Automated Quality Control of Pharmaceutical Packaging Materials

Inspection systems help print shops perform a 100% print inspection and save time at the implementation of new jobs, due to automated job set-ups and high-speed inspections. The customer proof is loaded and used automatically based on the entered job data. Even composite jobs, for instance front and back labels, can be checked against corresponding PDFs in one click. The information contained in the PDF is used to define priority regions and adjust inspection sensitivity automatically. The accuracy of web inspection systems enables the detection of defects at full machine speed.

Thanks to intelligent technology, modern inspection systems alert the operator only in case of significant deviations. Thereby the inspection system reduces potential eye strain and fatigue. The clear presentation of deviations and key statistical information – such as the defect heat-map – help the operator to understand the location and origin of printing defects easily. A comprehensive inspection report is automatically produced at the end of each job offering a tracking, analysis and communication support for printers and converters.

Checking contents and ensuring the print quality of pharmaceutical packaging is essential. The strict normative and legal requirements within the pharmaceutical industry demand great expertise in the areas of data integrity and tamper-proofing of production and manufacturing processes. Print inspection systems help pharmacists to avoid user-side process intervention and ensure high quality standards through automated checks and flexible system integration.

Minimisation of Liability Risks

Potential sources of error can arise during the production and finishing of pharmaceutical print products, such as package inserts, packaging and labels, across various process steps. At the same time, illegible, incorrect or incomplete information can have life-threatening consequences for patients. For this reason, pharmacists face high liability risks and expensive recall campaigns. The development of reliable technologies for the automation of quality controls makes manual inspection obsolete today. In order to ensure the required standards, more objective inspection solutions are needed to be used in the various production steps in accordance with the standards and prevent undesired process interference. In the incoming goods department of the test laboratories, in production or already in the artwork or release phase of the suppliers, print inspection systems help to avoid expensive and image-damaging process errors, significantly shorten the inspection time and increase the quality of the packaging materials. Modern print image control systems enable even more detailed, language-independent checking of pharmaceutical labels and printed products such as package inserts by means of a pixel-by-pixel comparison with a resolution of up to 600 dpi.

Data Integrity and Traceability

By integrating automated print image controls into existing processes and workflows, manual and risky production steps are eliminated. Those systems provide the necessary interfaces to typical pharmaceutical information systems, such as a laboratory information and management system (LIMS), thus ensuring the integrity of the underlying test data. Within the framework of valid quality controls, the release of the automated tests is also carried out according to the four-eyes principle that is customary in the industry. Thanks to a secure database, all inspection orders awaiting approval can be checked independently of time and location. A second examiner then approves or rejects the results of the first examiner and adds his or her electronic signature along with a comment in the system. Final batch approvals or revisions can thus be handled within the existing workflow in accordance with standards and adapted to existing processes. For the documentation of each production and release step, as well as for reasons of traceability, comprehensive final reports are generated by the system and stored in a protected format in the network.

Simplification of the Audit Trail Review

Inspections and audits are required in the pharmaceutical sector by the legislator and based on regulatory requirements (e.g. GMP, DIN-EN-ISO) – here too, print image control systems can actively support pharmacists. Thus, the documentation of all inspections and system configurations carried out within the workflow takes the form of an audit trail. The events and necessary interventions occurring during

The EyeC Proofiler 600 DT is used for print sample testing in the incoming goods department of test laboratories and provides all the necessary functions for testing in accordance with the guidelines set out in U.S. FDA Title 21 CFR Part 11.

the inspections are stored in a protected, unchangeable format and assigned individual identification numbers to make the evaluation more comprehensible and traceable. For the identification of critical events, database-based tools such as an audit trail viewer make use of individually adaptable filters and a clear interface. The recorded trailing data can be flexibly loaded and visualised in the system, and reveal staff training needs or manipulative interventions. The saving and loading of search queries within the tool speeds up the review process and hence minimises the effort required by quality managers. With the help of the finally generated PDF reports, the audit trail review can also be prepared more comprehensibly also for external auditors.

Testing of 1D/2D Codes and Braille

With the increasing individualisation of printed products, the use of 1D or 2D codes (barcodes, data matrix and QR codes) on produced packaging and labels is also increasing. For this reason, print image control systems enable automated code grading in accordance with applicable guidelines such as ISO 15426, replacing a separate "barcode verifier" and visualising the barcode evaluation throughout the entire print job in a comprehensive test report. In addition to the verification of texts, graphics and codes, the systems also enable the testing of Braille in accordance with ISO 17351:2013 in a single pass. Besides visualising missing Braille dots or faulty Braille grids, the system also automatically checks the height of the Braille dots and provides a clear evaluation in the form of a comprehensive test report. Modern print image control systems thus increase the efficiency of necessary checks, make the purchase of additional devices for barcode evaluation or Braille measurement obsolete and ensure the production of compliant print products.

With the EyeC Review Station, inspections are now carried out according to the dual control principle, supported by a database and thus independent of time and location.

Comprehensive Support

The inspection systems available on the market, consider the latest requirements for data integrity, data security and audit trail

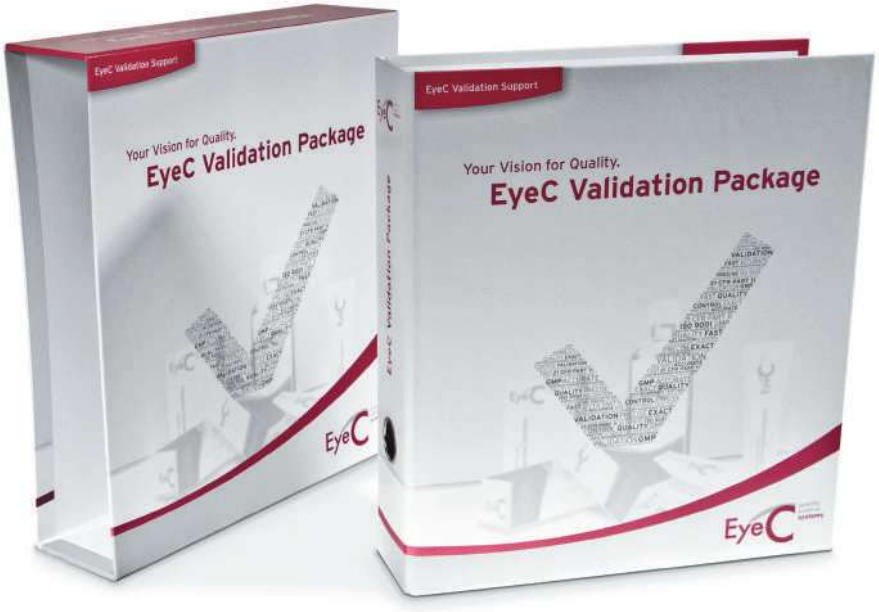
The EyeC Audit Trail Viewer is used to review and track critical events in total confidence.

when inspecting pharmaceutical packaging materials. Pharmaceutical companies can therefore not only carry out fast and automated random checks on their print products, but also increase the security of their processes. All data can be easily and securely accessed and presented in the course of subsequent audits. User-friendly systems also offer a comprehensive quality control solution at every stage of production: during design and approval, in the print shop or during incoming goods inspection in the testing laboratory. The underlying software must be developed in accordance with the applicable ISO 9001, GMP and GAMP 5 guidelines and must include all the necessary functions for inspection in accordance with the guidelines set out in U.S. FDA Title 21 CFR Part 11. Some companies also provide their pharmaceutical customers with all validation-relevant documents, such as URS, IQ and OQ in a corresponding validation support package.

Trends

In particular, the label and packaging market is facing shorter time to market today. For this reason, manufacturing and processing operations are becoming increasingly automated. In order to meet the increased quality requirements and strict customer specifications, for example in the pharmaceutical sector, automated inspection processes are more and more implemented as a standard in production to increase the accuracy and traceability of quality controls. Serialisation has brought a lot of challenges, especially for pharmaceutical companies and their suppliers. Modern inspection systems must therefore be able to support pharmaceutical companies and their suppliers with managing the data along the entire supply chain.

The increase in sustainable but highly refined print products also reinforced the necessity to use automated inspection systems. Modern solutions for quality controls help to carry out valid tests of printed products independent of material and format, delivering precise results to avoid waste and machine time during production and processing. In addition, print inspection providers offer single system solutions for cross-product inspections throughout the entire manufacturing process, including service and maintenance, for preventive measures and to reduce press downtime.



The EyeC Validation Support Package provides the pharmaceutical customers with all validation-relevant documents, such as URS, IQ and OQ in a corresponding validation support package.

Nico Hagemann

Nico Hagemann is the director of the EyeC product management and product manager of the inline inspection systems. As an engineer in print and media technology, he has 15 years of experience in the printing industry. He started out in development at All4Labels (formerly Rako) and was responsible for inspection systems before joining EyeC as Application Engineer.