THE
PHOENIX GROUP
OF COMPANIES

Guide

Pharmaceutical Printing and Data Integrity 101

What's Inside

① Learn what data integrity is

② Explore common errors in pharmaceutical printing

③ Get tips on how to reduce your data integrity risk

The Importance of High-Quality Pharmaceutical Printing

For companies in the pharmaceutical industry, marketing can be particularly challenging, especially when it comes to printed packaging and promotional pieces. Pharmaceutical packaging, labels, and inserts all must be one hundred percent accurate and clearly legible, or patient outcomes and brand equity could be adversely impacted.

To ensure that their pharmaceutical printing is accurate and error-free, companies need to be cognizant of:

- Data integrity

- Associated data risks

- Regulatory changes

- Potential compliance issues

All of these challenges only reinforce the importance of working with a print vendor who specializes in high-quality pharmaceutical printing.

Learn more about the importance of data integrity and high-quality pharmaceutical printing, common printing errors, and how to reduce your data integrity risk in this eBook.

Contents

What Is Data Integrity?

The term data integrity refers to the degree to which data is accurate, complete, and consistent over its entire lifecycle. For data to retain its integrity, it must not be corrupted in any way, making data security a top priority.

Data integrity can be compromised in a few different ways. Think about how often files are transferred or replicated throughout their lifecycle—each time, the data within could be corrupted or compromised either intentionally or unintentionally. It can also be compromised by things like bugs, computer viruses, hackers, and even device or hardware crashes.

To ensure data maintains its consistency throughout the entire lifecycle, it is critical to keep it secure. However, **data integrity is not data security**. There are many different processes necessary for maintaining data integrity, and data security—and its systems, processes, and procedures—is only one of them.

In highly regulated industries like the pharmaceutical industry, maintaining data integrity is critical to maintaining regulatory compliance. The U.S. Food and Drug Administration (FDA) defines good data integrity practices with the acronym ALCOA+.

To follow the FDA's good data integrity practices, data must be:

Attributable:

Data must be able to be traced back to the person or entity who generated it.

Legible:

Data must be permanently recorded and easy to read.

Contemporaneous:

Data must be recorded at the time of execution and as observed.

Original:

The source data must be preserved in its original format.

Accurate:

Data must be complete, truthful, and free of errors.

Complete:

To be considered complete, no deletions of data must have taken place from the date of documentation.

Consistent:

Throughout its lifecycle, data must remain consistent.

Enduring:

Data or information must be maintained throughout its entire lifecycle.

Available:

Data must be accessible throughout its entire lifecycle.

At the Phoenix Group, we go to extra lengths to establish advanced quality control procedures, like the use of unique scanning and inspection technology to ensure data to print integrity.

Typical Errors in Pharmaceutical Printing

Flawless labeling and packaging are both key to the success of pharmaceutical companies, however, mistakes can still occur when proper proofreading and quality assurance processes aren't in place. Here are some of most typical errors found in pharmaceutical printing.

Incorrect Packaging Information

Incorrect packaging information, such as a label or brochure featuring an improper dosage or dosing schedule, can put the safety of patients at risk. **Even so much as an additional zero or a misplaced decimal point can have dire consequences**. In the instance of errors like this, there can be serious long-term repercussions for the pharmaceutical company.

Recalls are costly—but having to recall a product in addition to rebuilding trust with consumers is even costlier. However, even with the awareness that such mistakes could be hugely damaging to a company, these mistakes still happen every so often. Only with a proven, trusted proofreading process are they avoidable.

Lost in Translation

Whenever pharmaceutical companies sell to foreign countries, there's always a risk of losing important information in the translation process. Often, third-party companies are in charge of translating pharmaceutical packaging content. They may not always have all of the information or context necessary to complete the translation, which can result in errors.

After it's been translated, the content is sent back to the pharmaceutical company and may be proofread by an employee who isn't a translation specialist, allowing the original errors to make it to the printer—and sometimes, even to the market itself.

Color or Artwork Issues

Throughout both the design and printing processes, there a number of different problems that can occur. Artwork can be designed or exported incorrectly for printing, colors can be off, fonts can be imported incorrectly or not at all, and other various issues can impact the finished product, perceptions of quality, and the company's reputation and brand equity.

If enough issues arise, costly recalls may even be necessary.

How to Reduce Your Data Integrity Risk

For companies like those in the pharmaceutical industry that are consistently using data and relying on data-driven processes, learning about data integrity and how to reduce the accompanying risk is imperative.

To reduce your data integrity risk and ensure that your data remains reliable, you need to think proactively and implement some strategic initiatives like those we've illustrated below.

Foster a Culture of Integrity

Reducing your company's data integrity risk starts by fostering a culture of integrity. In an integrity-focused culture, your employees will be honest when mistakes are made and will work together to make sure that instances of improper data use and shortcuts are reported to the necessary department or personnel.

In addition to making culture changes, employees must also be trained adequately so they can perform their jobs successfully. Documenting the training process and providing training records can also serve as proof of following proper protocols.

Utilize Quality Control Measures

Data integrity quality control measures refer to specific processes that are put into place to confirm that all employees are working with data according to company security and data governance policies. The verification process can involve people within your organization as well. IT personnel and data stewards can both help to ensure that internal processes are being followed.

Validate Your Computer Systems

You can plan out and dictate what's meant to happen with data, but unless you regularly test and validate your computer systems and IT infrastructure, you won't know for sure that everything is functioning as it's supposed to and meeting quality standards. Working with IT and cybersecurity vendors who can provide validation is an easy way to make sure that it is.

Employ Audit Trails

Audit trails are an effective tool for reducing data integrity risk. Computer-generated audit trails will record the identity, date, and time of data entries, as well as any changes or deletions. They enable a trustworthy data file, provide proof of ownership, and help guarantee that the data has not been modified in any way or deleted. Having this information available can also make it easier to maintain regulatory compliance.

Implement Error Detection Software

Due to the nature of pharmaceutical printing, error-free files and accurate documents are a necessity, and manual proofreading often isn't thorough enough to guarantee this. Using an automated proofreading software can help verify critical components such as barcodes and guarantee that copy and other text elements are free of errors and potentially detrimental typos. Some proofreading and error detection software can even detect inaccuracies in images and fonts too.
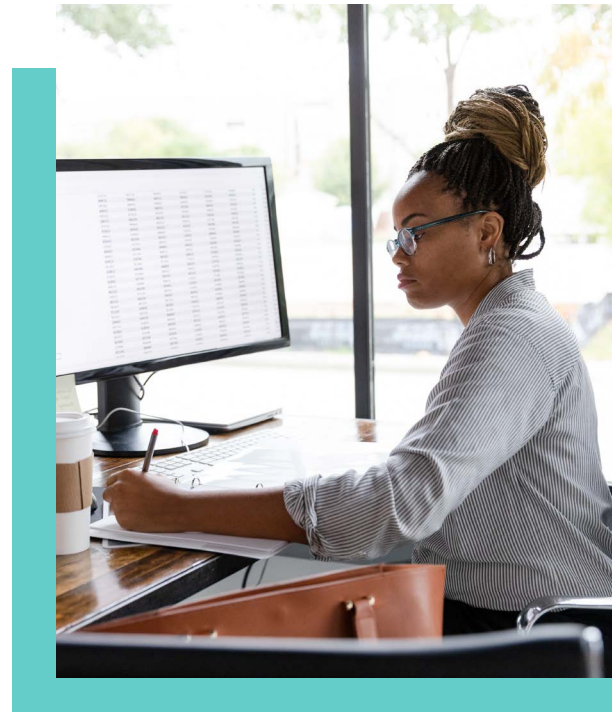
Maintain Existing Backup and Recovery Procedures

Since some data integrity risk lies within device, hardware, or application malfunctions, it's necessary to ensure that you're maintaining your existing backup and recovery procedures. Data could be lost due to a malfunction or error at any time, and not backing up your devices and systems can make the recovery and reconstruction process difficult—and sometimes even impossible.

Benefits of Working with a Trusted Pharmaceutical Printer

Only a trusted pharmaceutical printing partner like the Phoenix Group will understand the intricacies of printing for the pharmaceutical industry. When a print vendor recognizes how critical their role is to the success of your company, they will work closely with you to meet your needs, and you'll benefit as a result.

Here are a few of the benefits of working with a trusted pharmaceutical printing partner:

Guaranteed Data (and File) Integrity

A trusted pharmaceutical printing partner will have adequate systems and processes in place to ensure that all data and files maintain full integrity throughout their lifecycle. Whether they utilize an automated proofreading process or implement another type of error detection software, trusted print vendors will be capable of protecting your company from serious risks like product recalls, expensive, time-consuming reprints, and reputation-damaging complaints.

The Proof Perfect™ Process

Proof Perfect™ is the standard of quality and accuracy that we set for print solutions at the Phoenix Group. Through our suite of advanced quality control processes, content verification, and inspection technology, the Proof Perfect™ standard ensures complete file integrity for all products from proof to plate to print. Each project, whether electronic, hard proof, or printed piece, is checked using multiple digital scanning and content verification stations at every stage—proofing, plate making, and off the press—before the full job goes to print. Our Proof Perfect™ process catches even the smallest of anomalies and imperfections—including those that are easily missed by human visual inspection.

With these advanced quality control processes in place, trusted pharmaceutical printing partners like the Phoenix Group can help you protect patients from receiving incorrect product information as a result of data, file, or printing errors.

Improved Regulatory Compliance

A print vendor that fails to have defined validation systems and quality assurance processes in place can have a significant impact on your business. From noncompliance fines to reputation damage or even jeopardized patient safety, the risks are great. Working with a pharma print vendor that takes data quality and data security seriously will help ensure that each piece produced meets government compliance guidelines.

Effortless Version Control

Throughout a file's lifecycle, new versions are created constantly—and keeping on top of them can be difficult, especially with often-updated pieces like product information booklets. Pharmaceutical print vendors you can trust have the ability to inspect content at every stage of the process and detect errors and changes that crop up from one version to another.

Ability to Print On Demand

Some print vendors even have the ability to print on-demand, which, in a volatile industry like pharma, can be hugely beneficial. This ability may come with a slightly higher cost per unit, but it can easily be offset by not having obsolete materials. Printing on demand also enables you to target your marketing even further by personalizing it.

Faster Go-To-Market

In the pharmaceutical industry, short go-to-market timelines are critical. When you work with a print vendor like the Phoenix Group where everything is in one place and time-consuming processes like proofreading have been automated, your go-to-market time improves, making important objectives like new product launches and meeting existing deadlines a breeze.

Make the Impossible Possible with the Phoenix Group

At the Phoenix Group, we pride ourselves on being able to make the impossible possible. Our advanced technology, systems, and suite of equipment enable our teams to ensure the consistent packaging and labeling of every job, no matter how large or small.

Do You Have a Pharmaceutical Printing Partner You Can Trust?

The importance of data integrity in pharmaceutical printing can't be overstated. Corrupt or compromised data can have significant, long-lasting effects on pharmaceutical companies both large and small that can be difficult to recover from. However, when you start to think of pharmaceutical printing and data integrity as intertwined, maintaining data integrity, reducing its associated risk, and achieving a high-quality finished print product is stress-free.

**Looking to learn more about data integrity?
Need a new printing partner?**

Contact the Phoenix Group to learn about our solutions for pharmaceutical printing.

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Sources

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- 5 Common Errors in Pharmaceutical Labelling (and How to Avoid Them)
- Guidance on Good Data and Record Management Practices
- What is Data Integrity? Definition, Best Practices & More
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- 8 Ways to Reduce Data Integrity Risk