



Automated, GAMP-compliant production monitoring in the pharmaceutical industry

Digitalisation does not stop at the pharmaceutical industry. The use of new technologies opens up opportunities for process optimisation along the entire life cycle of pharmaceuticals and pharmaceutical products, from research into new active substances and therapies to production, packaging, distribution and application. However, digital innovation not only offers many opportunities, but also poses major challenges for the industry due to the strong regulation of drug production. Because anyone who violates guidelines when developing drugs or medical devices not only puts a lot of money and his reputation at risk, but also the health of the patient. This makes it all the more important for companies to have access to reliable systems that support them in complying with legal requirements such as Good Automated Manufacturing Practice (GAMP).

Application

The GAMP regulation is intended to ensure the quality of the production of pharmaceuticals, active ingredients and cosmetics. In addition, quality demands are placed on processing, packaging and storage. One of the increasingly stringent guidelines is that the printing and marking of products and packaging must be reliably recorded and tested. This is intended, among other things, to prevent product mix-ups due to incorrect labelling and to ensure traceability of ingredients and end products as well as protection against counterfeiting.



Forgery-proof: GAMP-compliant image processing according to FDA and GMP guidelines

With GampBOX, the German company i-mation GmbH based in Rottweil has developed a Plug & Play image processing system that facilitates process optimization for manufacturers in the pharmaceutical industry as well as for suppliers (for packaging materials, equipment) in compliance with GAMP guidelines.

The maximum configuration level of the system consists of a space-saving BoxPC, a GAMP-compliant user interface, up to four robust GigE uEye FA industrial cameras from IDS in combination with the HALCON image processing software.

To protect a medicine from counterfeiting, the one-time allocation of a serial number in connection with individual production data (e.g. product identification GTIN, expiry date and batch number) is essential. It is the key to complete traceability through the entire logistics chain from production to distribution and wholesale to the customer. The GampBOX is a reliable and compact solution to meet the legal requirements of Directive 2011/62/EU regarding the protection against counterfeiting of prescription-only drugs.

Among other things, the system offers complete traceability of operating actions (by users with a time stamp), the creation of audit trails (for monitoring and recording process changes) and the safeguarding of important process steps with electronic signatures or electronic approvals. In addition, recipe management and versioning, archiving of user actions subject to verification of a serial number in connection with individual production data are possible. The GampBOX series is divided into three expansion stages: the first integrates smart cameras into a single batch production. The second stage integrates smart cameras into a serialised production, for example to verify a serial number in connection with individual production data. The third stage integrates classic industrial cameras, such as the IDS GigE uEye FA camera, into a PC-supported system with database synchronization (for GS1 and ePedigree) in a serialised production.

Up to four cameras, such as the IDS GigE uEye FA camera, can be connected to a GampBOX via Ethernet. The GampBOX takes full control of the cameras and provides an OPC UA interface for the higher-level control or the host computer to the outside. The HALCON image processing software is responsible for implementing the inspection task.

Partnership

For the development of the GampBOX, i-mation GmbH decided to cooperate with industrial camera manufacturer IDS: "Optimized process flows at IDS make cooperation very effective. Fast support for any challenges guarantees prompt solutions for our common customers", explains Kai Weisser, project manager of i-mation GmbH and underlines the "excellent camera design especially for rough industrial environments".

"With many years of experience, i-mation is one of our best solution partners for the medical/pharmaceutical sector," emphasizes Florian Nadolny, Sales Manager System Integration at IDS. "We are a well-rehearsed team, not only looking for the optimal, individual camera solution for every GampBOX user. In this way, we ensure the most economical, reliable and simple GAMP-compliant integration into the respective customer-specific environment possible".



GigE uEye FA - robust industrial camera for factory automation

Camera

The models of the uEye FA camera family from IDS that are available for this purpose are particularly robust and therefore ideally suited for the above-mentioned use in factory automation. Camera housings, lens tubes and the screwable connectors (8-pin M12 connector with X-coding for data transmission and Power-over-Ethernet and 8-pin Binder connector for GPIO, trigger and flash) meet the requirements of protection class IP65/67. This means that the models can withstand even the harshest industrial environments. The extensive accessories, such as lens tubes and drag chain cables, are just as tough. Since functions such as pixel pre-processing, LUT or gamma are already integrated into the camera, the required computing power is reduced. The cameras are also suitable for large format sensors and are typically used for machine vision tasks in industrial plants and quality assurance. In this way, the reliable solution of the testing task is also guaranteed in this application.

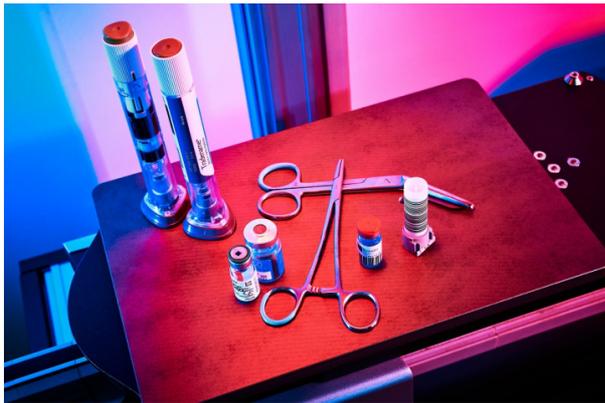
Benefit

The main concern of i-mation, however, is the GAMP and FDA (US Food and Drug Administration) compliant integration of this system solution for the pharmaceutical industry, both in new plants and in the form of retrofits in existing plants. The GampBOX is currently the only plug & play system worldwide for implementing image processing applications according to the GAMP guidelines.

Among other things, the system offers traceability of user actions and reduced engineering and validation effort. It is therefore ideally suited for machine builders who have to meet high quality requirements, e.g. when supplying machines and subsystems to applications requiring validation.



Machine builders and end customers from a wide range of industrial sectors can thus obtain their individual solution for the increasingly demanding requirements and stricter guidelines from a single source - including serialisation where required.



The GampBOX enables GMP-compliant implementation for various industries, including the necessary serialisation.

Outlook

The constant entry of new competitors into the market requires pharmaceutical companies to differentiate themselves increasingly in order to distinguish themselves in terms of quality and shortened time to market. Dealing with digital innovations is of crucial importance for this. Digital technologies are already creating high added value and have further potential. At the same time, the strong regulation, as in the case of counterfeit protection (in Directive 2011/62/EU), poses new challenges for these and other sectors. In the food, medical technology and explosives industries, traceability is also required by law. These demands are gaining in importance due to the increased increase in counterfeit industrial and consumer goods on the global markets.

There is great potential for the GampBOX with IDS camera, especially when the target is: Avoid mix-ups in future.

GigE uEye FA - robust industrial camera for factory automation



Only with IDS: if you opt for cameras of the new [GigE uEye FA series](#), you have the freedom to choose between the proven IDS Software Suite or support of the GigE Vision standard.

Thanks to the unique IDS software, you also experience real USB plug & play, even for GigE cameras: The cameras are automatically detected in the system and are ready for use immediately.

Client

i-mation GmbH, Germany, develops and implements individual solutions for industrial image processing as a system integrator, with manufacturer-neutral consulting, technologies from leading suppliers and self-developed solutions for the automotive, solar, pharmaceutical, packaging, electrical, printing and robotics industries. The company is divided into three divisions: Smart Factory Machine Vision, Human Like Machine Vision and 3D Machine Vision.

<https://www.i-mation.de>

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