Traceability through serialisation

Empowering consumers helps fight counterfeits

As pressures increase in industries such as food and drink, cosmetics and pharmaceuticals to reduce counterfeiting and improve consumer information, Dan Rossek of Omron looks at the demands this places on data management and production processes, and compares the two main approaches to tackling these demands.

With counterfeiting of popular drugs and cosmetics now becoming a real issue, and after a number of high profile food and beverage industry product recalls, companies across these sectors are coming under increasing pressures to provide improved consumer information and to implement improved inspection systems for product traceability.

A number of initiatives and legislative measures have either taken place or are in the process of being implemented, most notably in the pharmaceuticals industry where the Falsified Medicines Directive (FMD) is defining new traceability requirements for prescription drugs and over the counter medicines that may be subject to counterfeiting. Coming into force in 2018, the FMD addresses the very real threat of counterfeit drugs to public health and safety as falsifications become more sophisticated.

It is not simply a case of taking money away from licenced manufacturers; falsified medicines may contain active ingredients which are of bad quality or are in the wrong dose – either too high or too low. Without the proper evaluations on their quality, safety and efficacy, such counterfeit drugs could represent a genuine health hazard.

"Changes to packaging designs and additional inspection tasks, the maintenance, training and documentation demand for multiple and different inspection systems in a production line is expected to be a very challenging task."

Dan Rossek,
Marketing Manager

The FMD imposes a requirement for item-level serialisation, where individual packs of medicines are marked with a unique, machine-readable identifier that will provide traceability from the point of sale all the way through the manufacturing processes so that the authenticity of that medicine can be checked anywhere in the supply chain.

OPINION

While the FMD specifically tackles the manufacture and retail of pharmaceutical products the legislation and pressures impacting on medical device and food and drink manufacturers are no less stringent. What this all means is a requirement on manufacturers in all of these industries to ensure the ability to trace individual products and batches – not only through their own manufacturing processes but right through the whole supply chain to the consumer.

Traceability via databases

Further, it is not enough that this traceability be managed internally. Product data must be uploaded to a national or international database where product IDs can be held and verified as required.

While it has long been required practice to print machine-readable identification coding – bar codes, 2D codes, etc – onto packaging to deliver some degree of traceability, the stringent requirements of the FMD for serialisation presents two key challenges for manufacturers. The first is to look at how they manage data internally, with supply chain partners and with consumer oriented servers. The second is to look at how they will need to change production hardware and processes. Each impacts upon the other.

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New ways to meet recent demands

Two main approaches to meeting these new demands to data management and production processes have emerged: the single-system point-to-point solution and the flexible layer solution.

Single-system point-to-point solution (closed single supplier solution)

The single-system point-to-point solution for serialisation is promoted as a ready-to-use system that fulfils all requirements from printing, inspection to data handling and exchange with the supply chain and government servers. ,. But what initially looks like the easiest and most straightforward implementation can quickly become a limiting factor on production lines, lacking the flexibility to change as production lines evolve.

Further, while the single-system point-to-point solutions address the serialised data, other FMD required inspection tasks – such as tamper evident seals – or existing quality control measures are not addressed. This would then require the use of additional inspection systems or specialised sensors and may lead to doubling the amount of printers, inspection systems and thus also doubling the effort for operator training and documentation.

An alternative to the single-system point-to-point solution is the flexible layer solution, which separates the data / content handling aspects from the hardware considerations in the production line. Furthermore the flexible layer solution works towards an open structure with defined interfaces between the different solution levels. The goal is to provide the freedom to select the printers, serialization software, ERP/ master data environment and integrate these into existing IT and machine environments. Especially for companies working with a large number of different partners and thus most likely also different systems (e.g. contract manufacturers, re-packers,..), the open flexible layer system may significantly reduce the complexity in being able to communicate to those different systems.

Flexible layer approach (open solution)

With the flexible layer approach, data handling solutions can be tailored to the needs of individual stakeholders, including producers, re-packers, CMOs and supply chain partners. The system is highly flexible, so users can readily adapt to changes and new demands on the production line.

The flexible layer solution also means simpler user-training and compliance management using the same core inspection technology that is on existing machines when upgrades or retrofits are required, and simplifying the integration of new inspection and serialisation stations when specifying new machines in the future.

Importantly, existing inspection systems and tasks can be easily merged with the new serialisation solution, avoiding double handling issues with changeovers and changes in multiple inspection systems in the line.

Omron's expertise not only in machine automation but also in vision systems technology makes it ideally place to advise and assist in implementing serialisation systems. For example, Omron's FH vision technology at the heart of an inspection and serialisation solution can provide leading edge quality inspection and code verification.

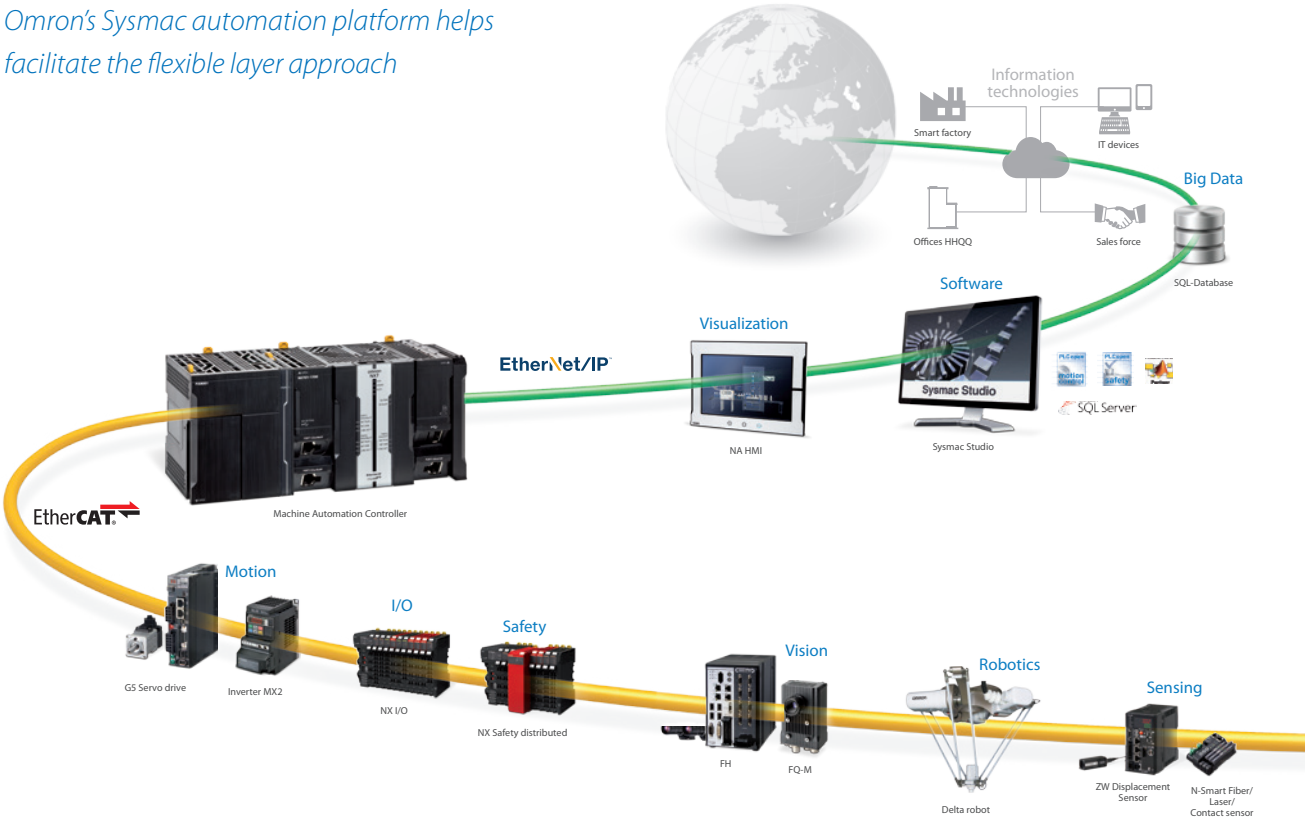
FH vision implementations support not only the serialised code integration but also the other various inspection tasks, all set up in one system accessible via one interface. Adding or modifying inspection tasks, as well as ensuring compliance management, user training and maintenance are all significantly simplified.

As an integral part of Omron's Sysmac automation platform, it allows data management integration into various SCADA, MES and ERP solutions as well as global compliance management concepts to support the serialisation implementation throughout the supply chain.

By utilising the ERP layer as the interface between the production line and the external server also managing multiple sites, the flexible layer solution offers numerous benefits over the single-system point-to-point solution. It provides not only a strong advantage for future flexibility in the market but is also expected to solve issues that are likely to arise over time with the single-system point-to-point solution.

With many upcoming changes to packaging designs and additional inspection tasks, the maintenance, training and documentation demand for multiple and different inspection systems in one and the same production line is expected to be a very challenging task. In this context, the advantages of the flexible layer solution for serialisation will far overweigh any initial 'advantage' of the seemingly easier end-to-end solution.

Omron's Sysmac automation platform helps facilitate the flexible layer approach



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