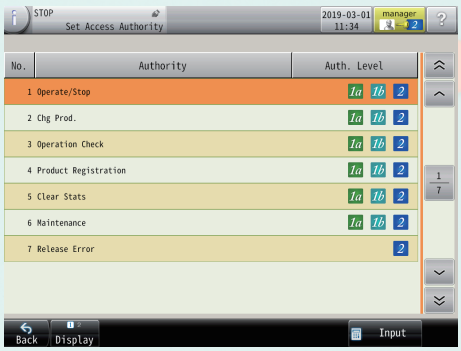
See details on the following page.

• User Authorization

Part 11 requires "limiting system access to authorized individuals" only. Our systems limit user access with the User Authorization feature.



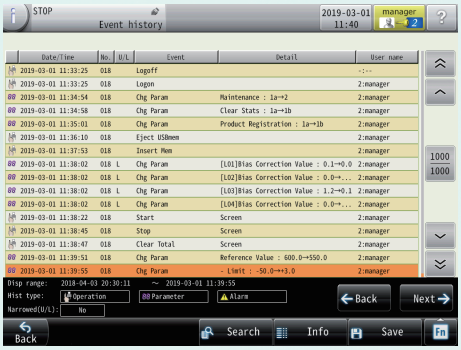
Log on screen



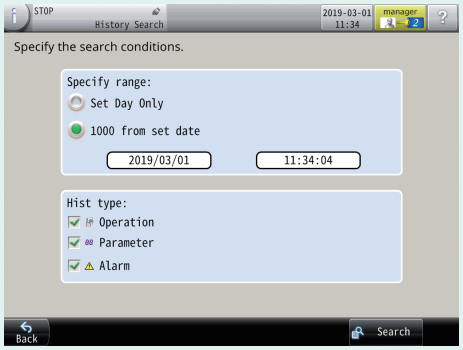
Access-level registration screen

• Audit Trail

Part 11 requires "the protection of records to enable their accurate and ready retrieval throughout the records retention period". With Anritsu's inspection systems, users are able to easily retrieve parameter and operation history, statistical data, and the results of performance accuracy checks, which are all recorded in the device as an Audit Trail.



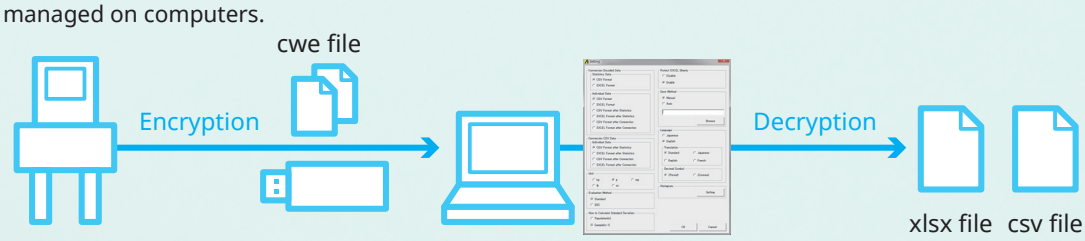
Event history



Retrieve History screen

• Data Output to USB Flash Drive and Encryption/Decryption

Part 11 requires that you should "consider the impact" your computer systems "have on the accuracy, reliability, integrity, availability, and authenticity of required records and signatures."
Anritsu's inspection systems can export encrypted inspection records and device parameters locally to USB flash drives. The encrypted data can in turn be decrypted (using a proprietary software tool) and managed on computers.



• Summary

To learn more about Anritsu products and its Part 11 support, please contact us.

Anritsu products information: https://www.anritsu.com/infivis/
Contact us: https://www.anritsu.com/infivis/contact-us