



Case Study

Krewel Meuselbach GmbH

Stainless steel IPCs control, monitor and document the production of pharmaceuticals in compliance with GMP



noax Industrial PCs in the production of pharmaceuticals in different dosage forms at Krewel Meuselbach GmbH

100 percent safety in the production and documentation

"We're just different. We invest in high-quality technical equipment and systems, and we count on the qualification of our employees," said Dr. Peter Stahn, Production Division Manager, as he introduces his company. "Naturally, the choice of our business partners

"The noax IPCs, they just work. There's really no other way to say it."

is also based on our philosophy. We count on our expertise, know-how and technical knowledge.

It is the only way we will achieve our objectives. This is precisely the expertise that I have experienced with Klar Partner AG and noax Technologies AG."

Positive feedback

One project where expertise of an outside company was crucial was the introduction of a Manufacturing Execution System (MES) in connection with Industrial PCs in production. The goal was to control and document all of the process steps in the manufacturing of pharmaceuticals seamlessly. Dr. Stahn points out emphatically how quickly the combination of noax IPCs and the validated MES COSREWIS of Klar Partner AG was accepted by employees. "Some people have been working here for 20 or 30 years and overnight they had to enter data, previously written on route cards, using a scanner and an IPC. However, there were hardly any problems. This is because we consulted our employees in the decision-making process from the beginning. They had to operate the equipment right away during the presentation and decide for themselves if they wanted to work with them. noax Industrial PCs received positive feedback from our employees immediately." Dr. Stahn opens the metal doors to the production facilities

to demonstrate on the spot how the system composed of COSREWIS and noax hardware helps the employees. Krewel Meuselbach uses Steel S12 type Industrial PCs for weighing and packaging tablets. For the weighing of the ingredients, three scales – a floor scale and two table scales – are connected via an RS-232 serial port to a noax IPC. A scanner for reading barcode labels on packaging is also connected to the Industrial Computer. On the software side, the pharmaceutical manufacturer uses the COSREWIS weighing module. The employees use this module to check if the ingredients used meet the specifications. In addition, they check the condition of the quality status, the expiration date and other parameters. Furthermore, the software uses pictograms to inform the user of any hazardous materials and reports the quantities weighed back to the ERP system.

Perfect coordination

The Production Manager is very satisfied with the data exchange between the ERP system and COSREWIS, "Every time it went off completely without a hitch." In addition to weighing the individual ingredients and communicating with the ERP system, the main task of COSREWIS in the Krewel Meuselbach production process is to generate and execute manufacturing process instructions (abbreviated: MPI). This process starts as soon as the order is read from the ERP system. At this time, the MES software generates order-specific manufacturing instructions. The COSREWIS MPI controls, monitors and documents how the machines carry out the individual process steps. For example, this includes the stirring, heating, mixing, transferring or collecting of ingredients. The MPI module



Without them nothing works – the noax IPCs in the production of pharmaceuticals

Manufacturers of pharmaceutical products in the EU are obliged by law to maintain a documentation with state-of-the-art technology. So is ensured that the production history of every batch and every change that has been made in the development process of an investigational medicinal product can be traced. The long-established company, Krewel Meuselbach GmbH, relies on the stainless steel Industrial PCs by noax to control and document its production processes.

noax Industrial PCs and the COSREWIS MES software ensure the GMP compliant production of pharmaceuticals



uses a bidirectional coupling with the PLC to control the manufacturing processes in the machines. Dr. Stahn points to one of the shiny stainless steel IPCs, "Look at the screen. Here you see how the program runs through the process steps. In addition, with this module I can also register or retrieve other process relevant values manually. Here, I'll show you using the pH value." He briefly types on the screen and a window opens. In the window, in addition to the tolerance range, the setpoint value and the currently measured actual value can also be read clearly. In this case, the manufacturing instructions provide a tolerance range between 4.5 and 5.5. The current measured value is 4.75. "That's OK," comments the Production Manager on the result. "I don't have to intervene in the process. I just tap on the button with the green checkmark and the step is confirmed." Also, two rooms away Krewel Meuselbach is coating tablets using more noax IPCs.

Step by step

Tablets are often given a layer of coating. The coating makes the tablets easier to swallow, taste better and look better. In the case of pharmaceuticals, the coating prevents the tablets from being dissolved by gastric fluids. The employees use the noax IPCs and the MES to monitor and document this process, referred to technically as "coating". First, the weight of the entire coating material in the machine is determined. After the process is finished, the material remaining in the machine is weighed. The difference of a batch must be applied to the tablets. To verify the theoretical result, individual samplings are weighed again and the coating application is calculated subsequently.

This way Krewel Meuselbach receives double verification. COSREWIS saves and documents all the entries and process steps so they will be available for possible samplings or for tracing in the company network. The software also assumes a further role within the production process. According to Dr. Stahn, "The output of a finished process is the input for the following process." Using the example of tablet packaging,



noax IPCs calculate the coating application

the Production Manager explains what this means, "Since we monitor every step of the process, we know exactly how many tablets we have produced. This number is used as the basis for calculating the packaging material, that is, how many blister packs, boxes and package inserts we need." Exact entries, and above all, reliability have top priority in the production of pharmaceuticals, because that is the only way to ensure the GMP compliant documentation of the processes. Since the overall system, composed of MES and Industrial

Computers, controls and documents the production processes, it is especially significant in the production line. Dr. Stahn states, "The software is already very significant here but the best software is of no use if the hardware is not working." In response to whether he has experienced a failure of the IPCs, he answers curtly, "No, here nothing has ever broken down."

"They just work!"

Despite the fact that noax Industrial PCs are exposed to enormous pressures in the Krewel Meuselbach production process they continue to work. On one hand, employees constantly bump into the Industrial Computers with forklifts or other vehicles. On the other hand, all the production equipment – including the Industrial PCs – is cleaned regularly with special water and corrosive disinfectants. "For the IPCs this means they have to satisfy the cleaning requirements and survive the cleaning without damage. Otherwise, they would be out of place here," Dr. Stahn explains. noax IPCs are built in accordance with protection class IP65, therefore, neither water jets nor disinfectants can do any harm to the hardware. The robustness of noax computers was one of the main reasons why the Krewel Meuselbach management decided in favor of the noax IPCs. For the Production Manager, in addition to user friendliness, this is the most important argument, "We require that the device does not have to be replaced continuously." Then he adds, "The noax IPCs, they just work. There's really no other way to say it. From our standpoint, the investment in noax IPCs and in the MES software COSREWIS was right on the mark!"

"noax Industrial PCs received positive feedback from our employees from the very beginning."



Krewel Meuselbach GmbH

Company Profile:

The history of Krewel Meuselbach GmbH goes back to the year 1893 when August Krewel founded the company, Krewel & Co. Chemists. In 1922, Ernst Georg Blank took over the pharmacy and expanded it continuously into a producer of pharmaceuticals. After German reunification, the Krewel company took over one of the oldest pharmaceutical companies in Germany, Meuselbach Pharmaceutical Company from Thuringia, and was thus able to expand and broaden their product portfolio in a meaningful way. Krewel Meuselbach is known in particular for its various herbal-based medicinal compounds. This includes Aspecton or Hedelix. In addition to Germany, the company is represented today in more than 20 countries.

More information online:
www.krewelmeuselbach.de

Specifications and Application

Objectives:

- ✓ More exact documentation and monitoring of production
- ✓ Automatic data collection on scales and production machines
- ✓ Automatic generation of manufacturing instructions
- ✓ Production control according to manufacturing instructions
- ✓ Very detailed reproduction of all processes in the manufacturing
- ✓ Retrieval and exchange of data with the blending enterprise resource planning

IPC Requirements:

- ✓ Use in the production facilities of a pharmaceutical business with the highest hygiene standards
- ✓ Daily cleaning of the IPCs with disinfectants
- ✓ Resistance to aggressive chemicals
- ✓ Completely sealed construction in accordance with protection class IP65
- ✓ Protection from disinfectants, corrosive chemicals and splashing water
- ✓ Easy, intuitive operation by employees
- ✓ Easy-to-read touchscreen displays
- ✓ Robust, resistant construction
- ✓ Maximized operational stability and availability under extreme conditions

Overview of Components

Hardware:

- Industrial PC Steel S12
- In-house developed noax all-in-one motherboard
- Input: particularly robust touch panels
- Bright, high-contrast TFT display
- Protection class IP65 (NEMA 4)
- Completely sealed, without external fan

Software:

- Operating system:
All MS operating systems from Windows 2000 SQL database
- Application program:
Validated COSREWIS® MES for the batch-oriented industry
www.Klar-partner.de

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