

3M Integrated Packaging Tool  
*solutions to optimize the packaging process*



FDA CFR Part 11 and Packaging  
November 10, 2004

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# Agenda

Overview of the FDA CFR Part 11 Guideline

The Impact of Poor Quality

The Importance of Packaging

Getting an ROI



# Overview of the Guideline

“The intent of CFR Part 11 is to ensure data integrity, by setting minimum standards for accuracy, trustworthiness and reliability of records.

Computerized systems should provide the same degree of confidence as paper systems. The ability to store and retrieve ever-growing quantities of *e-data* is a challenge for most companies and should be an integral component of any comprehensive CFR Part 11 compliance plan.”

—Nancy Alcorn, Quality Consultant, 3M



# The Impact of Poor Quality

**Recent studies have shown that as many as 98,000 Americans die each year as a result of medical mistakes**

- ✓ Approximately 7,000 annually are due to medication errors

**Companies have incurred millions and even hundreds of millions in FDA fines**

- ✓ Some in excess of \$500 million

# The Importance of Packaging

**Approximately 50% of all recalls are due to packaging errors**

**Consumer safety cannot be compromised by mislabeled products**

- ✓ Instructions for use
- ✓ Allergen warnings
- ✓ Ingredient statements

# Integrated Packaging Management

## Time-stamped audit trails

- ✓ What happened, when, and how?

## Record retrieval

- ✓ Real-time reporting

## System security

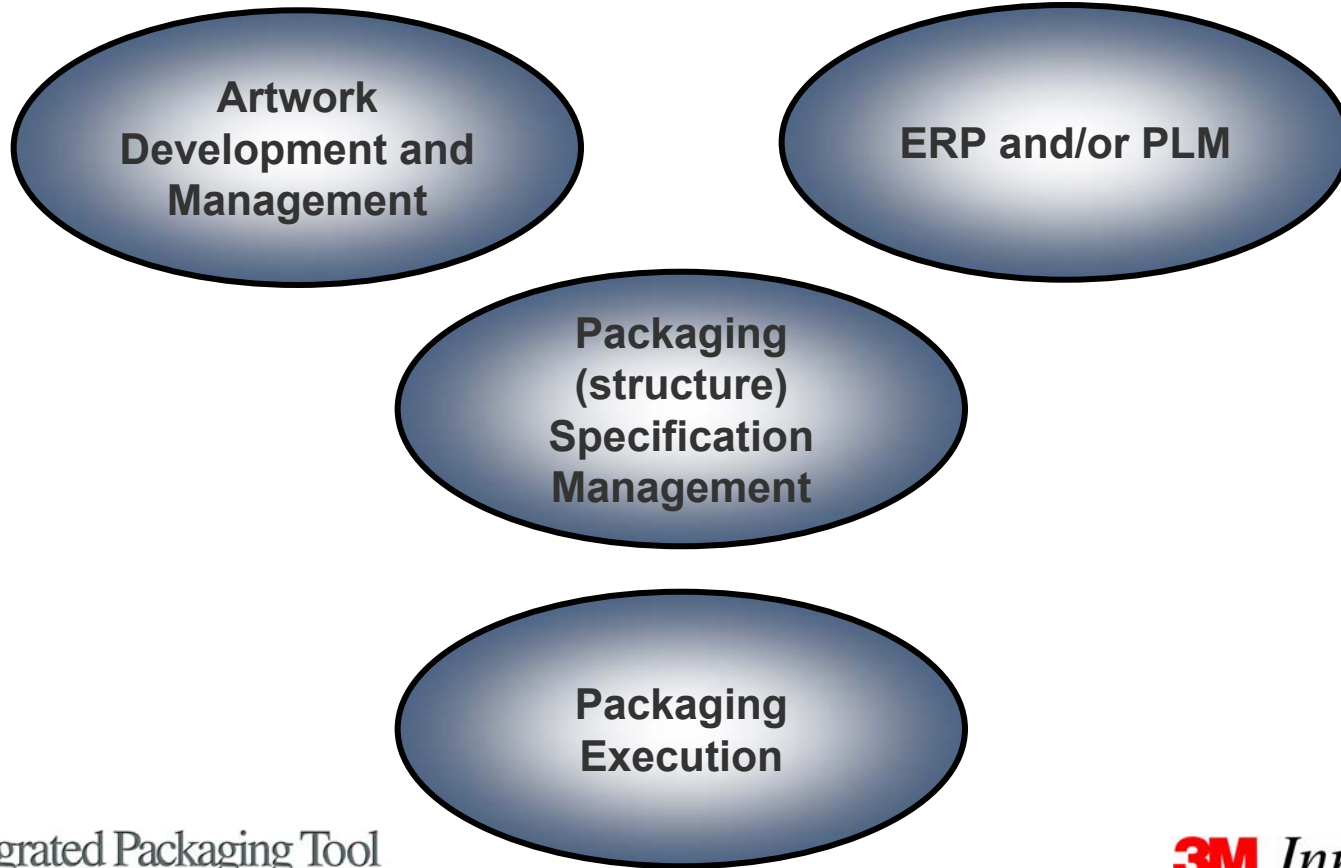
- ✓ Authorized users performing authorized tasks

## Electronic signatures

- ✓ Who managed what, when, and how?

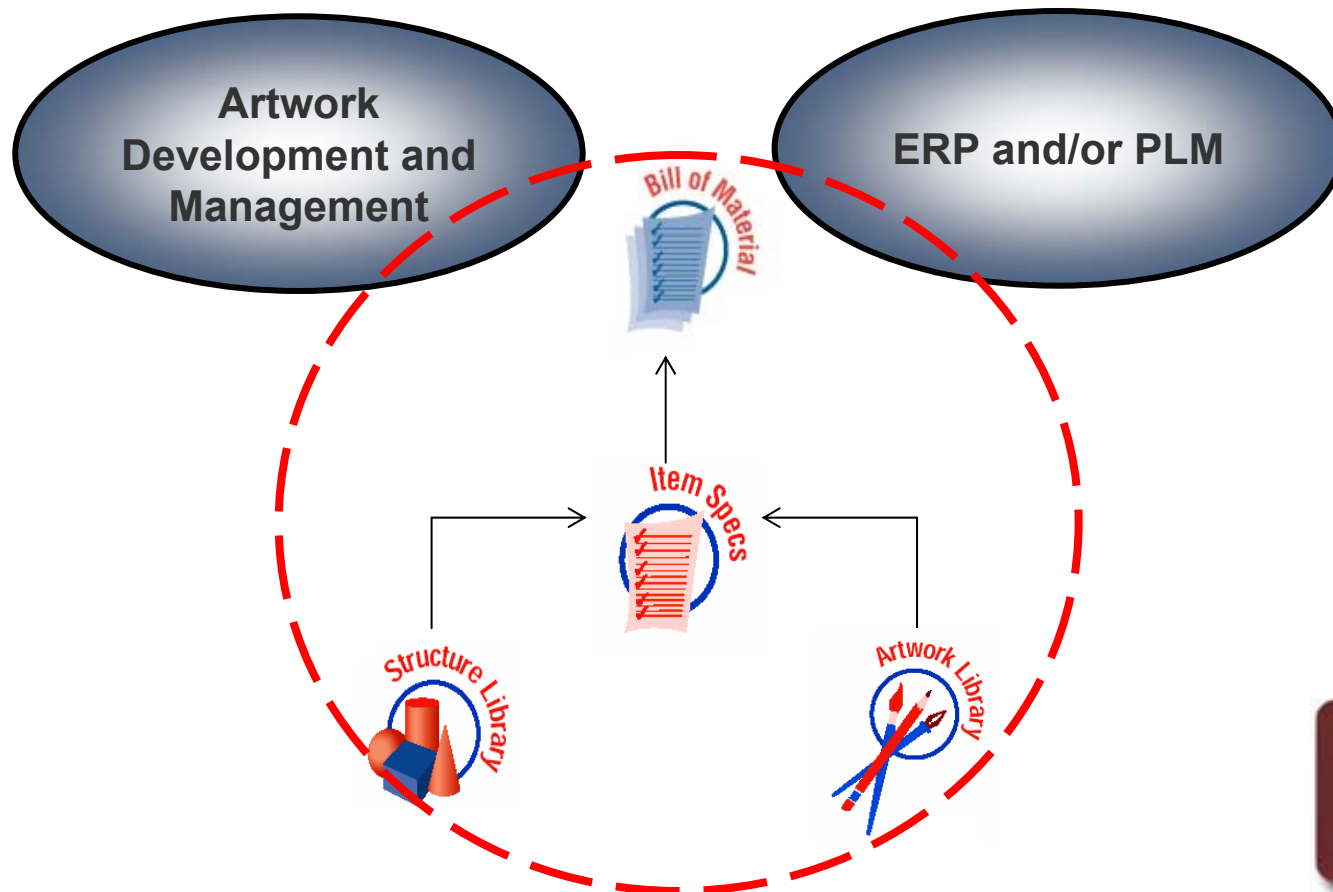
# What's the Issue?

**Vital systems are disconnected and document-based**



# The Solution: IPM

## A packaging system of record



# Why 3M?

## 3M is a life sciences company

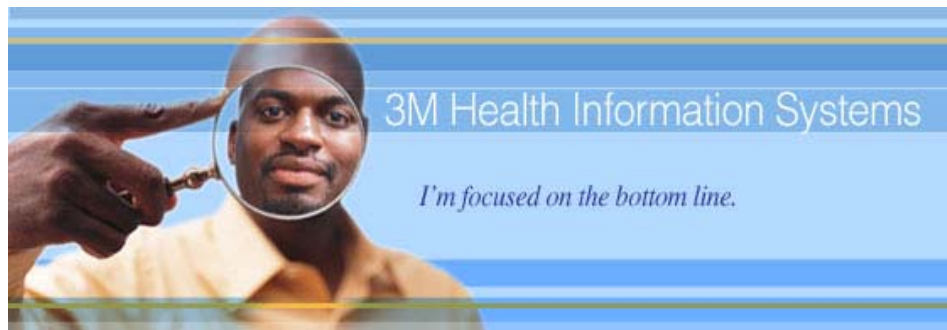
- ✓ Dental and orthodontia
- ✓ Drug delivery
- ✓ Infection prevention
- ✓ Medical device
- ✓ Microbial detection and control
- ✓ Pharmaceutical
- ✓ Wound management



# Why 3M?

## 3M provides its customers with innovative information technology products/services

- ✓ HighJump Software, LLC, a 3M company
- ✓ 3M Health Information Systems
- ✓ 3M Integrated Packaging Tool



# Getting an ROI

**Many pharmaceutical companies have over-the counter CPG products too**

**CPG companies have distinct packaging needs, that if addressed can produce significant financial results**

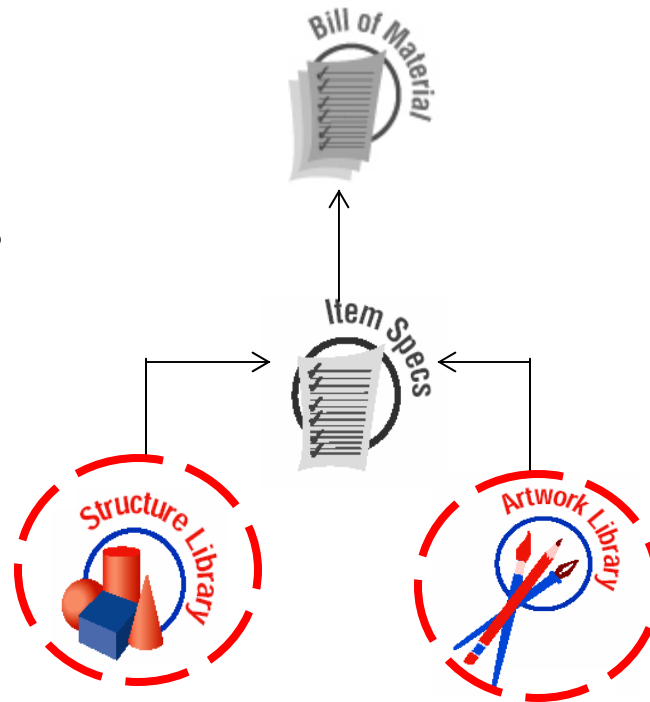
- ✓ Speeding time to market
- ✓ Reducing packaging cost
- ✓ Enforcing brand standards
- ✓ Complying with retailer mandates



# Productivity and Efficiency

✓ Data-enabled  
structure specs

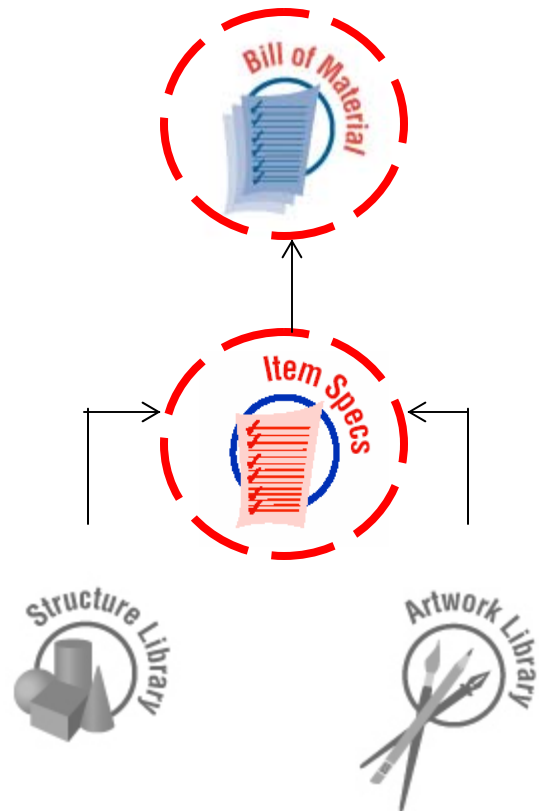
✓ Drives  
**productivity**  
in package  
engineering



✓ Data-enabled  
artwork specs

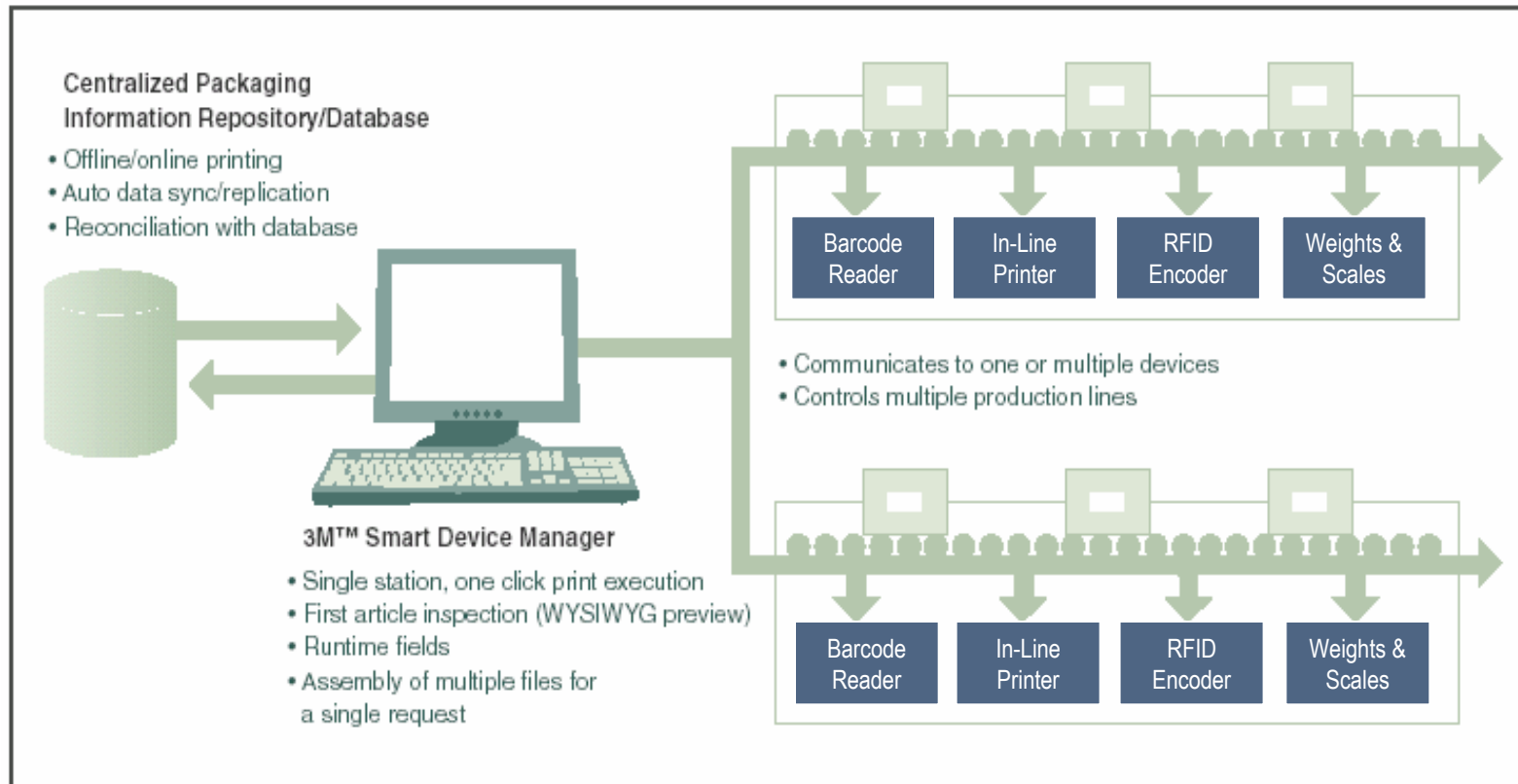
✓ Drives  
**efficiency** in  
marketing and  
creative services

# Collaboration and Sourcing



- ✓ All information necessary to build all levels of the package
- ✓ Drives **collaboration**
- ✓ Marriage of artwork and structure
- ✓ Drives ability to **strategically source** packaging materials

# 3M's Capabilities in Action— 3M™ Smart Device Manager



LANGUAGE TRANSLATION  
PRODUCT LABELING  
INFORMATION REPOSITORY  
ARTWORK MANAGEMENT  
SPECIFICATIONS MANAGEMENT

# Additional Capabilities

## Role-based security

- ✓ Field-level access to critical packaging data and graphics

## Archiving/Reporting

- ✓ Visibility to all key activity

## Automated eWorkflow

- ✓ Electronic approvals, event-triggered actions

## Print Client

- ✓ Off-line printing, print job scheduling

# Conclusions & Recommendations

**Life sciences companies cannot afford to compromise quality, in packaging or anything else**

**IT systems that are document-based do not address critical packaging issues in life sciences today**

**Integrated packaging management provides needed functionality to ensure top quality**

SPECIFICATIONS MANAGEMENT	ARTWORK MANAGEMENT	INFORMATION REPOSITORY	PRODUCT LABELING	LANGUAGE TRANSLATION
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# Questions?

SPECIFICATIONS MANAGEMENT	ARTWORK MANAGEMENT	INFORMATION REPOSITORY	PRODUCT LABELING	LANGUAGE TRANSLATION
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# Backup Slides

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SPECIFICATIONS MANAGEMENT	ARTWORK MANAGEMENT	INFORMATION REPOSITORY	PRODUCT LABELING	LANGUAGE TRANSLATION

*Centralize*

*Optimize*

*Create*

*Facilitate*

*Enter*

*Go*

*Economize*

*Track*

*Collaborate*

*Integrate*

*Comply*

*Update*

*Communicate*

*Translate*

*Regulate*

*Consolidate*

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