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Visualization coupled with visual appeal

Operator control and monitoring in pharmaceutical production

The operator control and monitoring systems used in pharmaceutical manufacturing have to comply with specific functionality requirements and at the same time stand up to scrutiny in the light of GMP regulations. The VisuNet GMP product family was explicitly designed to meet these challenges. This building block system spans a broad spectrum from simple industrial monitors through remote monitor systems, with an Ethernet connection to the host PC, to complete PCs in several different versions.

Both the development and the production of pharmaceuticals are regulated; they must be seamlessly documented and continuously monitored in the form of an audit trail and official inspections. In the pharmaceutical industry batch production is the norm, and the process control systems used for automation generally have a very large number of measuring points for quality monitoring. Batch oriented production presupposes detailed, recipe controlled sequences of steps, as provided by MES systems. Since it also involves frequent interaction with the plant operator on site in the production area, the monitors and input devices for monitoring and controlling the processes are installed directly in the equipment. They therefore have to conform to the same GMP regulations as the complete production facility.

Compliance with the following GMP requirements is particularly important:

- Optimal clean ability
- Chemical resistance to open products as well as to the cleaning agents and disinfectants used to clean the machinery
- No abrasion of materials
- Suitability for clean room environments where necessary
- Use of antibacterial membranes for the membrane keyboards that are meanwhile installed as standard

The operator workstations moreover need to be connected to the often very remote hardware of the process control and / or manufacturing execution system as flexibly and securely as possible. Operator-process communication must be absolutely reliable, for instance with the help of a fault-tolerant design and optional redundant structures. If the workstations are located in a dust or gas hazardous area, Atex approval is vital.

As an experienced partner to the pharmaceutical industry, Pepperl+Fuchs HMI collaborates with the customer during the planning phase for a new production facility to develop a solution for the operator control and monitoring workstations. Thanks to the configurable building block system of the VisuNet series, which comprises numerous different monitors, stainless steel housings, mounting options, and input systems, this solution is usually based on standard components. However, customized modifications or functional enhancements to the existing components are also possible to comply with specific requirements.

Tailored to practical needs

In a biopharmaceutical production plant, active pharmaceutical ingredients (API) are generally developed using genetically modified organisms (e.g. bacteria). The valuable bacterial cultures are grown and made ready for the production process – referred to as fermentation – in a preparation room. The bacteria then multiply with a nutrient solution in a bioreactor under ideal ambient conditions. The desired API is formed as a metabolite during the fermentation process. The API concoction is then separated, cleaned, in some cases chemically processed, dried, and concentrated in order to obtain the drug. After it has been metered very precisely and mixed with fillers, the product can be granulated, for example, filled into vials, blended into a cream or pressed into tablets. Regular samples are taken during all production steps and analyzed in the manufacturing lab prior to releasing the product for the next process step, to allow the formulation and production parameters to be adapted if necessary.

Operator workstations with two 19" VisuNet GMP Duplex Remote Monitors arranged one above the other on a single pedestal are installed at all workplaces in the production area and the laboratories. Both the DCS and the MES are consequently accessible at all times for monitoring and controlling the process as well as for processing the formulation. All workstations have a built-in RFID card reader to identify the operator in accordance with GMP directives. A radio barcode reader for 2D data matrix codes is likewise mounted on a holder next to the tillable keyboard, and the base station is connected to the monitor via a USB port. The remote monitors are hooked up to the process control and manufacturing execution systems over separate networks (the bottom monitor to the DCS and the top monitor to the MES). Image data is digitally transmitted in optimal quality over a standard Ethernet network. The MES system works in the background on a Citrix server farm with

dynamic load balancing (virtualization). The Remote Monitors support not only Microsoft's RDP protocol for the process control system but also the Citrix ICA protocol, which means they can each communicate directly with the network servers. The input system consists of a shared keyboard with an IP66 touchpad mouse, which in customized solutions can move the cursor across both monitors. A modified pedestal for the duplex monitors and a rotatable stainless steel copy holder for the paper manufacturing documents that are still occasionally resorted to were also developed for this specific project. Even the basic version of the VisuNet GMP was fully compliant with all of the biopharmaceutical client's functional and GMP requirements.

About Pepperl+Fuchs

Pepperl+Fuchs is a leading developer and manufacturer of electronic sensors and components for the global automation market. For more than 60 years, our continuous innovation, high quality products, and steady growth has guaranteed us continued success.

One Company – Two Divisions

Pepperl+Fuchs – PROTECTING YOUR PROCESS

The **Process Automation Division** is a market leader in intrinsically safe explosion protection. We offer comprehensive, application-oriented system solutions, including customer-specific control cabinet solutions for the process industry. A large portfolio of components is available from our various product lines: isolated barriers, fieldbus infrastructure solutions, remote I/O systems, HART interface solutions, level measurement devices, purge and pressurization systems, industrial monitors and HMI solutions, power supplies, separator alarm systems for oil and petrol separators, signaling equipment, lighting as well as emergency shutdown equipment and accessories.

Pepperl+Fuchs – SENSING YOUR NEEDS

With the invention of the inductive proximity sensor in 1958, the company set an important milestone in the development of automation technology. Under the motto “Sensing your needs”, customers benefit from tailor-made sensor solutions for **factory automation.** The main target markets of the factory automation are machine and plant construction, the automotive industry, storage and material handling, printing and paper industry, packaging technology, process equipment, door, gate and elevator construction, mobile equipment, renewable energies.

The division offers a wide product range of industrial sensors whether it’s inductive, photoelectric or ultrasonic sensors, rotary encoders, identification systems, barcodes, code readers for data-matrix-codes and vision sensors.

Key words:	Pepperl+Fuchs, VisuNet GMP, remote monitor, barcode reader, dust hazardous area, gas hazardous area

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Fig. 1: Cleanliness is paramount in pharmaceutical production

Fig. 2: The operator control and monitoring workstations have to conform to the same GMP regulations as the complete facility in the production environment