Bring field equipment up to regulative standard

Compliance with 21 CFR Part 11 for existing equipment is still a major concern and challenge for the pharmaceutical companies. Billions of dollars in equipment are still in use and work perfectly as it should, and changing the equipment only to get in compliance would cost huge unbudgeted investments and resources.

ZignX Medical is a new product on the market that uses a new technology approach to compliance. It has been developed particularly for legacy systems, taken into account the vast variety of equipment and systems, only to create a highly innovative and standardized solution.

The development of ZignX Medical is a result of 3 years of intense research and collaboration between ZignX and leading worldwide pharmaceutical manufacturer to bridge high-end patented technology with the requirements for 21 CFR Part 11 compliance. While achieving regulatory standards ZignX Medical takes the side of the operating end-user, not to cumbersome the daily work but secures straightforward and seamless operation.

How it works
The ZignX Medical is a mechanically build-in device, but can be considered as a “hardware shell” enclosing the system. Every device attached to the PC-system (e.g. keyboard, CD-ROM, power button, Com-ports, instrument) first runs through ZignX giving it complete control of every input and output that enters or leaves the system.

If the “shell” breaks, i.e. someone tries to bypass the system, ZignX Medical detects it, log it, and perform required measures. ZignX Medical can also be programmed to pass keyboard macros to the PC and also filter out defined input keys from the user.

A self-contained unit
ZignX Medical works independently of the host system. The host PC is by other means in no contact with the ZignX, and therefore no drivers or software is required that could inflict damage or cause validation problems. This also makes ZignX Medical completely Operating System independent and can be installed on other machinery as well, e.g. PLC systems and various instruments.

With the highly limited interference on the exiting system, validation of the new system is made easy and qualification reports can be provided for further customer support.

Data integrity
When ZignX extracts data, e.g. from an instrument, it stores the data onto a ZignX-internal storage which still has no logical or physical access to the host system. Only the Superuser (administrator) can export the data, which is protected by means of a checksum. Further, optional feature will enable ZignX Medical to transmit the data directly to a GxP network/database through the ZignX-internal network interface card. Keeping both logical and physical separation between ZignX Medical and the host PC system ensures optimal data integrity.

Key Features:

- Designed for existing and new equipment
- Little or no interference with host system
- A standardized “of-the-shelf” solution
- Can be installed by general IT technicians.
- Can be installed to a standard ATX compliant PC system within an hour.
- Highly adaptable for custom solutions and special demands.
- IQ, OQ and PQ’s can be provided for easy validation.
- Highly user-friendly interoperability.
- Central administration of user rights and passwords

ZignX Medical meets fundamental FDA requirements

Access control security
The access control consists of a combination of a SmartCard and a user pin-code. The code and SmartCard are verified internally in the isolated ZignX device, protecting against common methods of stealing passwords. The system design requires users to change pin-code regularly according to a set time schedule and to create a code along a given set of rules.

Recording of user log events
All login events, including unauthorised login attempts and erroneous log-ins, will be time-stamped and recorded in a log file in the internal memory of the ZignX box, which cannot be accessed by the user. To prevent attempted log-ins with stolen cards, the time-delay is doubled each time an incorrect password is entered, the maximum delay being 60 minutes. This makes it effectively impossible to sample the code in repeated attempts.

Recording of audit trail
To further ensure a complete audit trail on the PC system, all keystrokes are captured in the ZignX log file, retaining a complete log of who made what keystroke when. Where software is installed on existing equipment, a ZignX Com-component may be installed that allows audit trail extraction from existing software or databases and storage of such audit trail with a secure time and user stamp in ZignX's memory, which cannot be accessed by the user.

Recording of device data
ZignX Medical uses a recorder to generate an exact and complete raw data copy. The recorder logs all RS-232 compatible data exchanged between, for example, a research PC and measuring equipment. The data is time-stamped and recorded together with information on the user of the system in ZignX Medical's secure internal memory to create a complete log of who measured what when.

User Log-off function
Another mandatory FDA requirement is for the equipment to have a log-off function that prevents others from using the equipment if a user leaves it, for example during a test. ZignX Medical permits users, by taking their SmartCard with them when leaving the PC, to block access to the computer, even if other users normally have access to the system. ZignX Medical controls this by physically cutting off the keyboard and mouse.

Timeout function
After a specified period of time without user activity, ZignX Medical automatically logs off the user to protect against the eventuality that a user leaves the equipment without removing his or her card. In such cases, the user must remove his card, insert it again, and re-enter his password on the ZignX keyboard to unlock the system.

User Teams
Users may also be granted rights to use different user profiles or be attached to a user team, enabling team members to take over work initiated by others in the team. Any changes made by the Super-User to the rights of a user or to user profiles are recorded in the log file.

Hardware Profiles (closed systems)
ZignX Medical controls all the internal devices (e.g. hard disk) of the PC system simply by switching power on or off. Each device is controlled individually and associated with one or more profiles. A profile is therefore most adequately described as a combination of devices that are active (powered) when the profile starts up.

Using two hard disks in the same PC allocated each profile makes it possible to maintain two completely separate configurations on the same PC system. In the same way using two ZignX network cards can separate two networks on the same PC.

Optional Features

Proximity based token

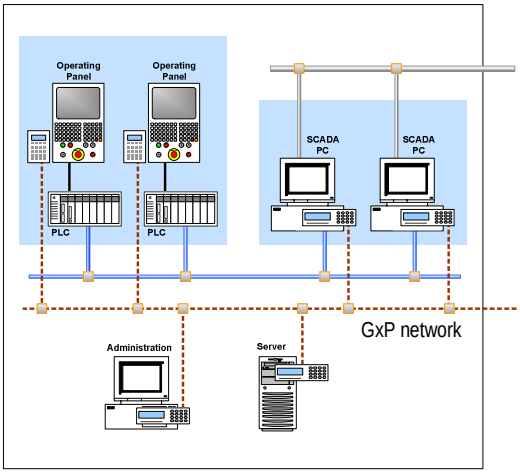
ZignX Medical can be equipped with the optional proximity-based tokens. Proximity based tokens makes daily user operation convenient especially when operating in clinical area.

IP54 environment

ZignX Medical can be mounted in IP54 enclosures to accomplish operating environment and clinical standards.

Storage on GxP network

ZignX Medical has its own built-in network interface card allowing direct communication with a GxP network, where relevant, with or without the equipment on which it is installed having access to the network.



Time Synchronization

ZignX Medical uses its own clock, which are separated from the user. There are various possibilities of synchronising the ZignX Medical clock, for example by using common network time.

PLC integration

The fact that ZignX Medical works 100% independent means that it can be integrated not only in PCs but also a vast variety of equipment e.g. PLC systems and instruments. It must however be custom adapted and wired to manage the individual switches, buttons and keys.