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### SOFTWARE

#### Ending the Paper Trail

Software solutions attempt to tackle virtually every pharmaceutical packaging issue.

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Software is available to help with nearly every possible packaging project. It would be impossible to cover every software offering in one feature, but this article will highlight a few of the latest solutions.

### RESEARCH



Large pharmaceutical companies rely on Kodak Design2Launch because it not only streamlines package design and labeling but also supports marketing, video, Web content, and printed materials.

Everything starts with research, and everything can be researched on the Internet today—but not always very easily. Web surfing can lead a lot of browsers down a lot of blind alleys. Using continually updated database servers may solve this problem. Elsevier Engineering & Technology (New York City) offers a Web-based subscription system for researching new designs, new materials, line equipment, changing FDA mandates, and other data needed during packaging development.

Illumin8 accesses Elsevier's full-text content, scientific abstracts from 4000 publishers, patents, and billions of Web pages. It extracts and analyzes solutions, which are then categorized under organizations, products, technologies, approaches, and experts. "It's about eliminating mistakes and avoiding reinventing the wheel," says Joe Buzzanga, product manager. "This helps zero in on the external world of information, discover what has been tried, and stimulate ideas that will work—things you didn't think of before."

### DESIGN AND DEVELOPMENT

Many things come into play when developing packaging: FDA regulations and guidances, product protection, marketing strategy, and manufacturability. New software packages are available to help with all of these areas.

Streamlining Package Development. Kodak's Corporate Solutions Group (Stamford, CT) provides a workflow solution for content management across the enterprise. It's called Kodak Design2Launch Solutions. Jennifer Bergin, corporate solutions manager, says that Kodak's comprehensive products fully integrate planning, analyzing, designing, executing, and managing enterprise processes for

artwork and labeling.

"We have had particular success within the pharma area because of the compliance issues faced and FDA approvals," Bergin says.

"Kodak Design2Launch Solutions is a combination of hardware and software and is highly configurable. This is a bonus, because most enterprises have a lot of legacy systems already implemented," explains Ron Malloy, vice president of sales and strategy.

The content management tool allows package designers to track the approval stage of any project. Projects are often handled in multiple divisions across countries. "The software is FDA 21 CFR Part 11 compliant and provides a trail for other types of compliance," Malloy adds.

"Eighty percent of packages that are recalled globally are recalled because of something that is wrong on the package," Bergin says. "Ingredients, use directions, claims, and disclaimers all need to be linked within the right routing inside the organization. Our Content Certification module essentially holds all the content so the stakeholders of the critical content are all linked."

Paxonix Inc. (Waltham, MA), a division of MWV, aims to streamline packaging development by "housing all assets in one place," says Kent St. Vrain, vice president of sales and marketing. "If you are the designer and you put up the latest version of your design, 99.9% of the people in your company can only access that latest version. They can't change it or download it, but they can make comments using what amounts to electronic sticky notes. And everybody's notes are on this same document for everyone else to see. No multiple versions or hidden comments are floating around."

When it comes time for actual approvals, this is where the true time savings lies. "Using this validated electronic system, all the approver needs to do is open his or her laptop wherever he or she is in the world and handle approvals electronically," St. Vrain says.



AutoProof Pro MultiCheck is an all-in-one inspection solution that performs image comparisons, text comparisons, OCR and reads bar codes on a single document in one batch process.  
(click image to enlarge)

Managing the Risk in Blister Packs. Peter Schmitt, managing director for Montesino Associates LLC (Wilmington, DE), says his firm works closely with customers designing blister packaging. Montesino offers "training, technical troubleshooting, business and product development, and technology development," he says. "One of these services we offer is finite-element analysis (FEA). We work with many parts of the supply chain: pharm aceutical companies themselves and their in-house packaging operations, contract packagers, machinery and tooling manufacturers, and even material suppliers."

Software can be key to successful design. "Customers will tell us that they have a certain shape of product and would like to simulate the packaging process," Schmitt says. "Usually the two most important things we are analyzing for them are the material distribution and barrier. We do this, and we then animate this process and produce a video so they can see what their process would look like when forming the blister for the package."

Currently, Montesino provides this service using e-mail to transmit files. However, in 2009 they will be launching the ability for customers to handle all of this online through a Web-based format. "Customers will be able to open screens, input the data themselves, and simulate what they need," Schmitt says. "The biggest benefit is the ability to make mistakes without repercussions. Mistakes can be costly in

pharmaceutical packaging, especially mistakes that impact the results of stability testing.”

Klöckner Pentaplast offers the use of FEA software through its BlisterPro service to speed development, reduce time to market, and increase line efficiencies. “Package designers, technicians, and engineers can explore the effects of tool geometry, film characteristics, and process conditions before running experiments, thereby avoiding expensive production line trials and tooling costs,” explains Daniel Stagnaro, business manager, pharmaceutical films, Klöckner Pentaplast. “The program provides thickness distribution, surface area and barrier evaluation, and permeability estimates of CAD-simulated cavities. Using these calculations, package engineers are able to design optimal blisters considering product shapes and barrier requirements and to select the right material helping to reduce the numbers of stability tests.”

## PRODUCTION

Sidebar:  
Focusing on Accuracy

Running a profitable production line demands good communication. Are all machines running efficiently? Are operators being used in the most effective manner? Are all data being communicated to the proper level? Software could be the glue that holds it all together.

Software for HMI. Parker CTC, Parker Electromechanical Automation, a division of Parker Hannifin Corp. Automation Group (Rohnert Park, CA), offers both hardware and software solutions to make HMI (human-machine interface) simple.

“The specific products that the CTC division provides are visualization, including HMI,” says Andy Balderson, product sales manager. “Our software is available as a stand-alone solution. It can be integrated into the user’s computer or hardware or can be integrated onto our own industrial computer platforms that are designed for use in harsh environments.”

Interact Xpress is a distributed HMI software product that is designed to interface with equipment in nonregulated areas. “This product is designed to streamline operations where all that is really needed is a simpler way for the operator to control general packaging,” Balderson says.

InteractX is the next step up. It is designed for validated critical process areas. “You can make the screen and operations very easy for the operator,” he says. “There are styles you can apply to the screens so they all have a similar look and style, which reduces training time and makes it very easy for the operator to understand and work with.”

InteractX will interact with the Interact Xpress product, providing cross-connectivity. The look and feel of graphics are exactly the same. “It provides tools for compliance, such as setting up full electronic signatures,” Balderson says. “Rather than needing extensive scripting as in other software products, InteractX lets [operators] use a simple check-box format to create any compliance application. A free demo version of both products is available on our Web site.”

Giving Operations a Shot in the Arm. Parsec Automation Corp. (Brea, CA) offers a product called TrakSYS that is designed to improve the efficiency of all processes, including packaging. “We manage the process so you can get more first-pass quality yield from your operation,” says Eddy Azad, CEO. “We do this by looking at the whole picture: what is happening on your line and what are the causes for stumbling blocks. Then we provide the information needed to improve line efficiency and productivity.”

“Our software works without disrupting the operations or impacting the validation,” Azad says. “It can monitor the different pieces of equipment and monitor the operations of the personnel. It looks at the impact of maintenance. It looks at the consumables used and ranks the vendors supplying them. To make this specific to the pharmaceutical industry, we have put in compliance for 21 CFR Part 11, so all the actions are kept in an accurate audit trail.”



Systech's Packaging Execution System consists of its machine, line, and plant-level products. Systech's software offering provides customers with protection, optimization, and clarity throughout their packaging operations.  
(click image to enlarge)

TrakSYS is installed on a main server. The location can be anywhere. It crosstalks to all existing software packages, PLCs, HMI applications, historians, and databases, including a number of proprietary systems made by specific OEMs. "We have developed all protocols. If there is absolutely no way to connect, we can put in our own sensors and also collect manual data," Azad says.

## INSPECTION

Because of the level of compliance and tracking needed and new product pedigree issues that are on the horizon, inspection is the fastest-growing area in software today.

Countering Mistakes and Counterfeiting. Complete Inspection Systems Inc. (Indiatlantic, FL) offers AutoProof Pro, a base system that can include various software modules to inspect original regulatory documents and compare them with finished labels, cartons, and inserts. AutoProof provides software solutions that compare unlike materials such as a Word Doc with a final insert. Multicheck reads and compares variable information labels. Q-Spec adds other features such as measurement, bar code reading, and color verification. Finally, Stealth checks returned goods to detect and eliminate counterfeiting.

Gary Parish, president, says that software modules can read and compare the original document format to the final insert document and check for accuracy, even if the original source is 20 pages long and the insert is one page. "It will match them automatically, in any language. It is in the Unicode format," he says.

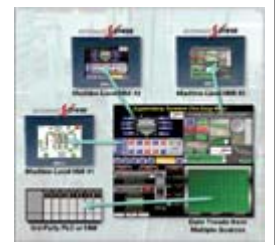
Digital watermark technology is an emerging capability the firm is starting to offer. Parish says that he sees this as a growing market. "A soft watermark will not transfer so it is impossible to counterfeit it," he says. "The watermark will not photocopy, and it is impossible to scan. Basically invisible to the naked eye, it can go right over the design, taking no space."

Line-Level Intelligence. Three software products from Systech International (Cranbury, NJ) together create a complete packaging execution system. "We primarily started as a company providing critical inspections for packaging lines: lot, expiration, date, color, and blister inspections," says Joe Ringwood, COO. "Over the years, we have evolved the software end and now have three product lines. Senti is our inspection product that sits at the machine level. Advisor is a line-management software product sitting over the line itself. Guardian is a plant-level system."

Guardian product resides on the packaging plant's main server. Advisor software communicates between Senti and Guardian. "From an optimization standpoint, Guardian also communicates to the main business application software," he says, adding that "we are able to upload to any format."

A packaging line will have cameras or bar code scanners that perform inspections. "Our software package resides inside of a high-speed computer with a graphical user interface (GUI)," Ringwood explains. "The computer is connected to all of the intelligent devices on the line in order to receive pass-fail signals." Ringwood says that one key advantage to using a packaging execution software system, rather than connecting directly down from an enterprise-type business system, is that it limits the need to revalidate when you upgrade or update the main business software.

## REGULATORY COMPLIANCE



Creating the screens that the operator will use for Parker CTC, Parker Electromechanical Automation can be done on a laptop, on a desktop, or on the Parker HMI hardware itself.  
(click image to enlarge)

Sparta Systems (Homdel, NJ) is an industry leader for global quality and compliance management systems. "TrackWise, a Web-based software solution, provides pharmaceutical packagers with a solution for managing quality and compliance across the entire supply chain," says Jon Rabinowitz, director of marketing. "The platform provides organizations with an enterprise-class solution to ensure quality and compliance in the highly regulated pharmaceutical industry with mandates such as FDA's CGMPs."

TrackWise addresses deviations, nonconformance, customer complaints and adverse-event reporting, corrective and preventative actions (CAPA), calibration and preventive maintenance, and more. Using the program, packaging engineers are able to manage, monitor, and report quality and compliance initiatives easily to streamline processes and promote industry best practices.

"Many companies are using paper-based or disparate software systems that only act as point solutions for each business unit," Rabinowitz says. TrackWise gives packagers a flexible, configurable platform to manage and view all issues pertaining to quality management and compliance across the organization."

Pilgrim Software (Tampa, FL) offers a software suite that automates all internal and external company activities, both regulatory and nonregulatory. Just a few highlights include audits to make sure everything in the plant and all suppliers are complying with all ISO, GSP, FDA, and EU regulations. Nikki Willett, vice president, marketing and regulatory affairs, notes that she is seeing packaging changing because of many diverse issues: added regulations, changes in harmonizing packaging across the globe, and the environmental movement. Software can help companies stay informed.

For instance, four key software modules can be used for monitoring packaging compliance. The CAPA solution can pinpoint sources of any nonconformance for fast targeting and correction.

The SmartEngineer solution allows collaboration of 3-D CAD models across the company from the design area, through all management routing, to the engineers on the line who can check for new package manufacturability well before any issues may arise in production.

An employee training and certification solution keeps everyone on the line aware of changes or new procedures.

"We also offer an equipment calibration solution that helps companies schedule their equipment maintenance and calibration schedules," Willett adds. "This program ensures that all key pieces of equipment are always in top condition."

## WRAPPING IT ALL UP

To address all packaging operations for regulatory compliance, maintenance schedules, out-of-spec conditions, and item-level data collection manually would be an impossible task. Even automation will need the streamlining that only sophisticated software can offer. Luckily, there is a range of solutions. Whether looking to integrate in-house or the Web, there is something to suit every need.

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