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Staying up to date on traceability in the medical industry

Strategic solutions for complying with medical device regulations and automating the clinical laboratory

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Introduction

As with many manufacturing industries today, the medical industry – whether referring to clinical diagnostics, medical device manufacturing or the production and packaging of pharmaceuticals – is facing the challenge of stricter regulatory oversight in addition to the trend of increased automation, particularly in the laboratory. Both are primarily safety-driven, sharing the important goal of helping patients get diagnoses and treatment that are quicker and more accurate. Traceability is the primary vehicle for success.

This white paper examines several traceability-related trends in the medical industry today, along with some strategies for ensuring regulatory compliance and making the most of the transition to automated processes.

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Medical device traceability requirements: Countdown to compliance

The medical device industry is familiar with the scrutiny of regulatory organizations, but compliance requirements have increased significantly in recent years. Given that patients' lives are at stake when faulty devices are introduced into the market, this is a trend to celebrate. Nonetheless, it does pose some challenges for medical device manufacturers. In particular, companies are under pressure to significantly upgrade their device traceability practices.

In the United States, the main driving force behind the effort to implement a robust medical device track and trace program is the FDA's Unique Device Identification (UDI) mandate (often shortened to "FDA UDI"). This set of regulations requires manufacturers to place a globally unique identification number on each medical device they produce. Depending on the type of device and its purpose, it may be necessary to place a permanent direct part mark (DPM) barcode containing the UDI on the device itself. Devices are categorized into classes based on their potential for causing harm to patients if they malfunction or are used improperly.

The next deadline in FDA UDI is September 24, 2022. This is when Class I devices both for single use and that are intended to be used more than once on different patients and reprocessed between each use are required to bear permanent markings containing UDI information.

For the upcoming deadline, details of each device must be submitted to the Global UDI Database, or GUDID. Omron's industry experts keep up with the latest developments in medical device regulation in order to provide manufacturers with the most comprehensive, future-proof solutions and help them navigate the convoluted path to full compliance.

Health Canada has similar regulations to the FDA UDI and GS1-Canada assists Medical Device Manufacturers with issuing UDIs which are used both in Canada and the US. GS1 has a Global Trade Identification Number (GTIN) which is a globally unique ID number which would allow a company to sell a product both in Canada and the US and keep the UDI information in both the FDA and the Health Canada databases.

A MicroHAWK reads data from codes placed on test tubes.

Product identification solutions for regulatory compliance

In order to meet the traceability requirements of FDA UDI, medical device companies need to start marking their products with durable, machine-readable codes packed with identifying information. The current Class II deadline presents a significant challenge given that many of the affected devices – including surgical clamps and scalpels – undergo harsh sterilization treatments on a regular basis. Several types of devices also leave little space for DPMs, meaning that the markings must be both very fine and also resistant to degradation. (FDA-approved issuing agencies such as GS1 specify in their standards what type of symbology is required when barcoding medical devices. GS1 specifies that a Data Matrix symbol must be used for medical devices.)

Given these challenges, it's important for manufacturers to take advantage of the latest technologies for applying, reading and verifying these markings. Laser marking technology is becoming one of the most popular methods for applying DPMs thanks to its high resolution and excellent durability. Omron's MX-Z series of fiber laser markers can provide either deep or shallow engraving on metal substrates as well as high resolution marking on plastics and resins. To give manufacturers more flexibility in placing DPMs on cramped surfaces, the MX-Z laser markers are capable of applying codes to curved surfaces.

Radio-frequency identification (RFID) technology is also gaining popularity as a traceability solution in the medical device industry. One of the major benefits of using RFID to track medical devices is that – unlike barcodes – it offers the option of writing information as well as reading it. This means that RFID tags can initially include the device UDI but also be updated to reflect delivery of the device to particular patients and to verify that the proper sterilization has been performed.

Omron's V780 UHF Long Range RFID Reader/Writer makes it possible to read up to 64 unique tags in a single read. Industry-leading features like focus mode and automatic power tuning help maximize read rates and minimize no-reads. Its long read range makes it ideal for high-mix production environments where the read range to the RFID tag may vary with the product being produced.

Did you know?

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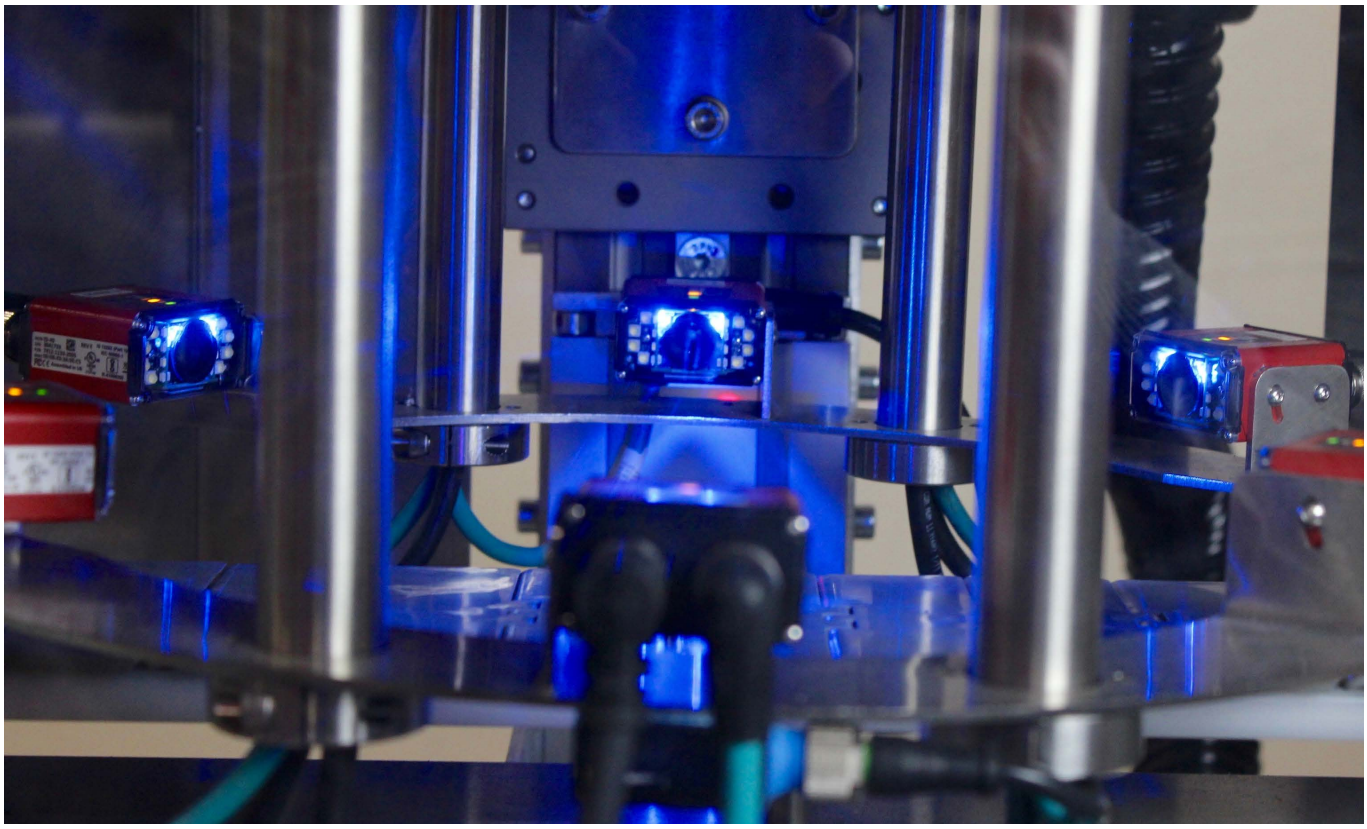
The importance of barcode verification

Barcodes are useless if they can't be read, and a barcode that contains identifying information on a medical device is expected to stay readable for the device's lifetime. To ensure lasting readability, barcodes and DPMs are graded to a number of internationally accepted quality standards, including ISO 15415, ISO 15416 and ISO/IEC 29158. These standards evaluate contrast, uniformity and other features of codes that can cause them to be more or less readable.

In order to determine the quality of a barcode according to international standards, medical device manufacturers need to use industry-standard barcode verifiers to produce a comprehensive report. Omron is known for its best-in-class verification solutions that include a full suite of in-line and offline verification and print quality inspection systems designed to help companies comply with UDI requirements in accordance with standards. These solutions also inspect the quality and layout of labels according to standards set by the global organization GS1.

For the miniscule DPMs that are placed on surgical instruments, implants and other small medical technologies, Omron offers two ultra-high-density handheld verifiers, the LVS-9580 and the LVS-9585. Both of these use a specialized lens that can grade a wide variety of direct part markings, even those with a cell size as tiny as two thousandths of an inch.



MicroHAWK V430 code readers provide 360 degree inspection of the bottle/label at speeds of up to 100 bottles per minute.

Automation in the clinical laboratory: An investment in tomorrow's healthcare

The benefits of automation in clinical diagnostics are enormous. Error rates using automated devices are a tiny fraction of what they are when human operators perform the same tasks, and in the medical laboratory, accuracy is vital. Furthermore, automation can speed up processes without sacrificing accuracy, making it possible to accommodate greater throughput and provide results more quickly.

While it can be a challenge to introduce automation into a clinical laboratory that has been relying on manual processes for specimen storage, testing and recordkeeping, technological advancements are making the transition easier by the year. Barcode readers and vision inspection solutions are becoming increasingly powerful, compact and user-friendly.

In addition, the latest technologies are built to last longer than before, and longevity is essential when these products are built into complex sample analyzers. Omron focuses on maximizing product longevity as well as managing obsolescence with effective transition plans for OEM customers, thereby making overall clinical diagnostics solutions much more dependable.

MicroHAWK V430 with ring light capable of capturing codes in all sorts of applications – including metal cavities – it is the scanner of choice for industrial traceability solutions.

Did you know?

Class II devices include powered wheelchairs, pregnancy testing kits and other simple devices that are slightly more complex than Class I devices but less complex and potentially hazardous than Class III devices. Not all Class II devices are meant to be used on multiple patients and reprocessed.

For the upcoming deadline, details of each Class I device must be submitted to the Global UDI Database, or GUDID.

Making barcode reading and machine vision solutions smaller, more flexible and easier to use

Traceability is an essential component of clinical laboratory automation, and it depends heavily on the use of barcode reading and machine vision technologies. Inside automated testing equipment, these advanced technologies track specimens, check the cap color and fill level of tubes, and even manage the use and supply of test reagents.

In order to incorporate barcode readers and machine vision-enabled cameras into testing machines, these devices need to be as compact as possible. Omron's barcode readers – particularly those in the MicroHAWK family – have been miniaturized and optimized for integration into compact spaces. Omron also has a long history of partnership with manufacturers of clinical diagnostics equipment and has developed an expertise in integrating readers and machine vision systems into custom solutions for the laboratory. The ability to customize and provide a unique solution for every need is part of Omron's DNA.

The MicroHAWK line is also incredibly easy to use. With the browser-based WebLink interface, these barcode readers read right out of the box with no software installation whatsoever. This "out-of-box experience" is a hallmark of an Omron solution, as Omron has even managed to make machine vision technologies such as its HAWK MV-4000 smart camera intuitive to the average user as well as to the expert.

MicroHAWK industrial barcode readers are an integral part of Omron's overarching traceability solutions.

Summary

In response to the expanding requirements for FDA UDI compliance and the growing need for automation in the laboratory, medical device and clinical diagnostics equipment manufacturers have been dramatically upgrading their traceability systems. To make traceability as effective as possible, companies like Omron have been addressing specific challenges with advanced barcode reading, machine vision and DPM verification systems. Miniaturization, product longevity and ease of use are major themes in the design of new solutions for traceability in the medical industry.

Omron MicroHAWK with weblink software for precision traceability and inspection solutions.

Omron's LVS-9585 handheld barcode verifier is equipped with a special high-density lens that can comprehensively verify extremely small codes and DPMs.

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