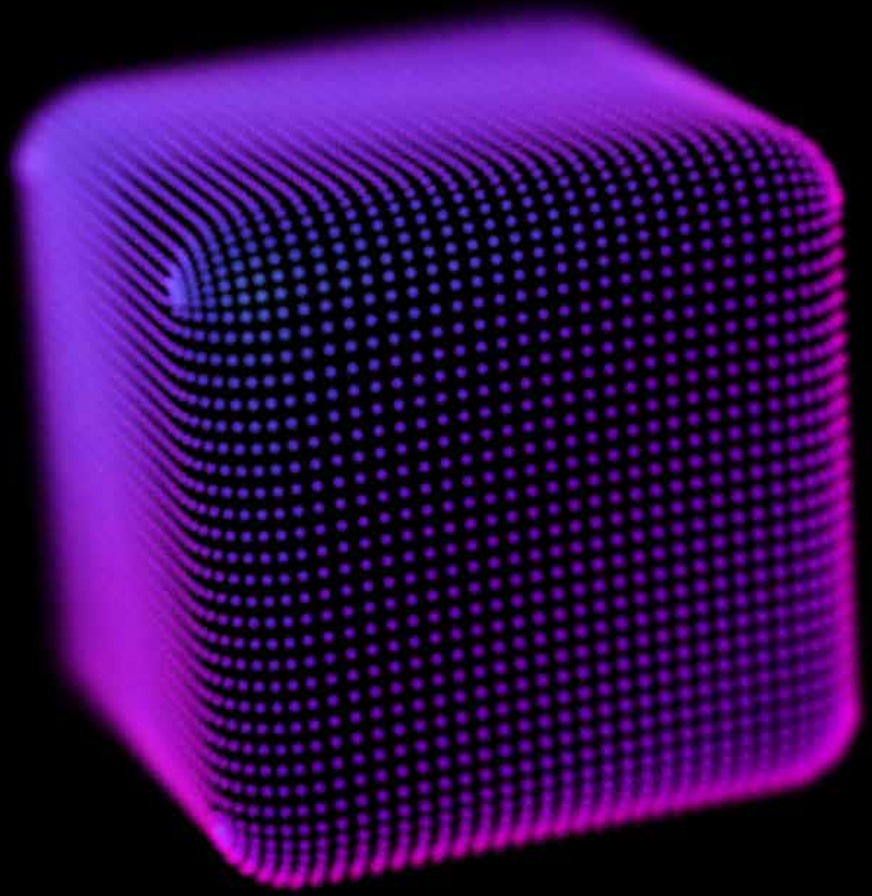
MasterControl™

Quality Remastered

Insights to help you thrive in the Digital Era

Architecting for Change: Embracing a Platform Approach



Digitize. Modernize. Elevate.

If you started a business today, how would you set it up?

Chances are you wouldn't buy a fax machine, install landlines and order checks.

Embracing digital is now so instinctive, you would digitize and automate everything. You would invest in cloud-based technology that was easy to use, connect and scale.

Take BraveHeart Wireless

Launched in 2017, this startup has created a cloud-based platform for medical wearables that's leveraging cutting-edge technologies. We're talking everything from the Internet of Things to big data to predictive analytics. Founded by long-term veterans of the medical device and analytics industries, there was no hesitation when it came to their quality management system. BraveHeart Wireless went all in on digital from the onset.

And from past experience, they knew they had to build quality and compliance into the DNA of the company. From design through production, technologies and structures have been put in place that allow for iterative innovation, fast approvals and repeatable quality.

"It's part of our entire ecosystem. We're on an enormously aggressive schedule. You have to get things right, quickly. We needed to make sure we have the right tools in place so that when our partners and OEMs come in to see us and audit us, that information is available quickly and efficiently and that we're compliant in all their standards."

Steve McCalmont, founder and CEO of BraveHeart Wireless

"We're a regulated Type II medical device and because of that we have limited resources. Our tools have to be more effective. And having a framework, templates and an integrated system to get ahead immediately lets us focus on moving the ball forward."

Unfortunately, not everyone gets to start from a clean slate.

Most organizations have to contend with the challenge of “transforming” legacy technologies, old ways of working and thinking. But as digital technologies are increasingly seen as critical business needs, more and more companies are taking the bold step of initiating transformation strategies to modernize and build on digital platforms.

The goal: connect content, data and insights across their organization.

Consider the example of a med device manufacturer.

Recently spun out of a larger multinational organization, this company seized a moment of transition to modernize their entire quality life cycle by choosing to host their quality, supplier and regulatory processes on MasterControl's cloud-based platform. Why? Because this gave them the agility, speed and controlled accessibility they needed to get their processes validated and products to market faster.

These two examples showcase how companies are reacting to the opportunities building a new technology foundation — or modernizing an existing one — represent. And they are not alone.

"Even though most [life sciences] companies are still developing their digital capabilities, 58 percent say that digital is a top management priority and 79 percent expect to realize the value of digital initiatives within the next five years."

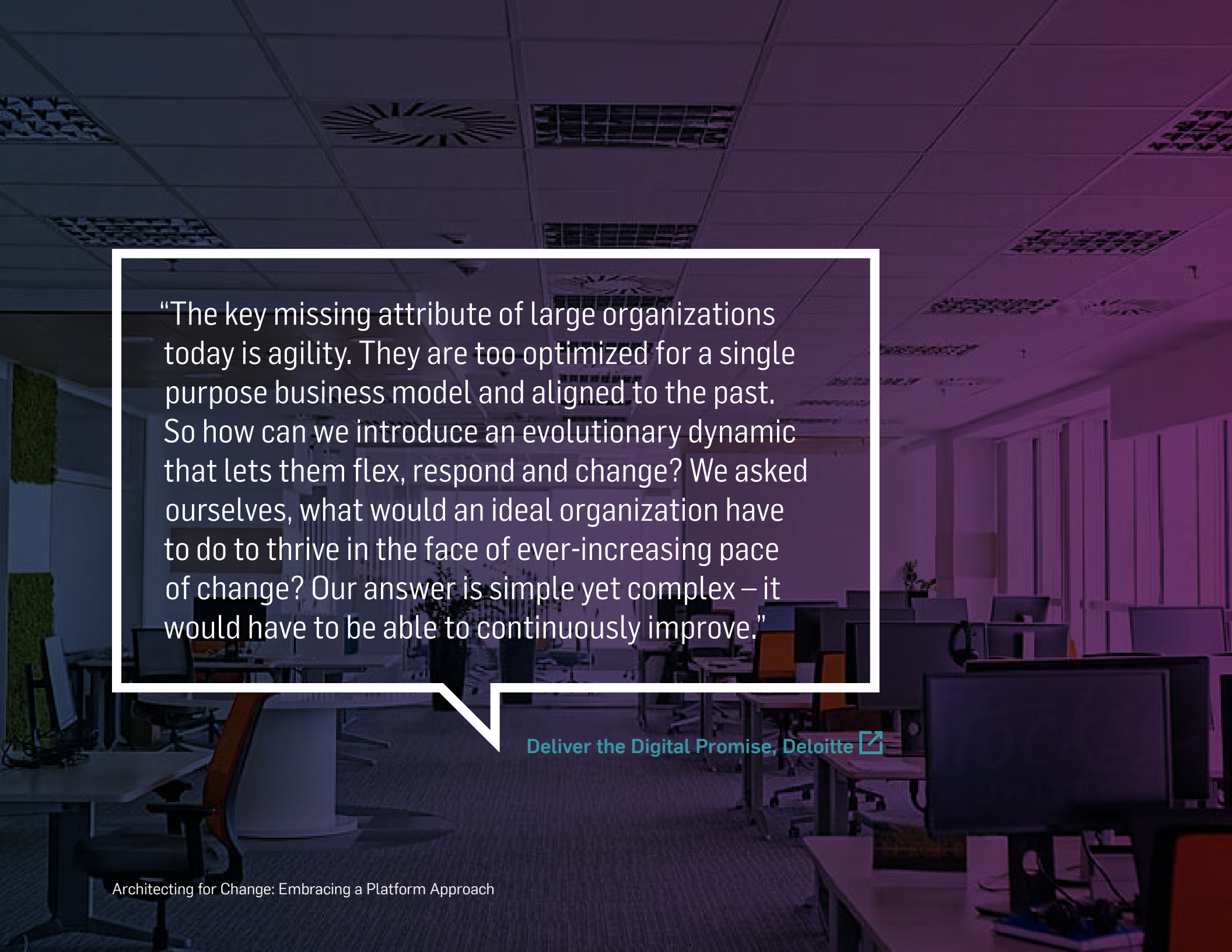
"Life sciences companies that want to move away from the tendency to treat digital initiatives as projects need to develop a digital DNA by which a company's digital activities, people, culture and structure are aligned with the organization's broad ambition."

Deloitte Insights October 2018

A modern technology foundation creates an agile ecosystem that lets you flex and adapt your business as needed.

Traditional operations and compliance processes are modernized through software, automation and connectivity. Instead of having to continuously react to issues, you're able to accelerate your predictive analytics capabilities and flag problems ahead of time. The idea of continuous improvement is real and sustainable.

When you have systems connected across a highly-scalable cloud, it's easier to free data from business silos, perform updates and install security patches. At the end of the day, it's this agility that will help accelerate processes and get products approved and to market faster.



"The key missing attribute of large organizations today is agility. They are too optimized for a single purpose business model and aligned to the past. So how can we introduce an evolutionary dynamic that lets them flex, respond and change? We asked ourselves, what would an ideal organization have to do to thrive in the face of ever-increasing pace of change? Our answer is simple yet complex – it would have to be able to continuously improve."

Deliver the Digital Promise, Deloitte

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Getting From “Yes, But” to “Let’s Go.”

For an industry that depends on life-saving discoveries, life sciences overall has been a laggard in its modernization efforts — especially when it comes to quality and compliance systems. On-premise, custom solutions or, shockingly, paper-based processes still remain the norm.

A recent PwC survey found that 66 percent of biopharmaceutical sector participants indicated that "outdated technologies" remain an existing obstacle.

Why? Going from the old to the new brings up a host of fears. "How is this change going to slow us down, impact validation efforts or FDA approvals? Will going to the cloud open us up to security breaches? Yes, we're focused on quality, but we don't have the time or resources to support this and the way we've always operated seems to work."

But here is where the narrative needs to change from focusing on maintaining the status quo to architecting for the future.

With cloud-based platforms, you can go from a state of working to maintain your systems — reacting when they break down or developing workarounds to address shortcomings — to focusing on what you do best, driving continuous improvement. In the end, it's all about how you want to utilize your resources. Do you want to be focused on constant maintenance or driving your business forward?

Would you rather have your design history and training documentation in a binder or in a cloud environment that you can access, perform real-time updates on and share within seconds? Would you rather file and receive approvals in three versus six months? Or have your audits take hours versus weeks?

Let's go back to the BraveHeart Wireless example.

As an early stage startup, they had an accelerated timetable and limited resources. They had to equip their people with tools that made them more effective "force multipliers" that literally helped them do more with less. That means the tool sets and platforms to do things right from the start — internally for validation but also externally to meet their suppliers' and partners' standards.
As these systems were implemented from the beginning, it's facilitated intuitive collaboration with their engineers. Engineers that have gained a deeper understanding of how to design and develop a product through a process that mirrors the regulatory requirements in place for approval. With a high-quality regulatory framework set in the early stages, they also know when they hit that tipping point in sales, their compliance systems will not fail them.

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Take the Right Risks Versus Follow the Right Rules.

As you know, professionals that operate in regulated environments are continually evaluating risk. It's their focus, passion and at the heart of what they do.

With today's technological advances, however, there are points of inflection where risk ratios shift. Most life sciences organizations are running legacy systems on aging technologies that are actually starting to create more risk than they remove. This can be seen in the perpetuation of dated approaches to security, configuration and validation.

With security, there is a persistent misconception that premise-based environments are more secure than cloud environments. Yet in reality, cloud-based solutions address changing threat landscapes with continual updates made by engineering teams whose sole focus is security. Compare this with on-premise environments that require your IT staff to try to stay current as part of a thousand other responsibilities.

Similar misconceptions persist with custom versus configurable software.

After decades of highly-customized forms and processes, quality and technology professionals realize that customization is holding their companies back. Why? Because broad customization inhibits the ability to update, add functionality, scale to other sites and rapidly adapt to changing business dynamics.

As a result, more and more companies are seeing the value of COTS or commercial off-the-shelf software. With COTS, 80-90 percent of the functional use cases are met out of the box, while still allowing for minor customization. COTS software is well aligned to today's business demands — enabling companies to deploy, adopt and modify solutions quickly.

Upgrades are fast and easy, bringing in added functionality and security enhancements.

"I can't tell you how many companies we work with that initially insisted on custom software, citing their very specific and unique needs and processes. In reality, the cost and complexity custom software requires to address this 'uniqueness', across locations and functions, creates a lot of ongoing headaches. Any time a new version is released, changes have to be made to the software and your software vendor has to come back in."

Matt Lowe, EVP of Product, MasterControl

Finally, there is the validation argument to overcome.

Validation is one of those institutional practices that is most resistant to change. It's the 'got ya' in regulated industries – the extra steps that accompany any decision to change processes and technologies.

But even validation is adapting to take advantage of cloud-based environments. Ironically, if you don't operate on a cloud-based platform the burden for validation is actually greater. Using risk-based validation tools, such as MasterControl's Validation Excellence Tool (VxT), you leverage what MasterControl has done to evaluate risk introduced from the updates and this serves as the basis of your validation strategy.

In addition to risk-based validation, MasterControl's solutions offer real-time validation at the manufacturing site. This means the batch record system can link to the training system and validate proper training has been completed — something both the FDA and customer audits seek out.

"We soon realized that quality management system software would give us the ability to accumulate everything in one place and fill needed gaps in our training system. It gives us real-time data and a better management feel for what's happening on the shop floor. It allows us to create management dashboards so that we can understand what's happening in products... Speed to market is a big driver for us, if we can cut a day or two out of that documentation control and review process, that's a big deal."

Tony Harnack, President & COO of Wellington Foods

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The Costs of Inaction.

"Legacy systems hinder connectivity, limiting access to data and insight for innovation. The large monetary outlays these systems require divert funds away from new technology investments that fuel future growth."

Beneath the Surface of Digital Transformation

More than 10 years ago, Gartner Inc. reported that 60-80 percent of IT budgets were spent to literally keep the lights on.

A 2017 American Council for Technology and Industry Advisory Council (ACT-IAC) report found legacy systems across federal agencies consume around 75 percent of operations and maintenance funding, going up to as much as 90 percent at certain agencies. That's a lot of time and resources spent maintaining systems that will continue to become more and more out of date as time goes on.

Often when presented with the benefits of the cloud, the argument is made that you'll be shifting from a capital-based approach to an operational cost model which offers greater predictability. True. But many CIOs push back as the capex represents a cost from 10 years ago and not something they face now. In addition, going from paying a license fee for your already installed product is a different mindset then paying a per user subscription fee. It's the own versus lease model.

But consider this.

Your on-premise software will continue to depreciate and age. You'll spend more and more resources supporting it over time and your security risks will increase.

Without the opportunity to leverage automatic upgrades, you'll miss out on the latest features, patches, security and enhancements.

In the end, the perceived pain of moving forward will be negated by costs associated with a data breach or unforeseen errors that staying with legacy software and processes can cause. By switching now, you're adopting a cloud-based platform that connects systems, automates processes, and delivers actionable insights across the whole organization. Quality is enhanced, continual improvement reinforced, and you'll have the ability to get your products to market faster.

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At MasterControl, we're passionate about quality. Our Quality Remastered series has been designed to help quality-centric professionals *remaster* 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.

To find out more visit www.mastercontrol.com/insights.