

ZignX, January 2004

Case Study

Upgrading existing SCADA and PLC system at
Novo Nordisk A/S production plant for
21 CFR Part 11 compliance.



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Case Study: Novo Nordisk A/S

Upgrading existing SCADA and PLC system for 21 CFR Part 11 compliance.

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Summary

At a Novo Nordisk manufacturing site, requirements were stated for upgrading two existing SCADA systems. These systems control recipe and batch data on Glatt Fluid-beds and Glatt Coaters in a Pilot production Plant for pharmaceutical products destined for clinical trials.

The objective of the project was to implement a solution to identified gaps in relation to 21 CFR part 11 and EU GMP annex 11 on existing equipments while preserving existing system as far as possible. It was essential that the system could be validated according to cGMP and the project carried out within the guidelines in GAMP4.

Novo Nordisk chose ZignX to integrate their ZignX Medical technology for system compatibility, minimal impact on the validated system, and easy-to-use operability. Upgrading the site using ZignX Medical technology could also be used as reference for future systems.

Existing System Description

The two SCADA Systems each includes 2 Glatt process units (fluid-bed units), that are independent of each other except for the mutual SCADA computer.

Each Glatt process unit is controlled by a Siemens PLC that is accessible by a MegaView1 (MVI) Operating Panel.

All the functions of the process unit can be controlled through the MVI and CIP can be run automatically.

The only functions not included in the MVI system are the handling of recipes and batches, data acquisition and reporting of batch data. The SCADA computer is responsible for these functions.

The SCADA system is constructed of two units; one for batch- and recipe control - which is made in MS Access, and one process related unit build in FIX32.

The FIX32 application sends and receives data from the PLC and it acquires process data to be shown and stored as trend data. The FIX32 user interface consists of a number of screen designs which visualizes process equipment and data. It contains a number of buttons to handle functions related to recipe and batch handling and to shift between screens.

Objectives

All existing functionality that has been documented and validated for SCADA applications and PLC's was to be maintained and unchanged as far as possible. The new system was built around the existing computer systems to handle non-compliance issues in relation to 21 CFR Part 11.

As no standard software or hardware solution was available for upgrading the existing SCADA PCs and PLCs in relation to 21 CFR part 11. A new custom made solution was developed and applied.

Customer Profile:

Novo Nordisk

Novo Nordisk is a focused healthcare company. With the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems, Novo Nordisk is a world leader in diabetes care. In addition, Novo Nordisk has a leading position in areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society.

Existing System



Objectives Addressed:

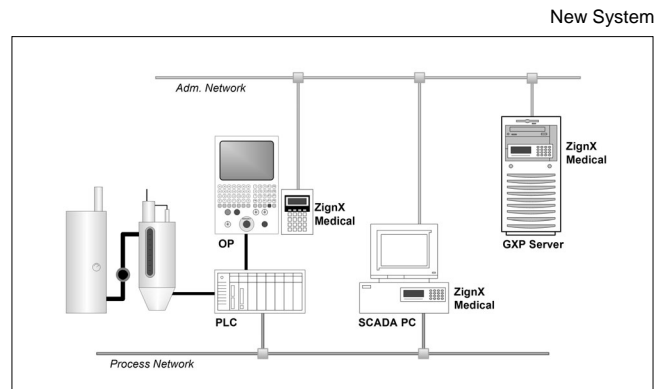
- Access Control & User administration
- Audit Trail function
- Data Integrity and Safety
- Report Generation

General solution description

Novo Nordisk turned to ZignX who have previously implemented access control systems in other Novo Nordisk cases. ZignX suggested a customized version of the ZignX Medial solution that would be tailored to fit the current system. The solution would not only meet the objectives but would do so with a minimum change and impact on the existing system.

A ZignX Medical unit was implemented into each SCADA PC and Operating Panel. The ZignX units operate fully independently of the existing system, but enforce user restrictions on the applied system.

The ZignX units were interconnected using an Ethernet network and tied to a server, running the ZignX Server application for administrative tasks and SQL database for storing of GMP critical data files.

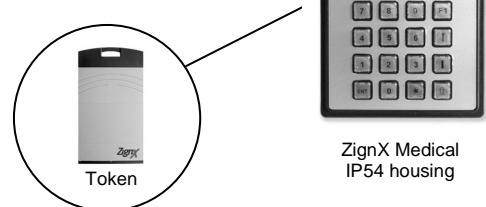


Access Control

The ZignX Medical units provided a uniform and regulative compliant access control to each PC and PLC managed centrally from the ZignX Server application. After installation all user log-events would be recorded with a valid time-stamp and stored in a secure SQL server controlled by the ZignX Server application.

In consideration of the clinical working environment wireless proximity based tokens were chosen for the production area. These tokens are easily attached under the clinical suits and provide convenient operation in the production area.

The log-in keypad uses IP54 approved housing and is situated next to the PLC operating panel. The system functions in such a way that when the operator came within working range (75 cm) of the panel, he or she would automatically be identified and, if not already logged in or had left the room, requested for a PIN-code.



Audit Trail

In order to provide access control and monitoring of the Operating Panel, the ZignX unit would have to take over the control of the Operating Panel keyboard and switch/push-buttons. To do this the optional ZignX Medical Auxiliary module was added.

With this module implemented, the ZignX Medical unit take control (disconnects/ connects) and monitor user inputs according to user rights. An Audit Trail of the actions is recorded in the SQL database along with valid time and user information.

Establishing Audit Trail on the SCADA PCs required dealing with both the FIX32 SCADA application and the Microsoft Access database. To keep an Audit Trail and secure the database files, a custom Windows Service was developed that runs in the background.

The additional Windows Service did not alter the existing programs but creates a logic shell around the FIX32 application. This controls access, user actions, and screens and also keeps surveillance of the Access database and record changes. The Windows Service stores this information in the secure SQL database.

The Windows Service is a passive program that made no interaction with the existing software, and was easy to validate.

Data Integrity

Each ZignX Medical unit keep all GxP critical data away from the user, encrypts data transmissions, and stores it via a Gateway in the SQL database. Once the data is collected it can not be accessed, deleted, or changed without being detected and recorded.

All communication between the ZignX Medical units and the SQL server runs through a Gateway which only allows records to written to the SQL database. Records can not be altered or deleted through the Gateway.

Also the ZignX Medical provides intrusion detection on the PC enclosures to ensure that attempts on physical break in will be detected and registered.

All attempts to unauthorized login is recorded and stored in the SQL database. In case of unauthorized login attempts or access, the system administrator's attention is addressed automatically by e-mail.

Report Generation

In excess of the existing reports generated by the system additional reports was generated using the ZignX Medical solution;

Audit batch report with identification of users in alarm log and message log performing GMP critical tasks.

User list report with information on users and user access levels for all users on the operator panels, the SCADA systems, and the ZignX systems.

Audit trail report from changes to the SCADA computers and ZignX server including who did what changes, and when. The report generator included query functions for batch no., recipe, time interval, and place of change, person plus log-in/out processes or other events.

Data Safety

Data safety was met using the following measures:

- Battery Powered Backup units was installed (UPS)
- Image storing and recovery
- Redundant disk storage (RAID)
- Regular Database Backup
- E-mail notification



ZignX Medical - for PC installation

Achievements

The Novo-ZignX Medical project showed that it is possible to get legacy systems in compliance with 21 CFR Part 11 at a fraction of the cost of buying and implementing new systems.

This project showed how adaptable the ZignX Medical solution is and how well it can be fitted almost any requirements. With ZignX Medical getting fundamental GMP requirements such as Access Control, Audit Trail and Data Integrity can be implemented fast, economical, and with high customer satisfaction.

Even with the Sep-03 updated guideline compliance and GMP will still be in great demand for high-risk systems and systems subject to predicate rules will especially be in focus.

Drawing of ZignX Medical modules to manage Operating Panel and Radio Token technology.

