

Shimadzu presents FDA 21 CFR Part 11 / Computer Validation Global Support

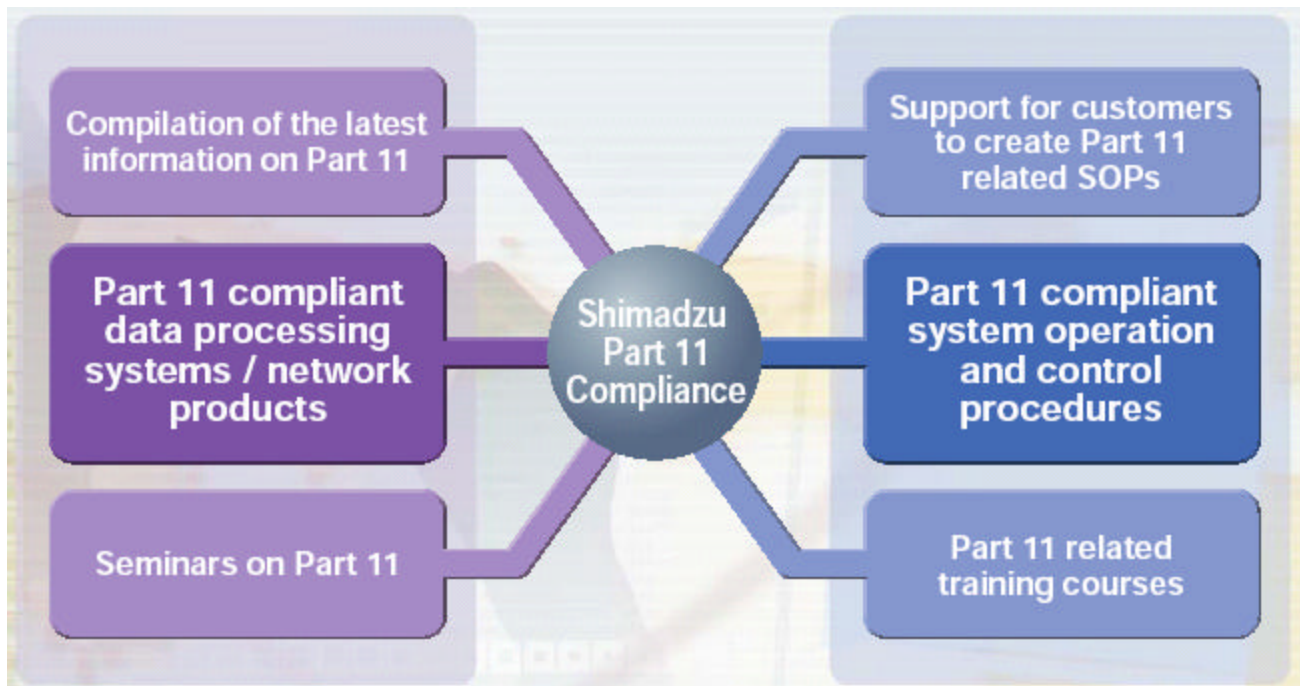
All Shimadzu network system products incorporate functions for the Part 11 compliance and computer validation functions required by GxP. Shimadzu provides documentation including IQ/OQ, Certificates of Compliance, and Inspection Test Result Reports based on Shimadzu ISO9001 certified system.

Shimadzu's accredited service personnel offer full support for validation of customer's Shimadzu products. Shimadzu provides comprehensive customer support for FDA compliance, including supplying the latest information on FDA regulations through seminars and workshops, participating in vendor audits demanded by the Agency, and actively assisting customers to comply with new FDA regulations.

Shimadzu Total Support for Part 11 Compliance

Shimadzu HPLC, GC, Mass Spectrometers, UV-VIS spectrophotometers, FTIR, AA, TOC and other products and their associated data processing systems all incorporate sophisticated, leading-edge technology for **audit trail, security, and Data integrity** functions to comply with GLP and cGMP demands.

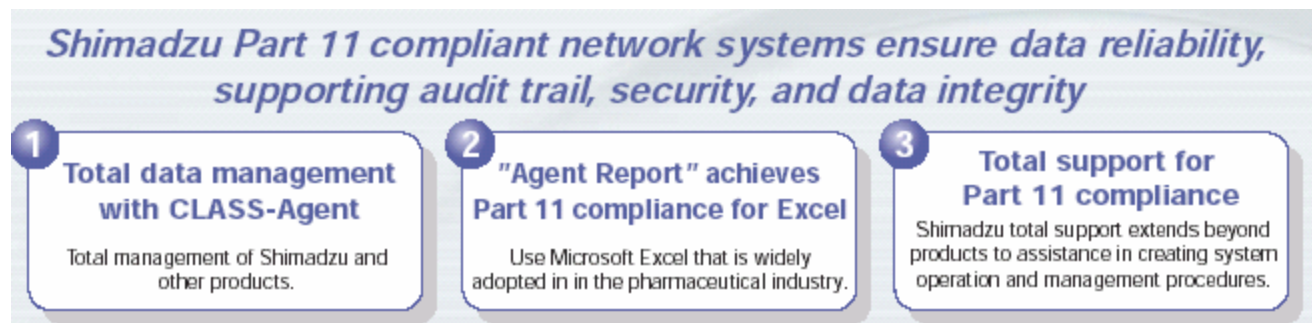
In addition to offering products and network-compatible software products, Shimadzu offers total support for creating system operation and management procedures, provides information, organizes seminars, and offers post-installation training on Part 11.



Shimadzu's Response for FDA Compliance

Shimadzu's basic policy is to comply with Part 11 requirements by integrating data management for all instruments used in the laboratory, including chromatographs and mass spectrometers (HPLC, GC, LC-MS, GC-MS), spectrophotometers (UV, FTIR, AA, etc.), TOC, and balances.

Shimadzu's CLASS-Agent products provide solutions for the Part 11 compliance of all essential laboratory analysis data from chromatographs and spectrophotometers to balances. Shimadzu supports networking for all analytical instruments so that the customer enhances working efficiency and data reliability.



Integrated Management of Analytical Data by CLASS-Agent



Full User Support for Part 11 and Computer Validation

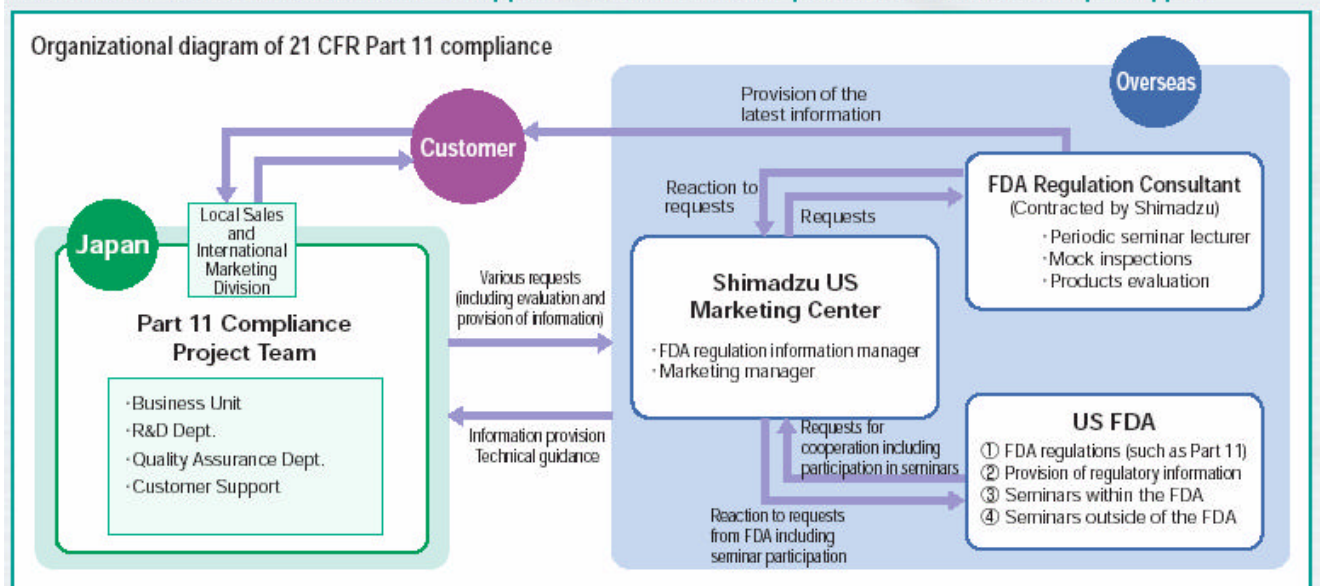
Shimadzu's commitment.

The FDA does not, and cannot, certify the hardware, software or services of specific manufacturers as Part 11-compliant. The reason being that compliance with the regulations requires management and operating procedures and the associated documentation for the system, which involves operational requirements additional to the functions offered by the product.

Consequently, the creation of the company policy and validation master plan by the customer is extremely important for Part 11 compliance.

Therefore, Shimadzu offers the user meticulous total support over the entire lifecycle of the product, from consultations before installing a new system to regular post-installation inspections. Shimadzu in-house systems remain alert to the new requirements of regulatory agencies and national and international trends to continue to offer comprehensive support for customer requirements.

Extensive Shimadzu worldwide customer support network for FDA compliance with flexible and rapid support





CLASS-Agent offers total data management of all laboratory instruments from chromatographs to balances.

CLASS-Agent complies with requirements of the FDA 21 CFR Part 11 (Electronic Records, Electronic Signatures). CLASS-Agent provides secure data management and electronic signature operations for measurement results registered in a database acquired from a range of instruments, including HPLC, GC, GC-MS, LC-MS, UV, FTIR, AA, TOC, and balances, as well as other manufacturers' products. The data is automatically saved in the database for subsequent easy searching of desired data. Additionally, the associated method and schedule information, date of measurement, operator's name, and analytical report image files (in PDF format) are stored together to meet Part 11 requirements for storage of machine and human-readable data. Client/server capability allows centralized management of data from all instruments and simple data referencing from a client PC.

Successful audit

In October 2003, an audit of Class-Agent System software Version 2.1 and 2.2 was conducted by Dr. Sandy Weinberg, an independent consultant with more than twenty years' experience of inspections and audits of biopharmaceutical systems. Dr. Weinberg visited Shimadzu Scientific Instruments headquarters in Columbia, Maryland and performed an evaluation of 9 Shimadzu Data systems (Table 1), which were presented alone and in combination with CLASS-Agent versions 2.1 and 2.2.

Dr. Weinberg concluded that CLASS-Agent version 2.1 and 2.2 conforms in all respects to all current and relevant FDA regulations including 21 CFR Part 11 for Electronic Records and Electronic Signatures, as well as with System Validation Standards and GAMP (US equivalent).

GAMP (Good Automated Manufacturing Practice) is a set of guidelines developed for suppliers and users of automated systems within the pharmaceutical manufacturing industry. These guidelines provide a framework for convergence with other existing standards and schemes, and will reduce the cost and time taken to achieve compliant systems.

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| <ol style="list-style-type: none">1. LCsolution 1.012. LCMSsolution 3.003. GCsolution 2.104. GCMSsolution 2.105. UVProbe 2.016. IRsolution 1.107. TOC-Control V 1.068. WizAArd 4.009. CLASS-Balance Agent 2.20 |
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Table 1. Shimadzu data systems evaluated for compliance with ER/ES regulations.

