Pepperl+Fuchs GmbH – Lilienthalstrasse 200 – 68307 Mannheim – Germany

Please indicate the following contact information for publication:
Tel.: +49 621 776-2222, Fax: +49 621 776-27-2222, www.pepperl-fuchs.com, pa-info@de.pepperl-fuchs.com
Editorial contact: Christa Blas (extension: -1420, fax: -1108), cblas@de.pepperl-fuchs.com

GMP-Compliant IT-Hardware

The GMP guidelines for the design and use of hardware in regulated industries are rather general. Standard approvals to identify appropriate products do not exist. The label “GMP-compliant” is not regulated. Therefore, system engineers, opinion leaders and journalists are faced with a variety of promotional statements from the provider and with certificates from GMP service providers that are not generally recognized.

Origin and Prevalence of GMP Guidelines

The term Good Manufacturing Practice (GMP) was coined in the early 1960s by the US Food and Drug Administration (FDA), the authority for food and pharmaceuticals. The main objective of the GMP was to guarantee a consistently high quality standard, especially in the production of pharmaceuticals. A corresponding system of rules and standards was also adopted in other sectors such as the food industry. In Europe, the “EU GMP guidelines for medicinal products for human and veterinary use” are essential for production in regulated industries. These are substantiated in Directive 2003/94/EC (for human medicinal products for human use) and 1991/412/EEC (animal medicinal products for veterinary use) and supplemented by numerous appendices (“annexes”). In Germany, operators and suppliers of GMP-relevant production operations have access to “Good Manufacturing Practice Guidelines” based on European guidelines.

Implications for Equipment Manufacturers

The GMP guidelines present the designer with significant challenges, especially in the mechanical design of a product. The general GMP principles outline the details of the requirements that a product must satisfy, but do not explain how the requirements must be implemented. Here is an example from the GMP guideline, part II, chapter 3.34: “The design, arrangement and maintenance of the manufacturing equipment should be adapted for the intended purpose.”

GMP approval is not possible because there are no construction features that can be used as a reference to determine whether or not a resource is GMP-compliant. Unlike with explosion protection, for example, a declaration of suitability cannot be made.

Origin of GMP-Compliant Design

There are no fixed guidelines that indicate how the specifications outlined in GMP guidelines can be implemented in a plant under all conceivable conditions. However, some general principles can be determined by collaborating with customers and by applying many years of experience in the business:

- Materials: There must be no chemical reactions between materials, products and detergent.
- Surface: In order to reduce cleaning times, cycles and costs, the surface finish should be easy to clean. The surface must, therefore, be smooth and flawless, i.e., free of scratches, cracks, and cavities.
- Seals: A permanent seal must be guaranteed under the specified ambient conditions. Standard processes in regulated industries are used to determine the requirements relating to the ageing, temperature and chemical resistance of the sealing material.
- Design and structure of surfaces that do not come into contact with the product: Surfaces should be designed in such a way as to prevent the accumulation of fluids and dirt and minimize or eliminate the chance of bacteria growth. Cleaning, maintenance, inspection and repair should be easy and safe
- Additionally, appropriate requirements to design these surfaces must be used to establish specifications for production equipment.

Implementation of GMP-Compliant Industrial Monitors and PCs

In order to meet GMP requirements, IT components were placed inside an additional enclosure. This frequently results in complex solutions that cannot achieve the same quality level as products designed consistently in compliance with GMP. When the development team from the Pepperl+Fuchs Competence Center “Industrial Solutions and HMI designed the VisuNet GMP product family, only one independent design was considered. An existing product family could not be redesigned satisfactorily using the design principles mentioned above.

The following guidelines are indispensable components of the technical specifications for VisuNet GMP industrial monitors and PCs:

- The use of stainless steel is essential to prevent chemical reactions between the material and products/detergents.

- A uniform surface roughness of 0.8 µm is recommended. If the degree of roughness is higher, the risk of pollution increases. If the degree of roughness is lower, the risk of pollution increases even more due to the higher adhesion forces.
- Display, seals, and keyboard must be resistant to the chemicals in standard detergents.
- Housings and enclosures must be designed to allow easy cleaning or sealed so that impurities cannot accumulate.

Verifying Conformity

Because of the uncertainty of the requirements in the GMP guidelines, product approval is not possible a manufacturer's declaration that explains how the corresponding sections in the GMP guidelines are implemented for the relevant equipment is useful from a customer perspective.

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, GMP, VisuNet, self-declaration, PC, remote monitor, KVM monitor, guideline, guidelines, pharmaceuticals, medicines, FDA, 2003/94/EC, 1991/412/EEC

Author:	Dipl.-Ing. Andreas Grimsehl Product Marketing Manager HMI Division Process Automation

Characters:	4,313, without space characters
Characters short text:	385, without space characters
Pictures:	No. MC7522_090305_01, No. MC5848_22872_10, No. MC7522_080305_18

January 2010

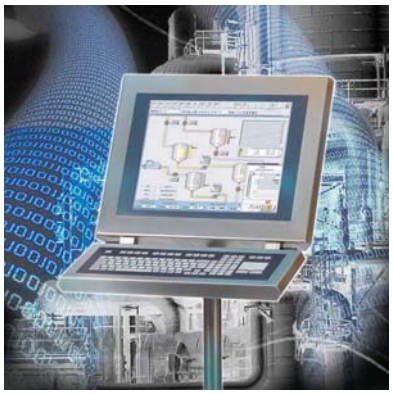

Fig. 1: GMP-compliant products should be designed so that impurities cannot accumulate

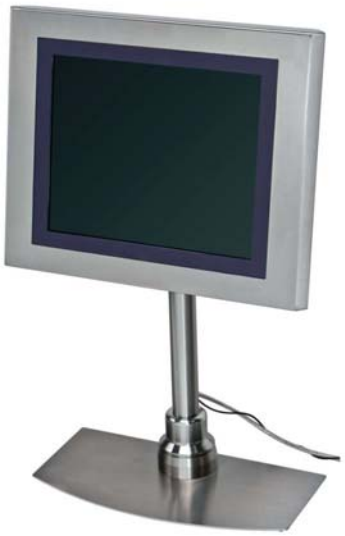

Fig. 2: No corners or edges - GMP-compliant mechanism