【GMP003】
US FDA 21 CFR Part11 Support
Recording and reporting for API manufacturing data
SMARTDAC+ GX10/GX20

Background

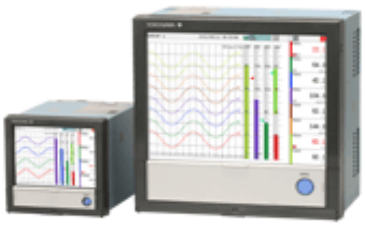
- ✓ Pharmaceuticals are strictly regulated by the Pharmaceutical Affairs Law because of the requirement of accurate efficacy and high safety.
- ✓ In the manufacturing process of a pharmaceutical company, it is general to make pharmaceuticals by adding an inactive ingredient excipient to the drug substance which is the active pharmaceutical ingredient (API).
- ✓ Regarding manufacturing the drug substance, sufficient control is required because the quality of pharmaceuticals depends on the drug substance.

Customer's Requirement

- ✓ API manufacturing data is required to be recorded and reported in compliance with US FDA 21 CRF Part 11
- ✓ These manufacturing data are required to be recorded and reported for each manufacturing batch with the product, manufacturer name, etc. .

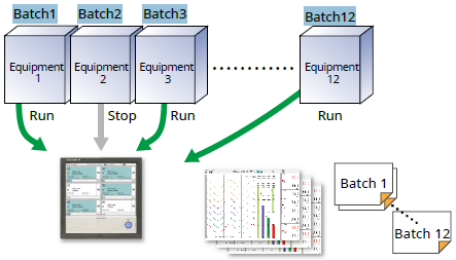

Yokogawa's Solution

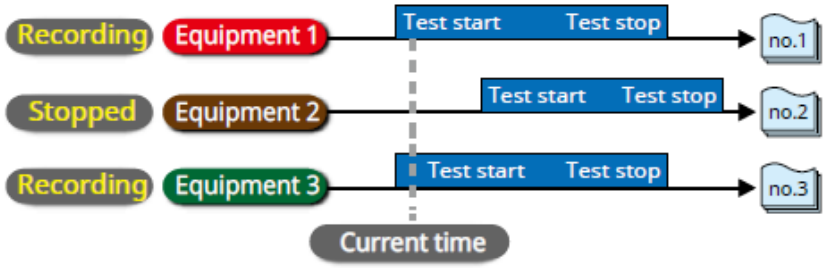
- ✓ Yokogawa's paperless recorder GX10 / 20 supports US FDA 21 CRF Part 11 with advanced security function option.
- ✓ Login function by user name, user ID and password, electronic signature function, audit trail function, data file tampering prevention function, password management function (Active Directory) can be available and It also supports data integrity in accordance with ALCOA mentioned in PIC/S, WHO, MHRA and FDA guidance documents.


GX10/GX20

Customer benefit

- ✓ Support US FDA 21 CRF Part 11 such as login function and audit trail function. Enhancement of security functions enable to prevent data tampering.
- ✓ Independent data recording is available for each batch
  - Batch name, time, product name, person in charge, etc.

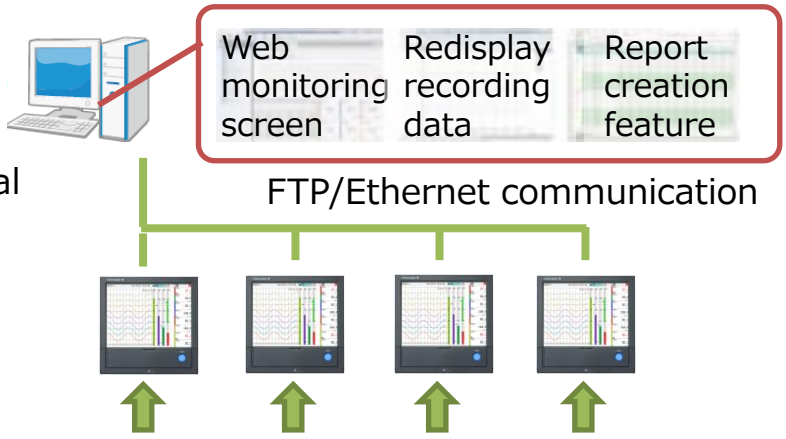




Product Solution for Pharmaceutical

GX10/GX20 Paperless Recorder with Advanced Security Function (/AS)

- Vertical panel mount
- 12.1"/5.7 TFT color LCD
- Up to 100 channels (built-in, GX20)
- Maximum 1.2 GB internal memory (GX20)
- Up to 32 GB SD/SDHC card
- Ethernet (built-in)



FDA 21 CFR Part11 Guideline for Electric recorders and signatures

- Login function
- Audit trail function
- Data file protection
- Electronic signature function
- Data integrity(new)

Clean Room, Stability test equipment, Refrigerator, Freezer, Thermostatic chamber

◆Validation document

Validation documentation (sold separately) is a validation protocol template that simplifies the validation of GX/GP/GM and SMARTDAC+.
The document is provided on the Yokogawa website as an MS Word file for easy editing.

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