Manufacturing

Process Quality Redefined

A case study of how the German company Fresenius updated and extended its SCADA system to provide more efficient generation of proof-of-process data, and reduce the risk of costly downtime.

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Strict regulations for proof-of-process and product quality apply in the production of sterile dialysis solutions. This article reviews how, in order to fill potential gaps and avoid the associated loss of production, a leading manufacturer updated its proven Supervisory Control and Data Acquisition (SCADA) system and enhanced it with additional functionality – mainly redundant data recording and storage, as well as convenient analysis capabilities.

SEAMLESS PROOF-OF-PROCESS

US FDA regulations 21 CFR Part 11 for electronic data recording and electronic signatures clearly define: pharmaceutical products must not be marketed if the data recording cannot be seamlessly traced. In the case of data loss – for example, caused by a failure of power, communications or a hard disk – the affected batch must be destroyed for safety reasons.

To prevent this, Fresenius Medical Care Deutschland GmbH has always employed comprehensive data storage; this also applies to their St Wendel plant that primarily makes products and sterile solutions for dialysis. The company had been using an open SCADA system (Simatic WinCC from Siemens) to control and visualise the preparation of such solutions; however, the proof of production conditions were delivered by means of an independent software package that was specifically developed for the company and for which development
and adaptation to relevant standards would only have been possible at a high cost.

For this reason, a modernisation project was undertaken, the aim of which was to increase the overall efficiency of production and – especially – to make the seamless proof-of-process data from the solution tank to the dialysis bag easier and safer. In collaboration with Jücker GmbH & Co KG, an automation provider and certified Simatic WinCC specialist, the WinCC application was updated to include the integration of additional subsystems and functionalities, as well as the implementation of redundant data management.

STERILE FROM TANK TO BAG

The production of about 120 different sterile solutions for all dialysis variants starts with the preparation of solid and liquid ingredients – mainly glucose, salts and water. The finished mixtures are subjected to sterile filtering and chemical analysis, and then stored in large tanks for filling into dialysis bags. During these operations, all process steps and data must already be seamlessly collected and archived so that – in the event of any complaint – they can be tracked and the cause of any potential problem subsequently analysed.

Several production lines are operated by Fresenius; the system described automatically feeds one line each for the filling of single- and dual-channel bags. The company usually develops its own products, process and production technologies in order to be able to act directly with regard to quality-related process parameters and to protect its know-how. For example, the film for the dialysis bags and the outer package, as well as the tubing, are all made by Fresenius; a patented polyolefin mix (Biofine) is used that is free from softeners and is therefore more suitable for human use and can be disposed of in an environmentally-friendly manner.

The bags – which are produced under cleanroom conditions – are fitted with welded hose connections and printed, and then automatically transported to the filling machines. After completion of the tube system, the bags are sealed in an outer package and transported from the cleanroom over a central packaging conveyor to the sterilisation step; this takes place in one of two large autoclaves that have numerous individual chambers – another in-house process and mechanical development resulting from collaboration between several Fresenius subsidiaries. Prior to autoclaving, robots take the bags and position them safely on one of eight levels in each chamber. For a defined duration, the bags are sterilised in hot water and steam at a constant temperature, before the robots pick them up again – now in a sterile condition. Following visual inspection, the bags are boxed as daily quantities and palletised for shipment.

PROCESS TRANSPARENCY REDEFINED

Fresenius had already been using the SCADA system Simatic WinCC as a proven human-machine interface (HMI) to the preparation plant. With the updated scheme, the lower-level Simatic controllers are still connected to both the system and to each other over a
fibre-optic Ethernet network including switches. However, with the existing documentation system, any interruption in the data flow and any gap in the proof-of-production always required the destruction of the complete product batch. This was not only costly but also jeopardised the ability to deliver.

Charged with the task of finding more efficient tools for these functions, Jücker presented a number of possibilities to extend and upgrade the existing system, and was finally awarded the contract for extensive modernisation. On this occasion, the existing OP 35 operator panel on the autoclave was replaced with a higher-performance Simatic PC 670 panel, which was connected to the WinCC servers as a client. This significantly improved the HMI convenience because it was now also possible to visualise the process locally in great detail, enabling faster intervention.

**REDUNDANT PROOF-OF-PROCESS QUALITY**

The main focus, however, was on the safe collection and archiving of process data under as many different conditions as possible; this was ensured by providing an uninterrupted power supply to the key components. In the first place, this was implemented with two WinCC servers that were installed in the control centre and connected to the process in parallel, enabling them to continuously monitor each other by means of the redundancy option package. Should one server fail, then the other would automatically take over its tasks. During recovery, the archives are automatically updated without affecting ongoing production, so that the integrity of the data is ensured under all circumstances.

Everything considered, a total of about 2,800 process variables are collected – such as temperature, dwell time, pressure and flow – and transferred over Ethernet from the lower-level controllers to the redundant servers. About 480 variables must be evaluated for the internal release of the product, and then analysed far beyond their expiry dates in order to allow subsequent offline analysis to determine whether the processes have been executed as prescribed.

The choice for these specific tasks was the Siemens WinCC add-on PM Quality – a modular, industry-independent archive system designed for the batch-oriented collection and evaluation of large quantities of freely definable process and quality data. These data can be archived, visualised and analysed in many different ways, from diagrams to logs. They show the quality manager and the plant operator at a glance whether the predefined set-point values have been achieved, if and where limits were exceeded, whether the process and product quality was correct, or at what point in time it was still correct. The batches from different clients can be

![Figure 4: Jücker Mess- und Regeltechnik has generated about 30 WinCC screens for operation and visualisation, acquisition and archiving of relevant process data](image)
called up quickly and conveniently at any time using filter and selection criteria, and analyses for potential optimisations or the addition of laboratory values are easily made possible.

To make plant information available throughout the company, a separate WinCC/Dat@Monitor web server was set up on a WinCC Client. This is a system option that provides different tools for the display and evaluation of current process states in process images, as well as historical data on any office computer.

The basis for the visualisation of the WinCC data by means of Internet-based standard tools (such as Microsoft Internet Explorer) is the Web Navigator from the WinCC toolkit – with operator interventions being prohibited by the system for safety reasons. However, all images from the WinCC projects, as well as custom-configured overviews, can be displayed. Jücker managed to implement the extended functionality of the then brand-new system version within a very short timeframe to meet the Fresenius schedule. Currently, work is also being done to implement access to current and historical process values; this will allow the operator to analyse the data by interactively configuring the presentation of WinCC data by means of a Dat@Workbook assistant in the MS Office program Excel from any office PC with great convenience. Following the online transfer to Excel, these process data can be presented and archived using the standard tools of the spreadsheet software.

Users of future WinCC versions might require even higher degrees of freedom, for example, for the creation of non-preconfigured, user-specific analyses and evaluations at the office level, and via connected wireless (WLAN) hand-held PCs or PDAs and Internet Explorer.

**A ONE-STOP SOLUTION**

According to Dr Uwe Rosenberger, Technical Director, Sterile Solutions, at Fresenius, the company chose WinCC because it wanted a standardised, yet flexible system that could be easily adapted to changing production conditions. For example, it is possible to add another sensor or a few lines of program code even without external support, in order to selectively analyse certain process parameters. Last but not least, this simplifies service and maintenance operations since the causes of errors can be identified and corrected more quickly, without having to use an oscilloscope or hardware recorder. Moreover, the company wanted to reduce its existing dependency on a single system supplier, while continuing to benefit from a one-stop solution in order to minimise the number of interfaces.

The extended system has now been providing a stable and reliable level of performance for about 18 months. By ensuring the redundancy, Fresenius is now able to provide seamless proof-of-process data in compliance with 21 CFR Part 11 more efficiently than ever, and the risk of costly downtime has been significantly reduced.

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