

Data Recording for Tunnel Sterilizer in Vial Manufacturing Plant

SMARTDAC+ GX10/GX20

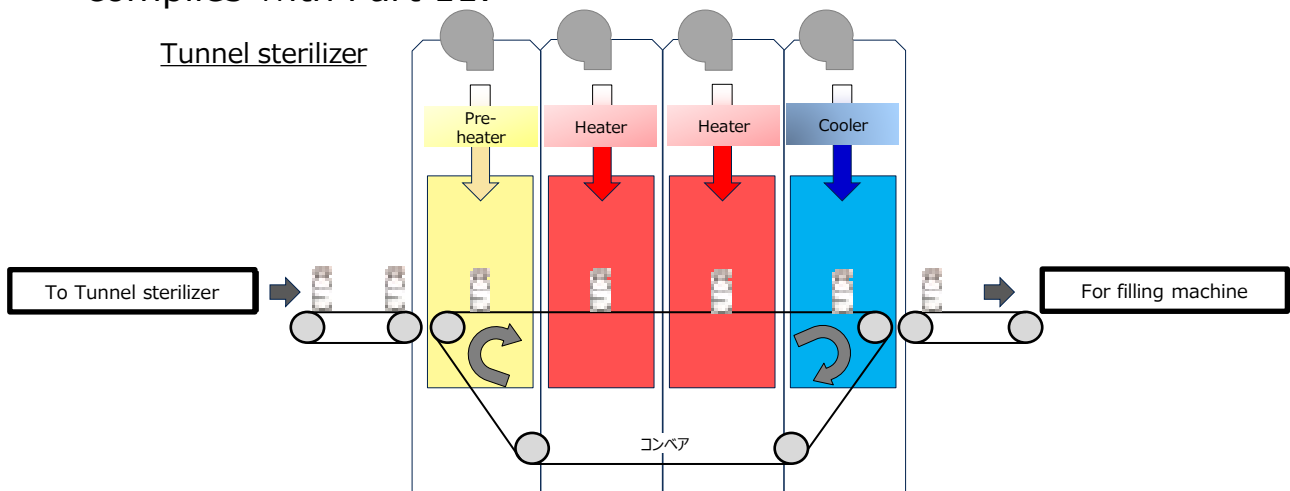
Backgrounds

- ✓ The vial formulation (injections) must not contain foreign substances, microorganisms, and exogenous febrile substances which called pyrogen (endotoxins) because they are administered directly into the body. For this reason, vial manufacturing plants require more advanced manufacturing facilities and control of bacteria and foreign substances in the manufacturing environment than oral (solid and liquid) and topical drugs.



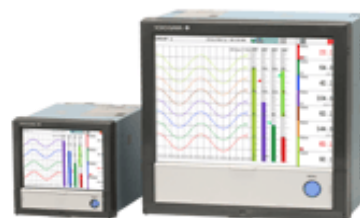
Customer Issues

- ✓ Vials (vaccine containers) are sterilized in a tunnel sterilizer before being filled with vaccine. The sterilization temperature and time of the tunnel sterilizer should be recorded and managed in a way that complies with Part 11.



Proposal

- ✓ Yokogawa's GX10/20 paperless recorder complies with U.S. FDA 21 CFR Part 11 with an extended security feature option.
- ✓ Login function with user name, user ID and password, digital signature function, audit trail function, data file tampering prevention function and password management function (Active Directory) are available.



GX10/GX20



Customer merit

- ✓ Eliminates human error caused by data transcription and manual input, enabling operations with highly accurate data.
- ✓ Sterilization data records can be managed electronically in a meaningful way
- ✓ Support for Part 11, including login and audit trail functions. Enhanced security features to prevent data tampering
- ✓ Enables computerized system validation of the entire system under GAMP5 guidelines



SMARTDAC+ Advanced Security Functions with 21 CFR part 11 Compliance

Electronic records regulation

Secure electronic records

Measured data, settings, and operation logs are saved to a single encoded binary file. Encoded data in binary format offers a high level of security as it cannot be opened in text editors.



Controlled system access

System administrator access allows for registration of other users and individual login. Username, User ID, password and password expiration can also be assigned for each user. Active directory allows for user name and password to be managed through a centralized server on the network.



Audit trail function

Setting changes and operation logs are automatically recorded and saved into a file along with measured data. The logs can be viewed on the GX/GP main unit and GX/GP/GM web. Or, the logs can be viewed on SMARTDAC+ Standard Universal Viewer software.



Electronic Signature regulation

An electronic signature can be added once measured data is loaded on the GX/GP main unit, or Universal Viewer. Three levels of signature are available: operator, supervisor and quality control.

Validation documents

Validation documentation (sold separately) is a validation protocol template that simplifies GX/GP/GM and SMARTDAC+ Standard system validation.

