Safety, Compliance and Quality Just a Click Away

The Crucial Role that Automated Print Inspection Systems Can and Should Play in Pharmaceutical Packaging.

Producing safe and compliant medicines – and harmless cosmetics, or good food for that matter – sometimes resemble a puzzle with countless number of components. It is only possible if all the individual parts are used and manufactured with the necessary care and precision. Quality and precision, reproducibility and exact documentation are therefore essential.

Every aspect of the manufacturing process must be closely monitored. Among the many critical procedures in this system, the inspection of the various packaging materials is an often overlooked but essential part. After all, compliant content reasonably requires compliant packaging.

This is the first point of contact between the product and the end user, where the latter receives information about the product, contents, dosage, or area of application, alongside the medicinal products. Incorrect or even false information can have fatal consequences, especially in the pharmaceutical sector.

In what follows, will be describing the importance of print inspection in the pharmaceutical industry – and it also applies, with only minor differences, to other regulated sectors such as the cosmetics and food industries – highlighting the advantages of automated inspection and discussing the safety aspects.

Why Printed Packaging Should Be Inspected

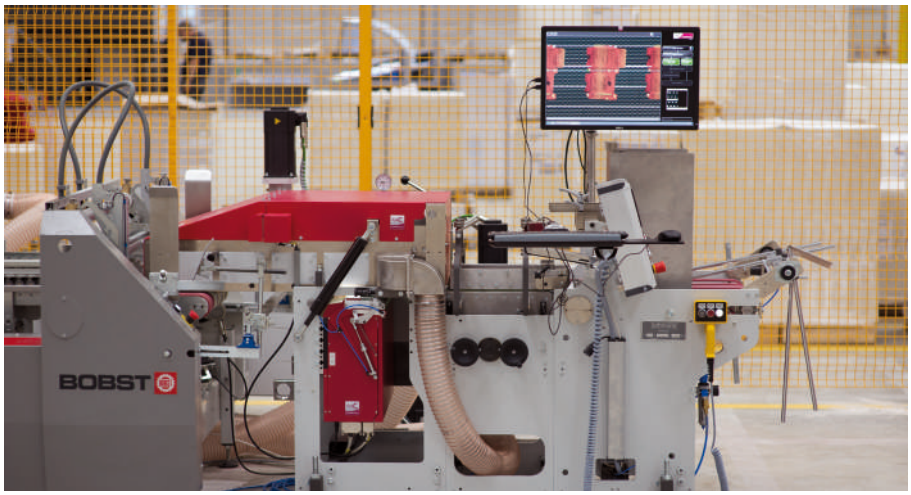
Compliance is the main keyword here. The pharmaceutical industry is subject to strict legal regulations issued by the relevant regulatory authorities such as the FDA (Food and Drug Administration) in the United States, the EMA (European Medicines Agency) in the European Union and similar authorities worldwide. The relevant regulations, such as 21 CFR Part 210 or in Germany the German Medicines Act, require clear and accurate labelling of

pharmaceutical products, including essential information such as dosage, expiry date and active ingredients. Any deviation or error in such labelling can lead to non-compliance. The consequences of such non-conformity can be manifold, including product recalls, fines, damage to the company reputation, or worst-case scenario, a health risk to the user. So how can you ensure that pharmaceutical packaging complies with regulations? A print inspection system plays a crucial role here by meticulously checking packaging materials for inaccuracies or defects. In such a system, the approved artwork is compared pixel by pixel with a sample of the packaging, and a scan-to-scan comparison is also possible. The system records all deviations between the two variants, which are displayed and documented for the user, much more accurately and precisely than the human eye could ever do.

This recording of deviations also serves to maintain the consistent quality of packaging. Maintaining the highest quality standards is non-negotiable in this area. Print inspection helps maintain these standards by detecting defects on packaging materials that compromise product integrity. These would include printing errors, illegible text, stains or material inclusions, missing information (such as an artwork element obscuring the text). Any of these technical errors can influence the perceived quality of the product and affect consumer confidence.

The consumer confidence in the reliability and quality of a medicine is also a significant economic factor, as brand reputation is a priceless commodity in the highly competitive pharmaceutical market. Any association with inferior or defective products can irreparably damage a brand's reputation. The use of a print inspection system serves as a proactive measure to protect brand reputation by ensuring that the packaging meets the highest standards of accuracy and quality. And the growing use of highly refined or complex packaging in particular increases the demand for the quality-related appearance of the product. By preventing defective packaging from reaching the market, pharmaceutical companies can protect their brand value and maintain consumer confidence.

As mentioned above, automated print inspection is far superior to any visual inspection done by a human. Even if the four-eyes principle is applied, it can never be completely ruled out that errors will be overlooked. Computer-aided inspections,

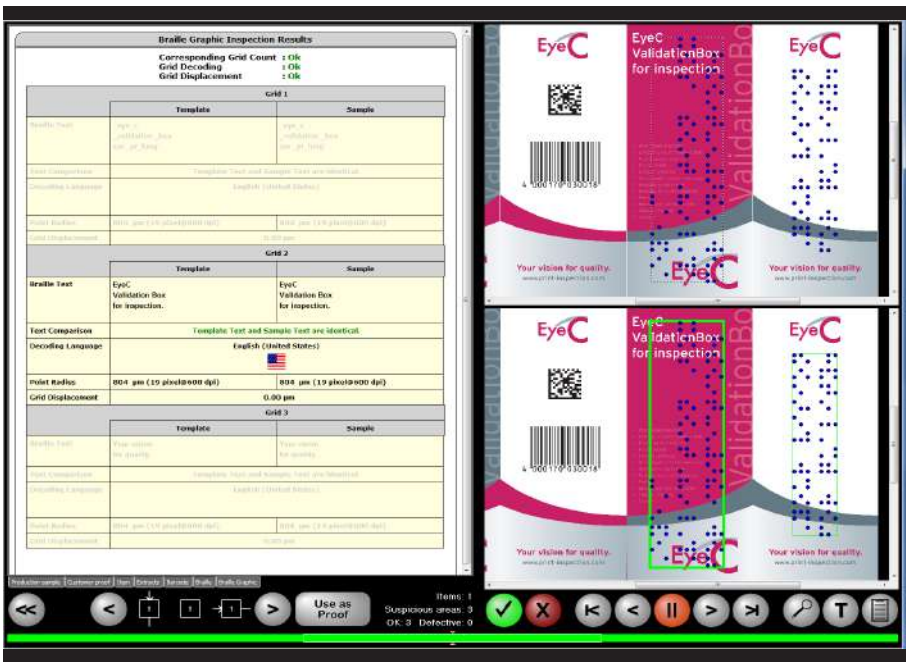


which analyse pixel by pixel, know no pause, no fatigue, no overlooking. Manual inspection of packaging materials is not only fragile, but also immensely time-consuming. In contrast, automated print inspection systems offer unrivaled speed, accuracy and efficiency. The scan of the packaging is completed within few seconds and the analysis is hardly any slower. With suitable systems, the accuracy and quality of codes or height and correct positioning of embossed Braille dots can be checked alongside the artwork in a single work step. In such a manner, production processes can be optimised and operating costs reduced by minimising the need for manual intervention and re-work. Such a system enables pharmaceutical manufacturers to significantly streamline their processes and maximise productivity while simultaneously reducing resource expenditure.

This efficiency extends to supply chains. These are complex and cover several stages from production to distribution. Any interruption or deviation in the packaging process can have far-reaching consequences that affect product availability. Packaging inspection ensures that packaging materials meet the required standards at every stage of the process.

What are the Benefits of Automated Print Inspection?

Automatic print inspection systems use advanced image processing technologies, high-precision camera systems, powerful computers and special software to analyse printed packaging with exceptional speed and efficiency. Even the smallest defects or deviations can be detected at 600 dpi resolution or in line with 8k cameras. The modern hardware and software also bring enormous efficiency. Manual inspection is labor-intensive and immensely time-consuming, often leading to bottlenecks and production delays. The inspection system eliminates these inefficiencies by enabling fast and continuous monitoring



of the packaging material, speeding up the inspection process and increasing throughput. With large format scanners, multiple samples can even be inspected simultaneously, allowing demanding production schedules to be met without compromising on quality.

Another advantage is the direct feedback on the quality of the packaging material; corrective measures can be taken quickly in the event of deviations or defects. This not only minimises the risk of faulty products reaching the market but also facilitates continuous process improvement, as potential problems can be identified early in the production cycle. Modern print inspection systems are equipped with sophisticated analysis functions that enable users to gain valuable insights into their production processes. By analysing inspection data, companies can identify trends, patterns and causes of defects and thus implement targeted preventative measures to improve overall quality. The systems are highly scalable, allowing users to seamlessly adapt to changing production requirements and volumes. Whether small batches or large quantities are involved, these systems can adapt flexibly to different throughput volumes while maintaining uniform inspection standards. This is an invaluable advantage – especially for globally active companies, as it means that sites worldwide can be equipped with identical systems – that also considerably reduces the validation effort. Once a pilot system and the underlying process have been validated, the effort required for all other locations is significantly lower. All systems can be qualified with the same measuring equipment, and URS, IQ and OQ documents or SOPs can be used and rolled out across all sites.

In summary, the print inspection of packaging is an indispensable part of pharmaceutical production and plays a crucial role in ensuring safety, quality and compliance. By using advanced technology and automation, pharmaceutical companies can improve the accuracy, efficiency, scalability and validation of their processes while minimising the risks associated with dosing errors, regulatory non-compliance or product recalls. Error-free and safe packaging is essential, and this can only be achieved with the use of advanced technology such as automated print image inspection.

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