

*Proofreading with
100% Accuracy*



Complete Inspection Systems, Inc.

Checking the Fine Print



A healthcare products giant turns to electronic proofreading.

As FDA tightens controls over the accuracy of labeling content, drug makers continue to respond with more-thorough means of checking all packaging components. Still, consumers and the legal system demand more—100% accountability for even the most minute of errors. Something as minor as a missed hyphen can turn a “1-2 tablet dosage” into a “12 tablet dosage,” a potentially dangerous oversight. To avoid such mistakes, current GMPs require 200% human inspection. However, even with this 200% inspection policy, labeling mistakes and omissions remain the largest reason for recalls.

Moving beyond human inspection, **Bayer HealthCare** (Morristown, NJ) has taken the lead by automating the proofreading process for its printed materials. The firm has partnered with **Complete Inspection Systems Inc.** (CIS; Indialantic, FL). CIS has created a new proofreading system designed to cover a full range of visual inspection tasks. Its flagship product, AutoProof Pro, is designed to locate any labeling problems from first draft through the final production process. AutoProof Pro is a suite of tightly integrated tools that work together to ensure the accuracy of day-to-day quality-assurance tasks. The software is designed to run on standard office computers and peripherals, so the system can be shared between publishing, printing, and production services.



Operators who once had the added responsibility of proofreading documents have been especially pleased with AutoProof Pro.

Labeling control manager Terry Cullen, along with system operators Karen Kunkle and Linda Lynch, who handle graphics and materials for a number of Bayer plants, championed Bayer's proofreading project. Bayer decided to incorporate AutoProof Pro into its label control department to act as the quality control tool throughout the entire process. Bayer's user requirement specifications included ensuring that operators could automatically inspect and compare text at each step of the process.

For instance, after the original printed regulatory material is created and submitted to FDA, it is often revised. After FDA approval, it is then sent to the graphics department so that artwork can be created for the product. The regulatory document is then compared against the insert, label, or carton. Such proofing can be very difficult, as the formatting, character size, style, and number of words per row may not even match. Multiple languages, graphs, charts, and images are also often used, further increasing the chances of proofreading errors.

To assist Bayer with these tasks, CIS incorporated two reading and inspection modules. The first, called the PDF Text Extractor, gives Bayer the ability to convert almost any electronic file to a PDF format. The user can then select or "zone" an area and compare it with 100% accuracy to other documents in almost any language supported by Unicode standards. The operator saves the extracted text for use with the AutoProof Pro Text Compare Module.

The operator can then take the finished insert, convert it to a PDF, read it, and save it as a text file as well. The operator can then go to the AutoProof Pro main menu, select the Text Compare icon, and load the regulatory document and the finished insert. The Text Compare function locates each character and aligns it as closely as possible to the other document. Any characters found on one document but not on the other are highlighted. In less than 5 seconds, AutoProof Pro highlights any differences in the two files.

Using AutoProof Pro, Bayer can automatically proofread material from the earliest stages of production to the final product. AutoProof Pro validates documents even if they have been reformatted, exported to other applications, or even authored on different operating systems. To inspect printed materials, AutoProof Pro uses advanced visual comparison techniques tuned to pick up even the smallest errors. Printed materials can be scanned using a variety of devices, ranging from desktop scanners to 50-in. sheet feeders. AutoProof Pro compares sample documents with the original approved master, looking for any changes in the written copy, document formatting, graphics, and bar coding, as well as imperfections created by mechanical printing problems. For complete end-to-end product validation, AutoProof Pro can be used to compare packaging components removed directly from production to validate them against a master.

AutoProof Pro was also designed to meet 21 CFR Part 11 standards.

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