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# Digital Transformation Solutions: Why and How to Go Paperless

## Introduction

Now more than ever, companies are turning to digital solutions for day-to-day business. For a medical device developer, that can mean uprooting a 20-year-old process that they trust. However, it's become apparent that moving from a manual process to digital platform can help a company survive unpredictable global events.

Such a transformation is a big one, and it may be difficult to choose whether to make a permanent shift to digital. This white paper will help you understand the benefits, obstacles, and strategies to creating a digital transformation solution.

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## Why Make The Move to Digital

While many companies have now been forced to work with remote teams, crisis is not the ideal reason to move to the digital space. Companies can benefit tremendously by taking advantage of modern business practices. Here is why:

### BUSINESS CONTINUITY

Established companies often depend on institutional knowledge for daily tasks. Someone there just knows how to perform a critical operation. Should that someone abruptly leave the company, key information leaves with that person. Suddenly no one knows how to do or where to find certain things.

Paper processes present the same danger. Files and papers can get lost, or worse, destroyed. Storing data and processes within a digital tool keeps important information reliably accessible.

### EASY ACCOUNTABILITY

Using Word to track information forces you to print off pages to have them physically signed, and also necessitates a physical filing system. Important documents are then vulnerable to being misplaced or given to the wrong person — which means spending valuable, if not frustrating, time figuring out where they went. Digital tools automatically track the critical information of who did what, and when they did it.

### DEPENDABLE ACCESS

We now know that there are unpredictable issues that can threaten attendance at meetings and conferences, requiring organizations of all types to rely on digital materials to share information. With digital solutions, your meetings, presentations, and daily business activities can be performed remotely — in most cases without disruption.

### SPEED OF DELIVERY

Taking the time to manually compile reports, track requirements, share data, or create a traceability matrix slows down your process. Digital tools can slash the time it takes to generate critical data, thereby moving your process along more quickly and improving your business as a whole.

## The Challenges to Transformation

While digital solutions do make it easier to complete your work, shifting your entire workflow to a new tool is a challenge. Here are the primary concerns of transitioning your manual practices to a digital solution:

### CHANGE OF PROCESS

Your workflow's architecture will be a barrier if you don't have tools that align with it. If people have been doing things one way for 20 years and are good at doing it that way, there has to be an incentive for them to move to a digital platform. Changing SOPs, updating processes, and other fundamental shifts can cause a lot of friction. And it can take months or even years to iron everything out as you marry your desired process with any tool.

### MAINTAINING HISTORY

When you switch to digital, you have to decide where to keep your historical data. Do you import or scan it into the new system, or do you archive it and start clean? The former is time consuming. The latter puts people in a position where they're working on version three in a new digital tool, but versions one and two are stored in an old filing cabinet where they can't be easily referenced. Deciding what to do with that historical data is not an easy decision.

### TRUSTING THE TOOL

When you depend on a new tool to have your back when you file a submission to the FDA, you need to be able to trust that process. Using a new tool puts your company's lifeblood on the line.

## How to Overcome the Obstacles to Change

Despite the valid concerns in making such a huge change, there are strategies you can employ to help make the transition a success. This is still true if your teams were forced to work remotely and struggled to adapt.

### PILOTING — LAND AND EXPAND

Whether it's piloting certain tools to integrate into an already-remote workforce or implementing remote capabilities for a team that's in the office, you'll find better success if you assemble the proper team to work out the kinks first.

It's important to get the right people on the pilot team if you want it to go well. About 10% of people are early adopters who want to make change happen. They like the challenge of solving the problem. They consider it a good professional opportunity. These are your internal champions.

When this 10% is successful and excited, it can get the next 10% on board. When 20% of your people are working the program well, it proliferates.

This is how to create your team of internal champions:

1. Find the people who want to be invested. Make it exclusive, so it's not open to everyone. If possible, put a barrier into applying to the pilot program. They'll have already sunk cost of saying yes when they went through the trouble of applying to be part of the pilot.

2. Ensure that everyone on the team also has the bandwidth to take on the project.

3. Open it to system experts, process experts, and people who've gone through the mud to help them out. They best understand the kinds of obstacles the rest of the team will encounter.

### TAKE TIME TO FIND THE RIGHT TOOL(S)

If you don't find the right tool for your team, failure is more likely. There are three boxes your new tool should check before you move forward with it:

1. It should be flexible enough to closely match your SOPs. You shouldn't need to restructure your company to fit the tool. Your team won't use it. The tool should be able to match 90% of the way you work and facilitate your process maturing to accommodate a tailored, hybrid approach that evolves with your team.

2. Your new solution should support the way you've chosen to handle historical data. If you want to integrate that data into your digital platform, choose one that makes it easy for you.

3. Ensure that the new tool is proven in your industry. This solves the issue of trust we discussed earlier. When you do your research, look for case studies about the prospective solutions being used in your field.

## Make Digital Easier With Helix ALM

One tool that's trusted in the medical device industry is Helix ALM, the modular application lifecycle management tool that simplifies the management of test cases, issues, and requirements. This solution provides scalable traceability for companies developing complex, high-quality products. Our highly configurable platform supports all product development methodologies, enterprise organizations, and development within regulated industries.

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