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REPORT ON NEW SOLUTIONS FOR PHARMACEUTICAL PACKAGING

OPTIMIZING FILL-AND-FINISH THE SMART WAY

HOW AN INNOVATIVE SOLUTION FROM THE BEER AND BEVERAGE INDUSTRY IS CHANGING THE PHARMA INDUSTRY

A CASE STUDY BY
FLORENCE BUSCKE,
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SCHOTT
glass made of ideas

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FIGURE 1:
Smart Skin Technologies vial drone

In recent years, data-driven technologies and intelligent solutions have become highly sought after in the pharma industry, as a means to increase efficiency and drug safety during production. Within the pharmaceutical manufacturing process itself, the goal is to optimize the filling line performance for a smoother flow and ultimately ensure that patients receive the medication they need safely and on time. So, how can pharma companies monitor what actually happens in their fill-and-finish process and determine where, exactly, any disruption occurs?

With the help of a smart approach, which originated in the beer and beverage industry, pharma companies can now do exactly that. These analyses performed by Smart Skin Technologies combined with decades of research by the glass experts at SCHOTT allow pharma manufacturers to identify weak points in the filling system in real time. Thus, significantly improving their operating efficiencies, while reducing waste and line maintenance expenses. Here, representatives from four leading pharma players share their experience and use cases.

TACKLING ERRORS WITH DATA

At the heart of the approach is Smart Skin's Quantifeel system, which is a patented sensor drone technology that mimics the shape of vials, cartridges, and syringes. The drone is paired with data mining software. "One of the major benefits of the drones is that they are capable of monitoring several different parameters in parallel," explains David Brückener at Roche, as hundreds of sensors measure how these packaging drones spin, tilt, and are experiencing pressure or shock as they move through the production line. This makes it possible to identify where they are exposed to excessive force.

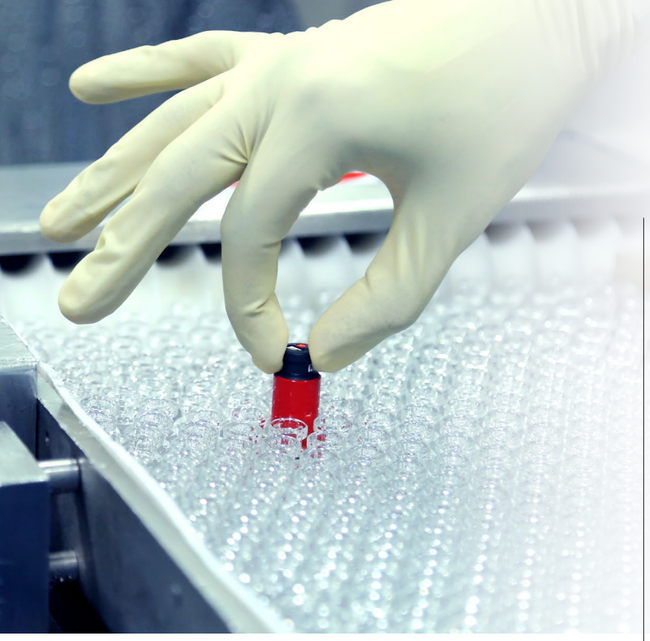

FIGURE 2:
Smart Skin Technologies drone on a filling line.

"It might be the case that you have some bruises, chips or scratches on the vial surface but you don't know exactly where within the filling process these occurred," adds Brückener from Roche. "That's why we decided to go with Smart Skin as we needed a replica like the drone that experiences the exact same process as the primary packaging."

The data is transferred to a tablet by Bluetooth and to the company's Quantifeel software, which prepares easily understandable heat maps and records data-indexed videos of the events. Companies can carry out vital adjustments in the filling line and thus significantly reduce breakage. Later on, the drones can help validate whether the corrective measure brought about the desired effect.

In the case of Roche, a pressure spike was detected on the line whereby the sensor range was exceeded due to an overly tight trunnion in/out setting. Corrective adjustments were put in place, which were later evaluated with a post-set-up check. The latter analysis proved the adjustments to be successful as the pressure at the previously critical spot was reduced by 75 %.

Fabian Thygs at The Janssen Pharmaceutical Companies of Johnson & Johnson credits the ease of use with his company's ability to reduce reject rates. As an example, he highlights how the 30 ml drone format from Smart Skin was used to reduce glass defects. While in 2016 the company experienced glass defects with an average of 2.46 %, the use of the smart drone reduced the average down to 0.87 % in 2018. The use of the drone did not end there: "We generate data so powerful in such an easy manner. We were also able to use the drone one step prior, when buying new equipment." More concretely, the drone was used in a proactive investigation to determine how the new equipment was handling the containers. The recorded data initially showed a number of force points due to the new equipment, which allowed the company to improve these areas for smoother runs. The drones were also employed in supporting qualification activities.

INCREASED PROCESS UNDERSTANDING

Optimizing the performance of fill-and-finish lines is a key goal in the pharmaceutical industry. Efficient operations smooth the path for the delivery of life-saving medications to those that need it most.

"At Novo Nordisk, we help people defeat serious chronic diseases including haemophilia, growth disorders and obesity," explains Etienne Barre from Novo Nordisk. With that in mind, the company set out to improve its filling line processes to reduce chips and crack on the cartridge. "It used to be difficult to evaluate if a change in the filling process was beneficial or not, but this changed with the use of Smart Skin's drones, with which we were able to divide the amount of defect by a factor of seven," Barre adds.

The key lies in having a way to measure accurately what happened on the fill-and-finish line. "Once you know where the forces are on the filling lines, you are able to take corrective actions to eliminate the damage," explains Evan Justason, CEO at Smart Skin. "As the Smart Skin saying goes, 'what can be measured, can be managed'." The overall quality improvement also has a direct profit opportunity of over one million to two million USD a year per line.

Some users of Smart Skin's technology liken the effects of the company's technology to gaining a new sense of perception.

"Now, we are able to identify exactly where high mechanical stress occurs in our process. For us, it feels like we were blind before and can now finally see for the first time," says Yannick Danguel of Lilly. "You could say we followed a firefighter mentality previously and were reacting quickly to fix problems when they occurred, which often involved invasive actions. Now, we can work with a Formula 1 spirit, where we are more efficient thanks to default elimination and predictive maintenance."

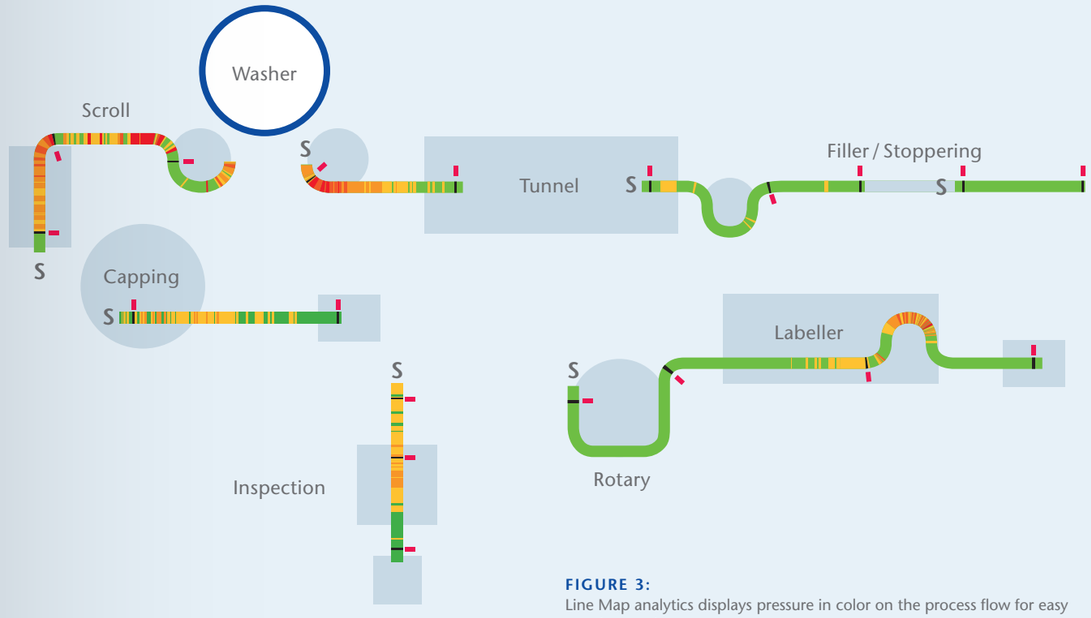

FIGURE 3:
Line Map analytics displays pressure in color on the process flow for easy visualization by maintenance teams.

THE FUTURE OF FILL-AND-FINISH PERFORMANCE

Fill-and-finish operations sit at a crucial juncture of the pharmaceutical industry – where costs and operational considerations intersect with the need to deliver life-saving medicines to patients. Interference of the pharmaceutical manufacturing process causes trouble in delivering the drug on time in a flexible and easy way. Inefficiencies also drive costs. Data can be a valuable source of gaining insights on the performance of lines as well as a helpful result of "pain points" of lines and primary packaging containers. With smart solutions such as Smart Skin's drones and analysis, pharma companies can enhance the fill-and-finish performance to reduce glass breakage, bruising and micro fractures.

And the progress does not stop there. As Thygs asks, "What's next, what else can we do with the drones?" Smart Skin is continuously working on further developments. Aspects such as measuring vibration, temperature, barometric pressure, sound and atmospheric gas are already in advanced stages, while topics such as light and temperature sensing features and machine learning will be added to the drone technology in the near future. VHP sterilization tests of the drones have just completed 10 cycle tests, while maintaining performance, as an example.

For more information, please visit:
https://www.schott.com/pharma_consulting/english/smartskin/index.html

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Florence joined SCHOTT in 2001 and has worked for several business units in various fields, including Marketing Management and Key Account Management roles for SCHOTT's Laboratory Glassware, Medical, Cosmetics and Dental applications. She has developed in her role as Product Manager Vials the coatings like Type I plus® and TopLyo® and launched the SCHOTT Vials DC. Florence holds a French and German Diploma in Economy and Business Administration (Johannes Gutenberg Universität, Mainz / Université Paris X).

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