



The Essential Guide to Pharma Labeling Artwork Excellence





Introduction

For pharmaceutical companies, the top priority is clear: deliver life-saving treatments to the patients who need them. Around the world, Health Authorities set strict regulations to ensure drug safety and efficacy, and the industry is held to one of the highest standards of quality with near-zero tolerance for risk.

Once clinical trials are complete and a product is approved, every delay means patients are left waiting. Speed to market matters but so does getting everything right the first time.

One of the biggest hurdles in this process? Labeling and artwork.

Organizing the right content, ensuring accuracy, managing translations, and creating compliant outputs like artwork and e-PILs can be complex, fragmented, and time-consuming.

But what if it could be simpler?

What if your organization could work smarter—with fewer bottlenecks, fewer errors, and less rework?

Imagine if you could:

- Work faster, without compromising quality
- Eliminate redundant steps and manual reviews
- Improve accuracy and compliance
- Empower teams to do their best work
- Greatly reduce risk across the product lifecycle



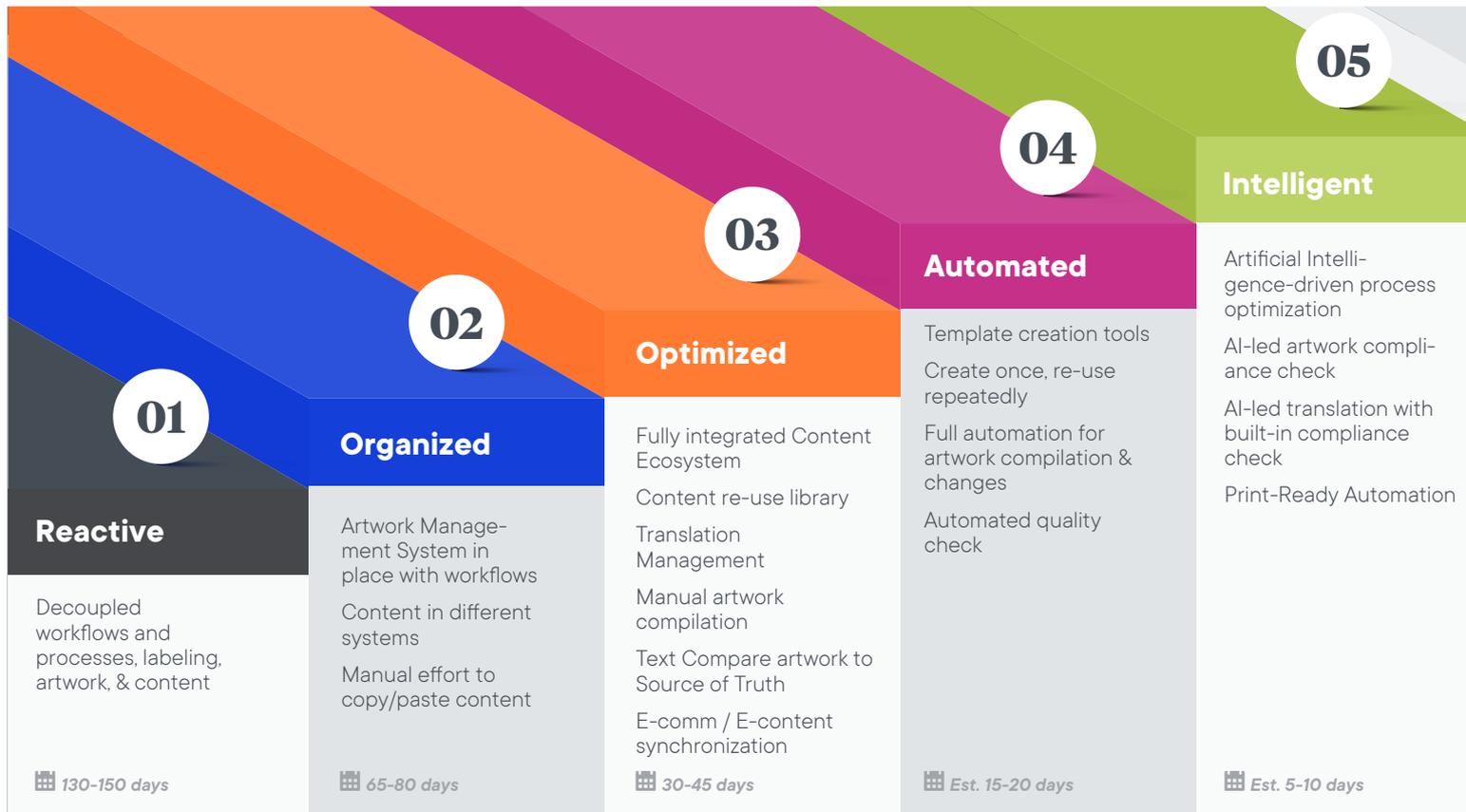


And the work doesn't stop at launch. Labeling must be maintained throughout the life of a product. As post-marketing surveillance uncovers new safety data, updates are often needed across dozens of markets, each with its own requirements and languages.

In fact, **labeling and packaging errors account for more than half** of all product recalls. Despite layers of manual QC and established quality systems, errors still happen—and the cost can be enormous. Clearly, the current approach isn't enough.

This eBook explores how life sciences companies can reshape their approach to labeling and artwork—making it faster, safer, and smarter. Let's take a closer look at what's holding teams back, and how the right strategy and technology can help you move forward.





A Smarter Path to Labeling and Artwork Excellence

Improving operational efficiency should never come at the expense of quality.

To help companies navigate this balance, Esko developed the **Artwork Management Digital Maturity Model**—a framework designed to help you understand where your organization currently stands, where you want to go, and the capabilities you'll need to develop along the way.

Here's a breakdown of the five stages:

1. Reactive

In this early stage, processes are inconsistent, cross-functional collaboration is limited, and data is poorly managed. Labeling change requests often require heroic efforts to manage, and tools like hardcopy documents, PDFs, and email are still commonly used—making traceability difficult and increasing the risk of errors.

2. Organized

Many life sciences companies fall into this category. At this stage, there is typically a structured workflow system in place to manage artwork changes and approvals. Electronic records and signatures are in use, meeting requirements such as 21 CFR Part 11 and Annex 11.

However, regulatory content may still be scattered across various sources, often in Word documents. While artwork change processes are defined, content management is still a challenge.

3. Optimized

Here, globally harmonized workflows are the norm, and best practices are followed consistently across teams. Content management takes center stage, with companies moving from scattered Word files to a centralized content database that enables reuse and localization.

Translation and version control are streamlined within this content ecosystem, improving consistency and speeding up impact assessments. Tools like content comparison and export-to-e-content systems help reduce manual QC and accelerate time to market.



4. Automated

While various types of automation may be occurring in the Organized and Optimized stages, the Automated stage describes the automation of artwork changes. Using artwork templates with pre-defined layouts, a content change can automatically flow from the approved content ecosystem directly into the artwork template. Automated quality checks will then be done to ensure the accuracy of the change.

While human review and approval remain essential, automation acts as a powerful assistant to eliminate tedious, repetitive tasks and increase overall efficiency.

5. Intelligent

This is the future of labeling and artwork management. AI-powered assistants enhance every step—from translation and compliance checks to artwork creation and print readiness. Like automation, these tools support human teams, optimizing quality and speed without removing the critical oversight required in a regulated environment.

Overall, with the Artwork Management Digital Maturity Model, you can assess your current capabilities, identify the next steps on your journey, and create a roadmap toward smarter, more agile labeling and artwork management.

Determine Your Goals

Now it's time to envision attainable goals for your organization. Consider the advantages of the following categories:



Reduced Risk

- Consistent content across all outputs through content re-use.
- Elimination of copy/paste.
- Single source of truth for base & translated content.



Operational Efficiencies

- Instant impact assessments when a change is needed.
- Reduced cycle times, faster speed to market.
- Visibility into jobs in progress.



Flexible & Scalable

- Meet regional and product specific processes with configuration.
- Manage highly complex process flows for content relationships (mutually recognized, etc.)
- Easy to adjust schedules, reassign tasks, add process steps and remain compliant.



Regulatory Compliance & Traceability

- Maintain compliance with EU Annex 11 and US Title 21 CFR Part 11.
- Operate in cGMP-compliant (current Good Manufacturing Practices) environments.
- Maintain compliance with multiple regulatory bodies to support localization and requirements such as IDMP.

What Savings to Expect at Each Stage of the Artwork Management Digital Maturity Model



Once you've identified where your organization sits today on the Artwork Management Digital Maturity Model and where you'd like to go, it's helpful to understand the potential impact at each step forward. These insights will help you plan for and build a compelling business case.

Esko has identified three core areas of improvement that organizations typically experience as they progress through the model:



Operational Efficiency



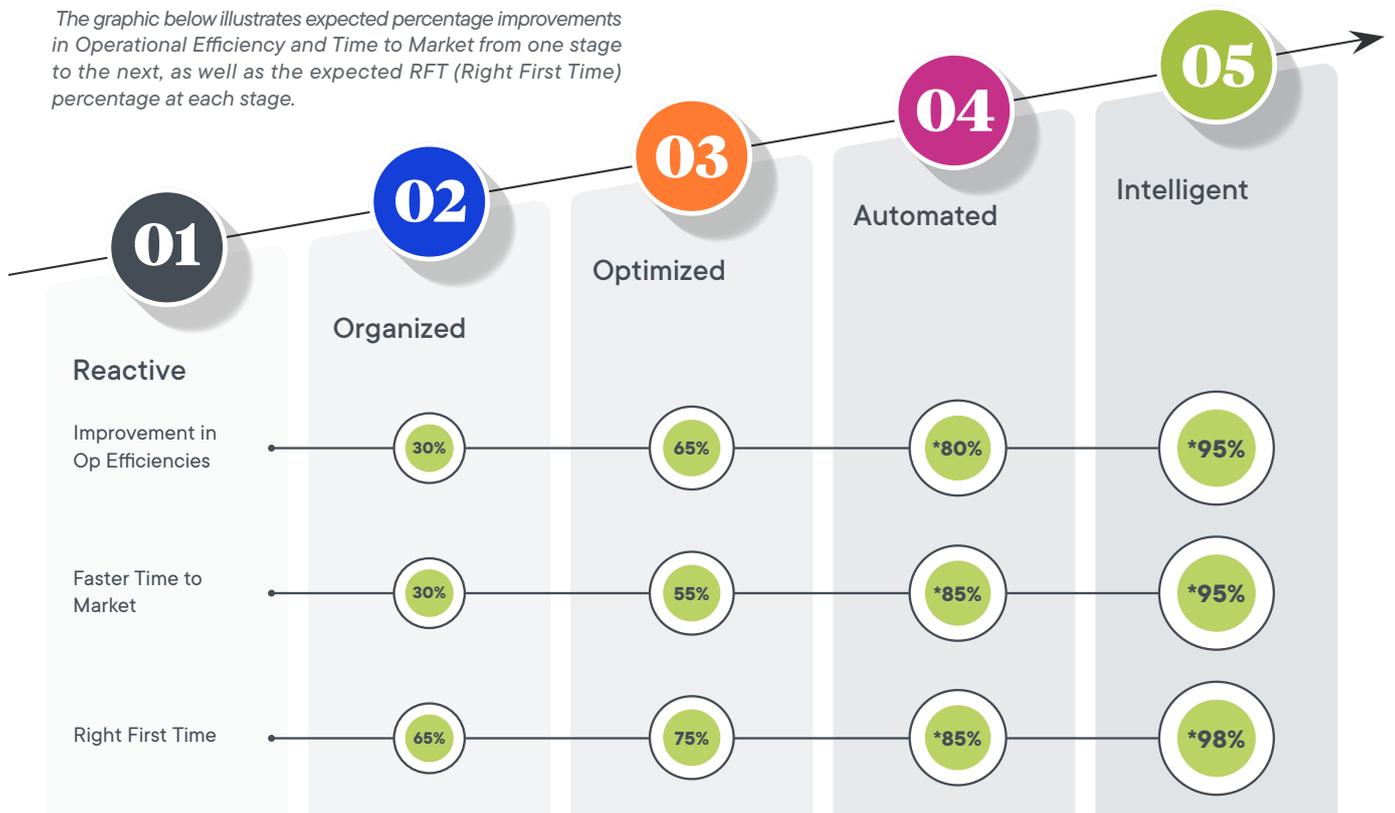
Time to Market



Right First Time (RFT)

Based on decades of experience and direct input from our customers, we've benchmarked average improvements between each stage. For the more advanced stages—Automated and Intelligent—where adoption is still growing, we've included projected targets based on emerging trends and pilot programs.

The graphic below illustrates expected percentage improvements in Operational Efficiency and Time to Market from one stage to the next, as well as the expected RFT (Right First Time) percentage at each stage.





How to Build a Business Case

You may already see the value in label and artwork process improvement, but your belief alone won't secure budget—you'll need data, insight, and alignment with business strategy to bring stakeholders on board.

Here's how to start creating your business case:

1. Analyze Your Current State

Start by collecting baseline metrics that show how your organization currently performs:

- How long does it take to complete an impact assessment for a labeling change?
- How often are project briefs sent back for clarification?
- How much time does an artwork change take—from request to print-ready?
- How much project management time is required per artwork change?
- What is your Right First Time (RFT) rate for artwork?
- How many review cycles does an artwork project typically go through?
- How long does the artwork review process take?
- What are the most common reasons for rejections?
- Have you had any CAPAs or recalls due to labeling in the last 2 years? What were the causes and impact?

These insights will help you identify the most urgent pain points and shape your business case around measurable improvement opportunities.

2. Explore Your Options

Speak with peers, attend industry events, and research how other life sciences companies are addressing similar challenges. Talk to solution providers who specialize in labeling and artwork management—many can share use cases and performance benchmarks that support your case. These conversations will also help you understand the likely costs and timelines involved.

3. Consider the “Do-Nothing” Scenario

Executives often ask, “What happens if we don't do anything?” This is your opportunity to highlight the risks and costs of maintaining the status quo.

Ask questions like:

- What if a change is missed on a leaflet or label?
- What if two versions of the same product contain inconsistent content?
- What if a product launch is delayed because labeling wasn't ready in time?
- What if our portfolio suddenly grows through acquisition and can't be managed manually?

These are real risks—especially in a regulated environment—and they help demonstrate the business value of proactive change.

4. Link to Strategic Initiatives

Align your business case with the company's broader goals. Here are a few examples of initiatives that labeling and artwork process improvement can support:



Speed to Market

Faster labeling processes lead to faster launches. In pharma, every day not delayed can mean additional revenue and patient access.



Continuous Improvement

Each stage of the maturity model unlocks new areas for improvement. With the right tools and reporting, you can analyze vendor performance, track KPIs, and optimize over time.



Digital Transformation

Every advancement along the model is a step toward enterprise-wide digital transformation.



Standardized Processes and Systems

By centralizing content and streamlining workflows, you break down silos and support a more consistent, integrated IT and data landscape.



Sustainability

Going digital means fewer paper documents, fewer revision cycles, and less waste—reducing your environmental footprint while improving efficiency.



Even if you can't assign a direct dollar value to each of these benefits, aligning with your company's strategic direction adds credibility and long-term value to your proposal.

A good business case connects operational pain points to measurable outcomes and aligns them with strategic business goals

Failing to act may result in:

- Increased rework and timeline delays
- Excessive translation cycles
- Reduced patient safety
- Product recalls
- Damage to brand reputation

But with the right tools, process improvements, and long-term vision, you can reduce risk, increase efficiency, and set your organization up for success.

Choose an Experienced Partner



Ensure your chosen software partner has an in-house global implementation team highly experienced in configuring and deploying the system to meet your needs. Thought should be given to:

- Track record of on-time, on-budget delivery.
- Extensive experience in validation for highly regulated environments.
- History of successfully completing supplier qualification audits.
- Stringent implementation methodology-based industry best practices.
- Defined RACI for the customer's team and the software partner's team.
- Extensive validation documentation package.
- A validation plan for initial services and ongoing change control procedures for maintaining the system in a validated state.
- Options to contract on-site administrators from the software partner.
- Ensure your partner has a methodology for meeting CFR Part 11.



Meet the Needs of Your IT Department

Your chosen partner must also provide authentication and security. Focus on reliability, security, and ease of use, including:

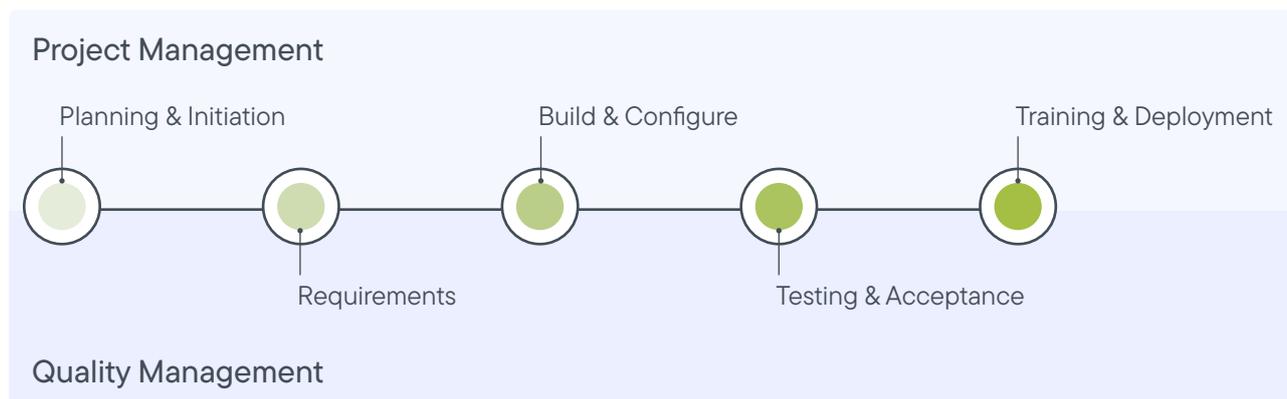
- 99% uptime
- Daily backups and disaster recovery site included
- Annual disaster recovery testing
- Highly redundant/fault-tolerant system
- SSAE 16 Certified
- 128-bit SSL encryption for 100% of all web traffic
- Roles-based security model
- Secured 3rd party access (for agencies, vendors, printers, etc.)
- Intrusion detection systems
- Extensive physical security
- Dedicated and expert support staff
- No hardware to purchase and support internally
- Utilizes Industry Standard, SAML 2.0 protocol
- Single sign-on enables users to use their company username and password to log in to the system



What to Expect in a Validated Implementation

The Esko System Implementation Life Cycle (SILC) methodology governs the implementation of software solutions using a multi-step process from planning and initiation through analysis, build, testing, training, deployment, and ongoing account management. Validation Services are embedded within our implementation methodology.

5 Phases of Implementation



CASE STUDY

Getting it Right the First Time

Top 20 Global Pharma Increases RFT from 50% to 80%

Company Type	Leading European pharmaceutical manufacturer
Challenge	The company relied on a legacy, homegrown artwork management system that lacked integration, traceability, and external access. With obsolescence looming, they urgently needed a fully validated, scalable solution to support global operations.
Solution	Esko implemented a fully validated, pan-European artwork management platform with SAP integration, end-to-end traceability, and digital asset management capabilities. Validation included IQ, OQ, and PQ documentation.
Result	<ul style="list-style-type: none"> • Right First Time increased from 50% → 80% • On-time completion rate increased from 19% → 66% • 25,000+ projects completed annually • 1,900+ global users, 615,000+ assets in DAL

"Esko became our global controlled repository, not just for packaging files, but also for SOPs and secured third-party documentation."

– EMEA Artwork Business Lead

CASE STUDY

Esko & SAP – A Powerful Connection



Global Pharma Eliminates Risk with Full Integration

Company Type	Global pharmaceutical manufacturer
Challenge	The company's ERP (SAP ECC6) and artwork systems operated separately, requiring manual coordination. This increased the risk of out-of-date data, obsolete artwork, and planning errors across the supply chain.
Solution	Using Esko Connect, Esko and SAP were fully integrated. Artwork workflows are now automatically triggered from SAP, with bi-directional data flow that ensures synchronization and eliminates manual entry.
Result	<ul style="list-style-type: none">• End-to-end visibility between artwork and supply chain• Improved forecasting accuracy• Reduced risk of stock-outs and labeling errors• Automated data transfer and approval processes

"The integration streamlined operations and provided real business value, particularly in keeping our Packaging BOM data accurate."

– Head of Artwork & Technical Operations

CASE STUDY

Organizing the Packaging Process

Global Animal Health Division Goes Digital

Company Type	Animal health division of a global pharmaceutical leader
Challenge	The team lacked a centralized system for managing packaging assets and approvals, often relying on overnight mail and disconnected workflows. Managers struggled with visibility, timelines, and asset reuse.
Solution	Esko implemented its Digital Asset Library (DAL) and Workflow platform, providing centralized access for internal teams and external partners, along with digitized approvals and electronic signatures.
Result	<ul style="list-style-type: none">• 1,300+ projects completed annually• 3,000+ components managed• 500+ active users in 60 countries• Significant time and cost savings

Take the Next Step

Want results like these?

Let's talk about how Esko can support your digital labeling and artwork transformation.

Contact us today!

"We now have one source of truth for all assets and approvals—Esko helps us maintain accuracy and meet in-market deadlines."

– Manager, Printed Packaging Material Development & Control