Veronica Ghidotti
Product Manager, Visual Inspection Systems, Stevanato Group

A new way of looking at syringe inspection

How technology is rising to the challenge of inspecting prefilled syringes on the production line

Annual global drug spending has risen by $300 billion in the last five years to reach $1.3 trillion in 2022 — largely driven by biologics, which have seen a compound annual growth rate of 12%. The U.S. is the largest pharmaceutical market by value and its drug spending has continued to outgrow the global market — again, driven by biologics. Prefilled syringes specifically have flourished, growing by 19% according to IQVIA data.

Against this background, Pharma Manufacturing recently spoke to Veronica Ghidotti, Product Manager, Visual Inspection Systems at Stevanato Group, about the challenges of inspecting prefilled syringes on the production line — and how the company's new MAVIS automatic inspection platform is playing a vital role in streamlining inspection operations and reducing costs for pharma companies.

Q: What is driving the increased use of syringes to deliver drug formulations?

A: The increased use of syringes is part of the pharma industry's move towards simplified treatments for self-administration by patients. With chronic diseases such as diabetes and heart disease on the increase, the market for at-home self-administration drug delivery is rising. This has led to syringes becoming a popular choice for auto-injector devices.

Q: What are the advantages of prefilled syringes?

A: With a prefilled syringe, the process of administering a drug product can be safer, quicker and easier for health care workers and patients. Instead of having to prepare and draw the medicine into the needle, the correct amount is already present in the barrel, ready for injection. This reduces the risk of preparation and dosing errors and provides a more efficient drug delivery process.

Q: Why has syringe inspection been a historically difficult endeavor?

A: Syringes are arguably the most difficult containers to inspect, as they are delicate and require unique handling protocols. While other containers, such as vials and cartridges, largely 'stand still' and can therefore enter the inspection process independently, syringes typically have to be carried via a conveyor belt and then turned upside down. This is to ensure any particles hidden in the funnel sink into the liquid contents and can be detected.

> MAVIS automatic inspection platform is playing a vital role in streamlining inspection operations and reducing costs for pharma companies.

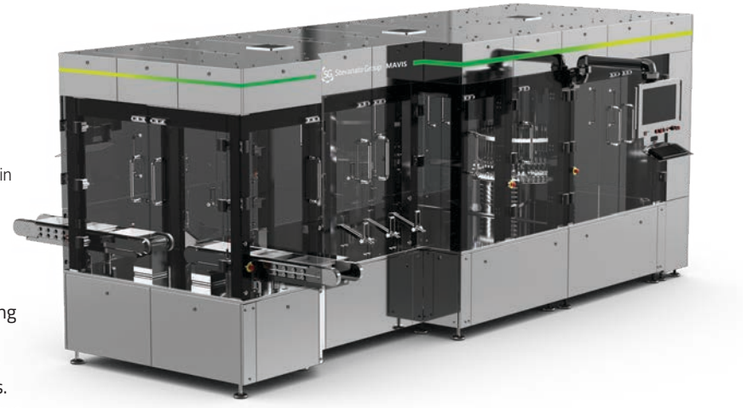
Another complication is that, if the syringes are sterilized, the containers are typically in a nest-and-tub arrangement, which means they have to be de-nested by a robotic unit communicating with the inspection machine. This requires gentle handling to avoid glass-to-glass contact to mitigate the risk of cracks or breakages.

The small diameters of syringes also present an inspection challenge because of the limited space in which particles can move and therefore be detected. This requires high-speed spinning so that any unwanted particles move toward the outside of the containers — this is especially important for turbid drugs. High-speed spinning also helps with the detection of bubbles — as bubbles go up while impurities go down.

Q: Are there limitations to the inspection techniques currently being used by drugmakers?

A: Inspection technologies range from manual and semi-automated through to fully automated, high-speed machines. When performing manual inspection, each syringe is inspected with fluorescent light against a black-and-white background. As manual systems remain subject to human error and do not offer the speed required for larger batches, they are mainly used for customized applications and stability surveys.

Semi-automated inspection systems can achieve more accuracy and reduce the need for manual handling. Automatic feeding, sorting and discharging functions enable inspectors to focus entirely on the quality control of prefilled syringes.



MAVIS PLATFORM
Advanced inspection performances in a small footprint.

But the challenges outlined above remain — which is why Stevanato Group has created the MAVIS automatic inspection platform, which can handle drugs ranging from water-like solutions and suspensions to viscous or lyophilized products. MAVIS can inspect up to 400 pieces per hour — and all in a compact footprint that includes all the inspection stations to ensure top quality results.

Q: What are the benefits of deep learning applications in syringe inspection?

A: Deep learning technology uses neural networks to mimic the human brain's ability to learn by example. Once trained on thousands of images, deep learning algorithms enable an inspection system to identify patterns so that it can recognize defects in an item on the production line and distinguish particles from false positives such as bubbles.

The main benefits are enhanced accuracy and efficiency. Deep learning models improve over time and can detect a wide range of complex defects. They can help reduce the number of false rejects — and also the number of grey items that need to be re-inspected manually. So, the whole process becomes leaner, with less waste.

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Q: What is different about the MAVIS automatic inspection platform?

A: MAVIS has independent motorized spindle rotation units that can be adjusted for different drug products. This ensures precise rotation of the syringes during an inspection, with no glass-to-glass contact. A smooth and stable transport system is provided by a servo-driven clip-wheel and belt continuous motion operation, with grippers available for Luer-lock syringes. A combination of matrix and line-scan cameras gives unrivaled inspection capabilities.

MAVIS has been designed to be user-friendly — the patent-pending visual interface requires no programming or scripting knowledge. And the de- and re-nesters are at the same end of the machine so that it can be run by one operator if required. It is also easy to install and maintain, and uses digital twin technology to enable the software configuration of the machine to be changed offline and validated during production — avoiding expensive downtime.

Q: What is coming next for the MAVIS platform?

A: In line with its clear focus on streamlining operations and reducing costs for pharma companies, Stevanato Group plans to launch a new machine as part of the MAVIS platform during 2023. It will enable the inspection of ampoules, vials and cartridges, as well as syringes. Instead of buying different units for different formats, pharma companies will be able to reduce costs by buying one single unit.