The War on Paper: A Corrective Action Plan for Going Paperless
We’re all familiar with the maxim “if it’s not broken, why fix it?” Practical. Pragmatic. Proven. Particularly when you’re operating in a highly regulated, process-driven environment.

But what happens when working well and delivering at a consistent standard is no longer good enough? This is the question facing executives across every industry as they weigh the pros and cons of upending decades of operational excellence practices and rigorous quality controls in order to better capitalize on the promise of digital transformation.

After all, digital transformation initiatives often feel overly ambitious, poorly defined and years away from having meaningful impact. So why disrupt the status quo? Why invest in going all-in on digital?
According to Dr. Amy Abernethy at Flatiron Health, a subsidiary of Roche – “About 50 percent, if not more, of the critical details we need for research are trapped in unstructured documents. They are in PDFs. Maybe a doctor put in a note by hand, maybe a doctor typed it. That note became a narrative. It is not something that can easily be put into a spreadsheet.”

New Cancer Treatments Lie Hidden Under Mountains of Paperwork, New York Times
That's a startling assertion –

Yet many professionals running clinical trials – or for that matter professionals that design and manage the processes essential to regulatory, quality, supplier and manufacturing operations – likely believe they have practices in place that “work.”

Standardized processes refined over years may not make Silicon Valley headlines, or utilize cutting-edge technology, but they are viewed as established and effective approaches to minimizing risk.

So, why fix them?
“Interconnect[edness] within the life sciences [is] accelerating....one of the most important factors driving this change will be the exchange of information between stakeholders – from patient data, R&D, and production through communication between suppliers, insurers, doctors and other key influencers. The digitalization of these processes and the exchange of data will be key.”

Digitalization in Life Sciences, KPMG
Although eliminating paper processes has been an ongoing mantra for years, recent data shows these initiatives are often unfunded or poorly adopted. Consequently, many clinical, quality and manufacturing professionals still use paper-based or hybrid solutions utilizing Microsoft Word and Excel.

According to LNS research, only 7 percent of the market have automated design transfer, while the majority use spreadsheets and documents. Much of the market has yet to take advantage of automated workflows and portals, and in fact, only 21 percent have adopted a core enterprise quality management system (EQMS).
Chronic Paper Dependence Is Killing Innovation.
“The three biggest challenges for more than 80 percent of companies are the lack of digital competencies, employee acceptance, and approved budgets for the digital transformation.”

“CIOs need to develop a sensitivity for human behavior and desires, and prepare an adaptable technology ecosystem that can respond.”
If the connective benefits are so great, why is going paperless not happening on a larger scale?

First, people are inherently averse to change.

This predisposition is heightened within environments with very high-risk profiles. If you’re conditioned to operate in a highly risk-averse environment, moments of change are by definition events you seek to minimize.

“Move fast and break things” is never going to be the guiding principle of a quality- or regulatory-focused organization. After all, continuous improvement practices have reliably demonstrated that small incremental changes, not major paradigm shifts, ensure quality.

Second, people use what is available.

Organizations already have Microsoft or Google suites that are accessible by every employee in every department. Neither requires specialized training. And, it’s nearly impossible to find anyone that doesn’t have the skillset or experience needed to use them.

Then, there’s a subconscious fear that technology – particularly technologies that automate and accelerate traditional processes – is the leading edge of replacing people. Let’s call it what it is – self-preservation. It’s natural. It’s powerful.
“Automation stokes fears that machines will take people’s jobs. But...experience suggests that many of the tasks being automated are activities people tend not to want to undertake, such as spending half the day pulling and loading data. Or they are tasks for which small automation can actually improve people’s performance – for instance, by introducing predictive algorithms that help them make better decisions and free up their time for more rewarding, interesting, and higher-value-add activities.”
We all know change is hard.

*We know new approaches or technologies can cause initial disruption.*

Yet this mindset is what may be holding life science and other regulated and
compliance-sensitive organizations back, preventing them from capitalizing on
truly exceptional opportunities that unlock a wealth of data-driven insights.
Insights that help you not only reduce errors and drive efficiencies, but also
accelerate innovation and bring more life-changing products to market sooner.
Say Goodbye to Your Paper-Based Processes.
In a highly connected, digital environment the flow of information across departments and workflows creates exponential value exchanges that will fundamentally change the way we work. It will also create greater connectivity and intelligence across every stage of the product development lifecycle – from concept to commercialization.

Replacing paper-based and hybrid processes with fully digital, automated systems is not a straight one-to-one value exchange – i.e., simply replacing one medium with another.
“New and unprecedented value is now available from the data unleashed from a growing list of sources: wearables, sensors, devices, social media tools and electronic records. Data generated by processes that stretch across R&D and manufacturing, supply chain and patient aftercare needs to be collected, stored, sifted and mined for meaning. For many companies, this calls for strengthening master data management architectures and strategies.”

According to Cognizant it’s this type of connectivity and data flow that’s transformational.
This “platform effect” is driving progressive organizations to digitize.

In the process, these organizations automate the discrete design, clinical, regulatory, quality, supplier, manufacturing and postmarket processes as they consider integrating critical systems. This means looking at ways to connect disparate solutions, such as clinical trial management systems (CTMS), regulatory information management (RIM), and quality management systems (QMS), on a single platform to facilitate fluid data and information exchanges.

Beyond future innovations and efficiencies, complacency with the status quo carries additional costs. The data stored in PDFs or spreadsheets reinforce silos and obscure data-driven insights, creating blind spots across organizations. This inhibits operational improvements, increases risk and makes it difficult to identify root causes and remediate. Which is why leading regulatory agencies are making it clear that the time for change is now.

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Two recent Deloitte reports highlight how regulators, such as the FDA, are pushing companies to conduct data-driven investigations and prove resolution with a data trail:

“This can be achieved with quality management system transformation or integrating a digitized quality management system into a digital supply network, starting with R&D and carrying through to product design, manufacturing, and service. Big data and analytics will be key enablers in unlocking the potential of disparate data and should improve the ability of companies to identify and quantify new and emerging compliance risks.”

“In the future, companies could be expected to provide their own metrics on internal processes and outcomes, and the FDA may mandate and evaluate those metrics to decide which companies pose the highest risk and warrant inspection. To date, many of the inspection site warnings have been associated with data integrity and human error.”
A Smarter, Faster and Smaller Approach.
To change behavior people often have to experience the benefits firsthand.

While a full digitization implementation feels daunting, a paperless pilot in a specific department or function helps provide the evidence people seek.
“A manufacturer used a paper-based system for maintaining device history records (DHRs)....Based on the amount of...data manually collected throughout the process, there were nearly 100 opportunities for documentation errors every day.

[When] the manufacturer replaced this paper-based system with a closed-loop manufacturing execution system[,] this system enabled faster detection and prevention of problems and improved investigations through greater speed and visibility in finding and correcting root causes.

The system likewise improved data consistency across plants and the supply chain and deployed dashboards for key metrics, enabling continuous improvement. [Results: A] productivity improvement of 6 to 10 percent and significant reductions in key performance indicators (KPIs) [such as] production noncompliance reports (41 percent decrease), overall complaints (58 percent decrease), workmanship complaints (65 percent decrease), and documentation errors (100 percent decrease).”

The results from a manufacturer implementing a closed-loop manufacturing execution system.

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This is a perfect example of how digital transformation can be initiated through an approach called “small automation,” in which organizations focus on fast implementation of flexible and adaptable technologies that fill the gaps left by current enterprise systems.

“The potential impact is striking: Small automation can improve the productivity of individual processes by 80 to 100 percent (the top of the range reflects a transition to a touchless solution) and overall functions by 20 percent or more.”

The New Automation Is Smart, Fast, and Small, Strategy + Business
Ultimately, focus on smaller, faster and smarter approaches.

Doing this to replace paper-based and hybrid processes delivers greater time-to-value, minimizes the disruption to operations and perhaps most importantly – eases the behavioral and cognitive barriers that make people resistant to trying something new.
At MasterControl, we’re passionate about quality. Our Quality Remastered series has been designed to help quality-centric professionals re-master their quality and compliance processes for the digital era. Each installment provides insights, strategies and best practices to help you implement the digital elements needed today to thrive tomorrow.

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