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What digitalization means for the pharma industry

Harnessing Pharma 4.0 for a new era of pharma manufacturing

The pharma industry is evolving, with innovation and digitalization quickly becoming business as usual and driving improvements in the quality process. Artificial intelligence (AI) is transforming product inspection, for example, with low false reject rates and reduced costs.

Pharma Manufacturing recently spoke with Veronica Ghidotti, product manager, Visual Inspection, Stevanato Group, about the company's use of AI as well as other digital applications — such as digital twins and data management — to enable its pharma clients to save time and money while reaching new levels of quality control.

Q: More and more pharma companies are beginning to apply Pharma 4.0 to plant floor practices. What are the main concepts and the top benefit driving this innovation?

A: Pharma 4.0 heralds a new era for pharma manufacturing. In practical terms, it means more connectivity, more productivity, simplified compliance and harnessing production information to respond to problems as they emerge. It all adds up to unrivaled high-quality medicines for patients. At the same time, pharma companies stand to benefit from time and cost savings through a holistic digital approach to their development, manufacturing and product delivery supply chains.

The key concept behind Pharma 4.0 is combining operational excellence with the requirements that are specific to the pharma industry — for example, regulatory and validation requirements. A lower-touch relationship with regulatory bodies is one of the potential benefits for pharma companies as data collection and sharing improves with Pharma 4.0, as well as a shift to risk-based regulation.

Other potential benefits include the elimination of data silos, with better communication across the life cycle of drugs; the elimination of paper-based processes; and improved agility, connectivity, and productivity — even in highly regulated facilities. It all adds up to significant competitive advantage for pharma companies.

Q: What role does digitalization play in pharma quality?

A: Digitalization is a crucial component of Pharma 4.0 that will connect everything — creating new levels of transparency and adaptivity for a digitalized plant floor. This will enable faster decision-making and provide in-line and in-time control over business operations and quality. It will also require higher levels of security since connected systems heighten vulnerability.

One of the main benefits of digitalization is the ability to deliver data-led enhancements to monitor and improve product quality. Historically, actions such as root cause analysis would have taken many hours, a great deal of intellectual energy and costly iteration. Today, data, combined with expertise and experience, can bring about big changes in performance in comparatively short timescales.

Data-based quality checks mean each machine is more productive due to fewer interventions during manufacture. Manufacturing space is optimized as fewer inspection stations are needed. And as the parameters for quality are established, many problems can be addressed agilely in-line. Data enables product design to be optimized and processes validated. And 'hidden' anomalies can be detected to help get to the root causes of any quality issues. This process creates a holistic cycle of continuous improvement, with data always circling back to improve product design and overall quality.

Q: How is deep learning contributing to the transformation?

A: Deep learning and artificial intelligence (AI) have enormous potential for activities such as vision inspection — delivering enhanced inspection performance and increasing the detection rate while minimizing false rejects. The number of gray items on the production line is also reduced — saving on manual reinspection time. So, the entire process becomes leaner and more efficient, with less waste.

That's why we have created SG Vision AI to realize the benefits of deep learning. It is an AI platform, based on Microsoft Azure, that complies with all pharma data management and security requirements while enhancing inspection performance. It offers an increase of up to 99.9% in defect detection accuracy for both cosmetic and particle inspection — as well as a tenfold reduction in false rejects.

Other benefits of SG Vision AI include secure protection of confidential data and full traceability, as well as the low total cost of ownership — a cloud approach avoids disk space limitations and high maintenance costs while protecting against data leaks.

Q: Is it essential to have more flexible equipment?

A: Yes. On the one hand, there is traditional large-volume manufacturing with all its economies of scale. But, on the other hand, the market is evolving towards personalized medicine which will change the manufacturing dynamics and involve much smaller volumes of many more different drugs. So, the equipment must be flexible and able to accommodate different needs.

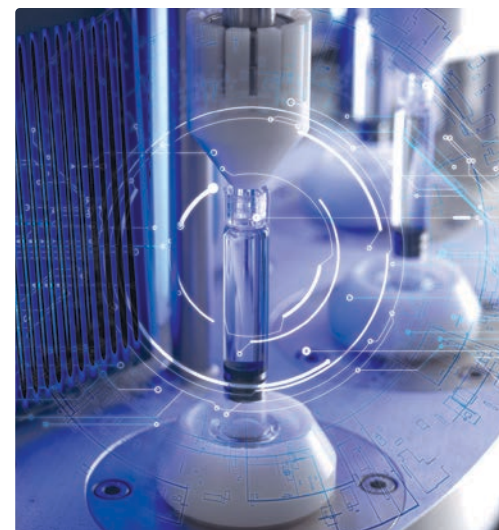
Stevanato Group designs and manufactures flexible standalone or turnkey integrated systems to address a wide range of different requirements and support pharma companies from the early stages up to commercialization.

Q: Can digital twin be considered an enabler for new business models?

A: For decades, companies worked with 2D drawings before 3D came along and transformed everything. Now digital twin has opened up the possibility of working in 5D. Digital twin is best described as a digital replica of a physical entity. Integrating IoT, AI, machine learning and software analytics, digital twins are viewed as a game-changer in the simulation and emulation of mechanical and automated performance.

It is now possible, for example, to create, manipulate and iterate the whole assembly process digitally — and only when the perfect parameters for success are determined is an investment made in the physical model. The return on investment from such an approach is substantial, with no more downtime or trial and error — just right-first-time modeling and fast time-to-market.

In process characterization studies, pharma companies can use digital twins to set acceptance criteria and normal operating ranges. During process performance qualification (PPQ), digital twin models can help reduce the number of PPQ batches required for validation. And, over the course of continued process verification, digital twins can be used to set alerts, predict changes and react to trends.



Q: How is digital twin applied to the inspection process?

A: Digital twin reduces costs and saves time when it comes to the variety of tests involved in the inspection process. It is a virtual server machine that simulates physical computers. Data can be aggregated in the virtual machine and used for test/data analysis without interrupting production. There is no need to work on the equipment directly — output during the production phase can be simulated.

As well as saving time, digital twin guarantees production optimization — with the lines free for production during the test phase. Different recipes can be tested before the production phase and performance can be simulated. False rejects can be challenged and pre-viewed — and recipes of products already tested can be validated.

Q: Is full traceability during the supply chain part of Pharma 4.0?

A: Yes, data management has a key role in digitalization. Stevanato Group offers primary container traceability, for example, that has several benefits. Uniquely coded containers with machine-readable 2D barcodes improve production efficiency and quality by providing insight into each stage of the manufacturing process — from forming through to filling and automated inspection. This data can help drive more detailed root cause analysis, corrective actions and adjustments to product design and process optimization.

Available across all drug containment solutions — syringes, cartridges and vials — Stevanato Group's primary container traceability is delivered through existing glass manufacturing operations, ensuring no impact on the integrity of the glass or container. It is compatible with all pharma sterilization operations and satisfies all regulatory compliance mandates and relevant product/process standards. 