

# Press Release

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## New solution for bringing existing automated systems in compliance with 21 CFR Part 11.

A joint force project between the two companies ZignX and Novo Nordisk A/S has resulted in a unique solution for fulfilling the EU- and American requirements EU Annex 11 and FDA 21 CFR Part 11, on existing production which were deemed incompatible with today's compliance solutions.

The project goal was to secure existing PLC controlled manufacturing systems with operating panels and SCADA pc's. The new solution ZignX Medical provide access control, system locking, control of user rights, data security and audit trail to the existing system all in regulatory compliance and according to GAMP4 guidelines.

The ZignX Medical solution makes it possible for Novo Nordisk A/S to identify and record what happened on the equipment during a manufacturing batch, i.e. *who did what, when*. The ZignX Medical solution is an interesting way out for the pharmaceutical industry as ZignX Medical is an answer on a general problem in the automated industry regarding access control and data security etc.

Novo Nordisk A/S, a global leading pharmaceutical manufacturer and among the top concerning quality assurance, set the requirements for a flexible and independent security system that could be used on a variety of computer and production systems. Novo Nordisk A/S solicited ZignX to develop a solution based on their patented security system ZignX, which fundamentally operates independent of the existing system. Hence the solution makes little impact on existing validated systems and validation can be made quickly and at greatly reduced costs and resources.

Actually Novo Nordisk A/S initiated the development of the solution. "The cooperation with Novo Nordisk A/S has been outstanding and joined technology with user requirements to a unique solution. The solution to Novo Nordisk A/S is generic and modular so adoption for other systems can be made easily" – says **Jacob Ringgaard, ZignX**.

**Ulrik Hjulmand-Lassen, Technical Advisor - Novo Nordisk A/S:** "The great challenge was minimizing the impact on the existing validated system and avoid cumbersome and difficult routines for the operator, but still to obtain access control and data security. The ZignX Medical solution successfully met our demands"

**Bent Højgaard, System owner, Novo Nordisk A/S:** "With the ZignX Medical solution our system is now in compliance with the 21 CFR part 11 regulative without impact on the originally validated system. The daily use of the system has not changed to any noticeable extent".