

# Solutions for Managing Pharmaceutical Packaging

*An Oracle White Paper*  
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# Solutions for Managing Pharmaceutical Packaging

## EXECUTIVE OVERVIEW

This white paper examines the complex process of managing labeling, text, and artwork for printed pharmaceutical packaging components as a segment of product lifecycle management. Developing packaging is the highest-cost process in manufacturing and selling a commercialized drug. Poor management can lead to errors that can be extremely costly in both financial and regulatory terms—with consequences including patient death and product recalls. This paper describes the process required to create and manage printed packaging components and explains how Oracle's Agile product lifecycle management applications support global procedures and documentation with a centralized business process solution.

## INTRODUCTION

Beyond the hundreds of millions of dollars invested in drug discovery and development, the highest-cost process for pharmaceutical companies selling commercialized drugs is packaging and labeling. The combined cost of managing and manufacturing the packaging can account for up to 60 to 75 percent of total product costs after development. Printed packaging components are a vital part of all pharmaceutical and medical products—no such product can be sold without some form of packaging for protection, identification, distribution, and use. Each drug can be sold as separate products in differing forms or doses. Further, each of these products can be distributed with a variety of components printed to meet the needs of country- and language-specific marketing and local regulations.

Current consumer and regulatory trends, such as those listed below, make the process of managing packaging components even more complex:

- **Customization.** Consumers of all ages are demanding more choices in packaging that are customized to their needs. For example, the elderly need packaging that is easy to read and to open, parents need child-safe packaging, and many consumers want packaging that is convenient in size and format.
- **Legislation.** Governments are legislating for greater controls on the information printed on packaging for product safety and on the materials used to enable recycling.
- **Globalization of brands.** Companies are increasingly adopting common branding across all markets around the world.

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- **Localization.** Local markets are driving more market-specific package inserts, such as leaflets, and extra label flash items.
- **Innovative delivery.** The manufacturing process is complicated by new modes of dispensing the product—from patches where the packaging is critical to dispensing the product to built-in dispensers that require specialized packaging.

## **THE HIGH STAKES OF PACKAGING MANAGEMENT**

At a tactical level, pharmaceutical companies might need to make changes in packaging because, among other reasons, the company has

- Changed its marketing messages
- Released relevant new medical information or indications
- Developed new or improved product forms
- Made required changes in the manufacturing process or recommended dose

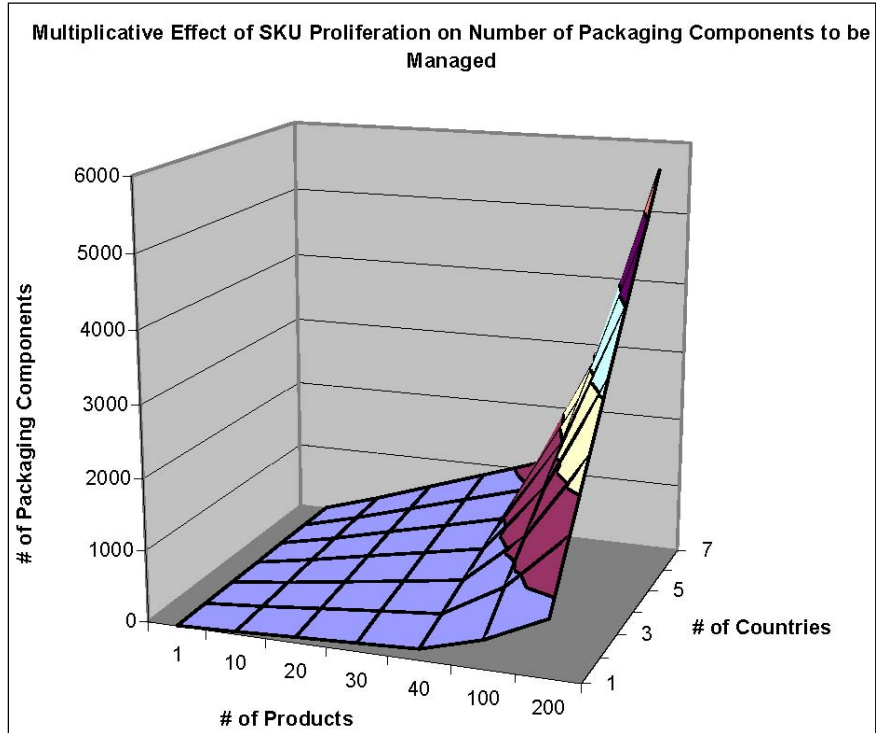
Once a change is approved, each printed packaging component will require new or updated artwork based on input from multiple and varied sources. These include external sources, such as the medical field and government and industry regulators, and internal sources, such as marketing and production. Making the change presents significant challenges, and the company will suffer high costs if it is not implemented correctly.

### **The Challenge of Packaging Management**

To illustrate the management challenge, consider a 100 mg tablet in a blister pack that might have an associated foil lid, insert or leaflet, carton, and printed dispatch label for each market. If it is sold in 40 countries, this can add up to 160 potentially different printed packaging components. If the product is available in three strengths, the total could rise to 480 different components. When this figure is extrapolated to all products in, for example, a 40-product company portfolio, the resulting number of packaging components is 19,200.

The company must not only manage this large number of components effectively, but also will require the infrastructure to create, purchase, store, and distribute the components before packaging. Additionally, many companies now must fill and pack products in more than one location—a very complex operation to manage, given the above scenario.

**The company must not only manage the large number of packaging components effectively, but also will require the infrastructure to create, purchase, store, and distribute the components before packaging.**



**Figure 1: The number of packaging components increases radically as the number of products, strength options, and target markets and countries increases.**

Pharmaceutical companies have organized departments and procedures to manage their packaging and to deliver the final product at the appropriate time and place. Though it might sound simple, the flowchart in Figure 2 shows that management of packaging components is a complex, multistage operation requiring attention to detail and accurate communications at every stage.

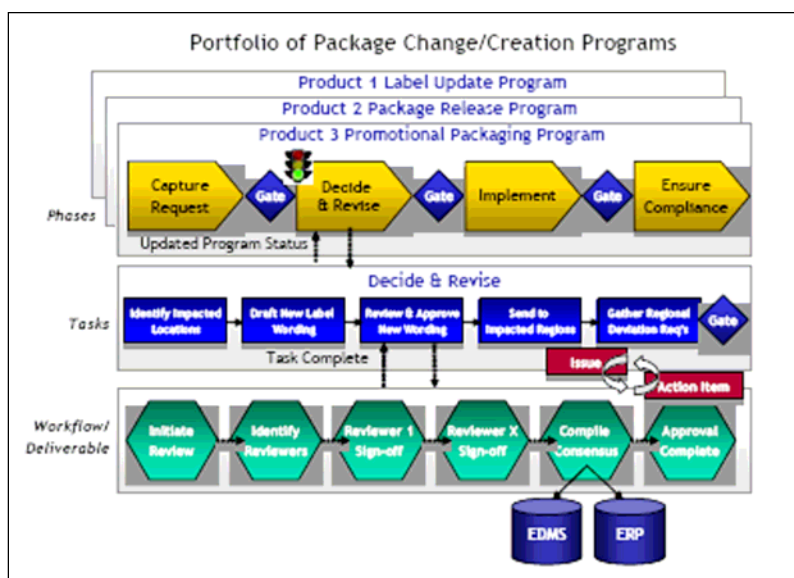


Figure 2: Managing packaging components is a complex, multistage operation.

### The Cost of Poor Packaging Management

Statistics from regulators—such as the Food and Drug Administration (FDA)<sup>1</sup> in the United States and the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>2</sup> in the United Kingdom—reveal that one of the most common causes of recalls is error in printed packaging components. Further analysis of these figures indicates that the most common problem with the printed component is incorrect or missing text.<sup>3</sup>

Investigations of recalls and regulatory inspections often reveal that companies are using a variety of systems, processes, and procedures<sup>4</sup> to manage printed packaging components. This is especially true when production sites are spread across cultural and geographical locations—a common scenario today, because many multinational companies have grown by merger and acquisition. Regulatory authorities want all sites of each company to adopt the same—or, at the very least, similar—procedures for similar labeling and package management tasks. Additionally, personnel that generate printed packaging components must have clearly defined responsibilities and enable transparency of workflow across sites.

In view of these statistics, poor packaging management practices are an expensive problem, with moderate to catastrophic consequences. When mismanaged product

<sup>1</sup> See FDA 2002 Drug Recall Data—Appendix, Table 1.

<sup>2</sup> See MHRA Pharmaceutical Label Error Report—Appendix, Table 2.

<sup>3</sup> Incorrect or missing text usually occurs due to one of three main causes: an incorrect brief, artwork creation errors, or printing faults.

<sup>4</sup> There is not a legal or regulatory requirement to have the same procedures across multiple sites. However, inspectors frequently cite a deficiency in procedures in their inspection reports.

Investigations of recalls and regulatory inspections often reveal that companies are using a variety of systems, processes, and procedures to manage printed packaging components.

information is printed on packaging and those supplies must be discarded, the unfortunate consequence is an unnecessary increase in costs. When a history of mismanagement leads to increased regulatory scrutiny and more-frequent inspections, the serious consequence can be that products are delayed and new product introductions are slowed. Finally, when a product is recalled or a patient dies, the consequences are catastrophic.

**Although each company has its own method of determining the cost of rework and lost opportunity, the overall loss to the pharmaceutical industry is estimated at several hundred million dollars each year.**

When a company has produced defective packaging, the time spent in producing replacement components is lost and can never be recovered. This extra production also often requires overtime resources at additional cost. There is also the possibility that regulators could ask a company to take its products off the market until they are satisfied with changes in the company's policies and procedures. Add to this the potential for bad company publicity—the cost of which is difficult to estimate but very costly to the organization—and the company image could be significantly eroded, impacting all products. It is fair to assert, given the potential consequences, that it is critical for any large, growing pharmaceutical company to effectively manage product packaging and labeling. Although each company has its own method of determining the cost of rework and lost opportunity, the overall loss to the pharmaceutical industry is estimated at several hundred million dollars each year.<sup>5</sup>

## **BENEFITS OF PRODUCT LIFECYCLE MANAGEMENT**

The Agile product lifecycle management solution optimizes how pharmaceutical companies manage their portfolio and projects, change requests and approvals, and compliance with industry and company policies. The solution offers robust collaboration, workflow, communication, and audit trail capabilities that allow companies to better manage a product's packaging documents, artwork, and components. Select features also include security provisions and support for management metrics and electronic signatures.

This solution is built on an electronic repository—the product record—that centralizes all product packaging management data. The central repository streamlines processes and protects the integrity of information required to manage product packaging, promoting global standards that improve cost efficiency.

The system's benefits fall into the following three general categories:

### **Faster Operational Processes**

- Reduce time to market by 50 percent.
- Reduce cycle time for completing packaging changes by 50 percent.
- Increase revenue with more time-efficient operations.

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<sup>5</sup> Estimates are from Calico Associates Limited industry research.

**Adopting the Agile product lifecycle management solution to manage pharmaceutical packaging and labeling could deliver seven-figure increases in profits.**

### **Reduced Product Costs**

- Reduce material costs by 5 percent by reusing intellectual property and standardizing components.
- Reduce scrap by 20 percent with more-consistent specifications and visibility of component changes.
- Improve throughput of packaging changes by 40 percent with existing organizational resources.

### **Improved Compliance**

- Reduce errors in printed product information by up to 75 percent.
- Reduce packaging errors during new product introductions by 10 percent.
- Establish consistent policies and procedures among geographically dispersed sites.
- Improve compliance with regulatory requirements.

The exact benefit for each company will be different depending on its size, structure, product portfolio, and organizational capability. However, adopting the Agile product lifecycle management solution to manage pharmaceutical packaging and labeling could deliver seven-figure increases in profits.

## **PACKAGING MANAGEMENT ISSUES AND SOLUTIONS**

The following sections cover some of the common issues that can become obstacles to effective pharmaceutical packaging management. The Agile product lifecycle management solution can help contain and offset costs while increasing revenue and ensuring compliance. Each of the three key factors in the management process are addressed—artwork creation and management, packaging components, and compliance with policies and procedures.

### **Artwork Creation and Management**

U.K. Health Minister Lord Philip Hunt summarized the importance of creating and properly managing artwork for product packaging: “Clear labeling and packaging of medicines is key to their safe use. It should be plain, clear, and should let patients, caregivers, and health professionals identify at a glance the information to make sure that the medicine can be used safely.”<sup>6</sup>

### **Streamlining Reviews of Artwork Briefs**

The importance of a clear, unambiguous brief cannot be stressed too highly in creating packaging artwork right the first time. Because the artwork brief is so fundamental to the success of the packaging, it is important that there be no room for those implementing the brief to misinterpret it. However, in many companies

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<sup>6</sup> Press release reference: 2003/0089.

artwork briefs arrive at the studio in a variety of formats—ranging from a simple verbal instruction or e-mail to marked-up copy to a complete electronic document containing the relevant text. Such inconsistency of process leaves ample room for misinterpretation and error.

The Agile product lifecycle management solution puts in place a structured workflow that will only allow receipt of artwork briefs in an appropriate—preferably electronic—format. In addition, the software enables administrators to authorize only qualified contributors to request and provide input on changes to packaging artwork. These features improve compliance and hence drive down errors and costs.

### **Improving and Automating Workflows**

Getting artwork approved before it is released to the supplier can often be a protracted exercise. This is especially true when dealing with colleagues who spend considerable amounts of time away from the office or who are in different time zones. Due to such delays, it can take some companies 12 to 24 months—from the initial change request to final execution—to completely implement packaging and label changes in all countries of operations.<sup>7</sup>

Agile product lifecycle management applications offer project management and collaborative workflow capabilities that will alert the proper individuals that artwork is available for them to review and approve. This means that, even if some sites work remotely across a modem, the right individuals have timely access to records. The application runs on the company intranet, applies appropriate role-based security models, and is usable across the internet, giving 24/7 access to authorized staff and external suppliers every day of the year. The solution's built-in security provisions allow suppliers to have real-time visibility of and input to the artwork for the packaging components they are responsible for supplying. Along with enabling visibility of the process, the Agile product lifecycle management solution has configurable metrics that allow pharmaceutical companies to resolve possible delays to meet required turnaround times.

### **Moving Toward Electronic Workflow**

There is a growing demand in the printing industry to have all artwork available in an electronic format. In fact, the industry is moving rapidly toward using only electronic files at all stages of artwork development and production. Increasingly, companies are sending electronic artwork files directly to the printing plates, bypassing conventional interim stages. Some companies are now even bypassing the printing plates and printing directly from the electronic file (such as Adobe Portable Document Format files). In addition, there is a trend toward no longer including leaflets or inserts in packaging, but rather having the pharmacist print them directly at the point of sale. This would require that all such artwork be available as an electronic file.

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<sup>7</sup> Estimates are from Calico Associates Limited industry research.

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**The central product record makes all product information available in electronic format simultaneously to all approved parties. This allows companies to implement a fully electronic workflow.**

The Agile product lifecycle management solution's product record is an electronic repository of information that contains textual information, such as labeling text and links to related documents such as artwork files. The central product record makes all product information available in electronic format simultaneously to all approved parties. This allows companies to implement a fully electronic workflow—driving industry trends, improving compliance, and decreasing delays and the associated costs.

#### **Reducing Duplication of Work**

When a company launches a new product in one market, managers in other geographic markets are invariably interested in, or actively planning on, marketing the same product. When they do finally launch the product in their own markets, their teams frequently create unique graphics and packaging when existing artwork from the initial launch would be sufficient as is—or would need only minor changes. Such redundant design and production causes inordinate cost increases.

The Agile product lifecycle management solution's product record offers a holistic view of up-to-date packaging information, enabling companies to easily construct a “library” of approved labeling text and packaging. These approved files are linked to their component material specifications, packaging engineering drawings, artwork, and associated documentation and correspondence. This drives a more-streamlined approach across markets and prevents the duplication of new or changed packaging, saving companies significant amounts in labor costs.

#### **Protecting Intellectual Property**

It is vitally important for companies to protect their intellectual property against imitators, counterfeiters, and other commercial competitors. To ensure such protection, company logos and trademarks must be represented in consistent formats to provide defense under legal challenge.

The product record stores correctly formatted company logos and trademarks in a central and universally accessible location, eliminating the need for multiple versions stored in multiple locations. Authorized staff centrally stores and manages these elements and can easily monitor the updated versions so that all changes made are correct and marks are not devalued. Devalued marks put a company at risk for legal challenge and, at the very least, expensive legal fees. The Agile product lifecycle management solution ensures a consistent brand and secures intellectual property, reducing legal expenses and maintaining company integrity.

#### **Managing Country-Specific Requirements**

Many countries have very specific packaging regulations for overprinting or batch details that indicate such information as lot number, expiration, or “use-by” date. To ensure timely and effective packaging change management, it is critical to correctly print these packaging elements.

The Agile product lifecycle management solution stores and manages a database of requirements for each country. When artwork is generated, it is automatically checked against this database to ensure the correct format for the destination country is used. This automated system reduces rework and associated manufacturing costs and significantly reduces the risk of product recalls.

### **Packaging Components**

Most companies are developing or changing components on an ongoing basis to meet production, supplier, customer, or regulatory needs—creating multiple printed variants in the process. This can lead to significant confusion as to which printed variant is current. Suppliers can be uncertain of which materials they should provide, and company staff can be uncertain of which variant to pack and deliver.

### **Managing Component Change**

Manufacturing managers commonly have to order larger quantities of component supplies than they need—sometimes up to a year’s supply in smaller markets and for low-volume products. Industry averages indicate that manufacturing supervisors often have to order up to two years of printed packaging component supplies when existing inventory runs short. These excessive orders can add significant cost and waste to a company’s packaging operation. A typical pharmaceutical company replenishes its stock of each part (stock keeping unit, or SKU, items) at an average cost of US\$50,000 to US\$75,000 per bulk order. However, such companies also typically make changes to components—and the parts required—two to three times a year. Because manufacturing managers lack visibility and knowledge of pending changes, a good portion of these orders often ends up as scrap. For a company that must keep thousands of SKU items in stock, this rapidly becomes a multimillion dollar problem.

The Agile product lifecycle management solution ensures that only approved versions of packaging are visible across the supply chain and can highlight those that are undergoing change. Authorized staff can set permissions to allow certain individuals to view the component supplies that will be required for new products the company plans to introduce. In addition, the system can be configured to automatically alert relevant parties of component changes coming through and can set instructions for dealing with all changes. The solution enables broad visibility and management of component change, minimizing the waste and cost of ordering obsolete inventory while maximizing revenues by getting the right product to market quickly.

### **Streamlining the Supply Chain**

Component suppliers, or converters, that provide components to a number of sites at a particular company invariably have a number of different contacts and follow different methods in delivering components to each site. This inconsistency can slow workflows, compromise security, and significantly delay product launches.

**The solution enables broad visibility and management of component change, minimizing the waste and cost of ordering obsolete inventory and maximizing revenues.**

The Agile product lifecycle management solution implements a common workflow, which ensures that suppliers will conform to the company's accepted methods of delivery across all company sites. In addition, the solution's Web-based security features grant suppliers access only to information they need. Suppliers have access to artwork the moment it has been approved and can then start work on producing the printed packaging component immediately. These automatic notifications minimize delays in getting the artwork to the suppliers, improving cycle times for packaging changeovers. As a result, companies launch products on time and revenue increases.

### **Achieving Consistent Coding**

Many companies have no common format for identifying packaging components. Often, there are several different codes for the same item, especially when the company has evolved through mergers, and has used different coding systems over the years. Inconsistency in coding can cause considerable difficulty for both suppliers and the company's internal procurement department, which also probably contends with a multitude of bills of materials.

**Companies that use multiple code numbers also often have, as a result, duplicate specifications and excess inventory. Streamlining these processes can release a significant amount of capital, while improving stock turnover.**

Ideally, a pharmaceutical company will have a single code number for each packaging component. The Agile product lifecycle management solution helps companies achieve this ideal with an allocation function that will allow only one code number per packaging component. This safeguard significantly reduces the risk of using similar but incorrect materials in packaging—an error that can compromise compliance. Companies that use multiple code numbers also often have, as a result, duplicate specifications and excess inventory. Streamlining these processes can release a significant amount of capital, while improving stock turnover. Companies that manufacture the same product in different production sites or countries benefit from the ability to specify the same base material by code number across all sites. They can consolidate warehousing and production of identical materials intended for different sites, reducing procurement as well as handling costs. The risk of error—and of noncompliance—is reduced.

### **Compliance with Policies and Procedures**

This robust solution has built-in functionality that will improve and demonstrate compliance with such regulations as FDA 21 Code of Federal Regulations (CFR) Parts 210 and 211. In addition, the software ensures compliance with FDA 21 CFR Part 11 by supporting approved methods for electronic records and signatures. Regardless of the policies and procedures adopted by a company, regulatory bodies expect all staff to comply with a company's stated policies and procedures at all times and to be able to demonstrate such. Many companies find it difficult to achieve this type of compliance and to maintain it over time.

### **Establishing and Following Procedures**

To achieve compliance, the first fundamental step for the company is to adopt a suitable workflow with common procedures throughout and across sites—both in-

**The mere decision to invest in a comprehensive global packaging management solution will improve the positioning of the company with regulatory authorities.**

house and among suppliers. In reviewing how companies manage packaging component artwork across multiple sites, it is common for different sites to evolve disparate procedures for the same or similar tasks. Regulators might observe and report this disparity as noncompliance during audits, and suggest improvements in the process. However, if a company does not implement these improvements at all sites, errors can be repeated across the company, and the product can ultimately be recalled. A major pharmaceutical company that continually fails to achieve policy and procedure compliance might expect between 4 and 10 recalls, and between 7 and 20 serious incidents, per year as a result of its operating deficiencies. Each recall is estimated to cost between US\$500,000 and US\$2 million.<sup>8</sup>

The Agile product lifecycle management solution's centralized product record and global automated workflow is a critical foundation to adopting a set of common policies and procedures companywide. In fact, company executives might choose to distribute and control the mandated policies and procedures themselves via a suitable workflow within the Agile product lifecycle management system. The mere decision to invest in a comprehensive global packaging management solution will improve the positioning of the company with regulatory authorities. Pharmaceutical companies should expect at least a 50 percent reduction in recalls and serious incidents due to errors in packaging management when they implement the Agile product lifecycle management solution.

#### **Distributing Procedures and Training**

Companies often delay in distributing new procedures and in training staff on those procedures. The Agile product lifecycle management solution electronically advises all appropriate staff of a new or updated procedure the moment the change is approved and goes live on the system. Administrators flag staff members who need to be notified of changes in certain procedures as “nominated individuals.” The solution also archives old documented procedures that have been superseded by new or updated procedures, and checks—through configurable metrics—that all nominated individuals have been approved on the current procedure. When the staff has visibility of the same current procedures that they should be following, the likelihood of error reduces, and the likelihood of compliance increases. As a result of significantly cutting errors in procedures, companies will invariably cut costs, introduce new products to market faster, and generate higher revenue.

#### **Updating Regulatory Information**

A frequent source of error is when a company inadvertently omits required regulatory information—such as warning statements—or inadvertently includes incorrect information in artwork. Often, personnel make such errors because they are not made aware of recent changes. In addition, as more companies export their products, it becomes increasingly important that teams working on artwork in the local country be familiar with the language in which product information is written.

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<sup>8</sup> Estimates are from Calico Associates Limited industry research.

The Agile product lifecycle management database stores current regulatory information and categorizes it by product, market, language, strength, and quantity. Because the centralized database is accessible by all company staff and sites, this information can be entered once and need not be duplicated, reducing the risk of typographical and translation errors and the cost such errors incur. Additionally, when changes are made in the regulatory information to be printed on one product's packaging, the system's "where used" function allows fast and efficient searching to discover other packaging that needs to be changed. Again, configurable metrics allow managers to monitor progress in real time without generating lengthy written reports.

## **CONCLUSION**

The process of managing labeling, text, and artwork for printed pharmaceutical packaging is complex and challenging. Poor management can lead to costly errors with grave financial and regulatory consequences. As a result, packaging is the highest-cost process in bringing a commercialized drug to market. Customers are demanding more-customized packaging, governments are legislating for controls, brands are going global, local markets are demanding specific components, and companies are pressured to create packaging that supports innovative drug dispensing methods. These consumer and regulatory trends make pharmaceutical packaging increasingly difficult to manage effectively.

Oracle's Agile product lifecycle management solution optimizes how pharmaceutical companies manage their portfolio and projects, change requests and approvals, and compliance with industry and company policies. The solution offers robust collaboration, workflow, communication, and audit trail capabilities. This functionality, along with sophisticated features and a centralized repository, allows companies to better manage artwork and its creation, packaging components, and compliance with policies and procedures. Such a system can complement other corporate initiatives such as Lean Sigma and other transformational or continuous improvement programs.

The benefits of the system include faster operational processes, reduced product costs, improved compliance, and a significant increase in company profits.

**Oracle's Agile product lifecycle management solution optimizes how pharmaceutical companies manage their portfolio and projects, change requests and approvals, and compliance with industry and company policies.**

**APPENDIX**

<b>Total Recalls</b>	273
<b>Market Type</b>	
Prescription	230
Over-The-Counter	43
<b>Problem Area</b>	
Labeling	55
Manufacturing	3
Potency	55
Dissolution	10
Other Product Specs	21
Contamination	120
Other Non-Compliance	9
<b>Total Recalls</b>	273

Table 1: FDA 2002 Drug Recall Data. *Source:* FDA Gold Sheet, March 2003.

<b>Defect Type</b>	<b>Reports Received</b>		
	2000-2001	2001-2002	2002-2003
Label Missing / Mix-up	26	13	20
Label Details Missing	0	4	6
Wrong Data	18	9	0
Poor Print	0	1	3
Re-labelling Error	5	3	21
All PPM Defects	49	30	50
Other Defects	134	110	162
<b>Totals</b>	183	140	212

Table 2: MHRA Pharmaceutical Label Error Report. *Source:* Data from MHRA as presented on June 30, 2003, Management Forum Artwork Conference, London.



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