MasterControl™

Business Case for Cloud Migration

Why the Cloud Is Essential for Business Success

MasterControl™

The Cloud Is the New Norm

An organization must align with the specific realities it faces. In January 2019, the U.S. Food and Drug Administration (FDA) started seeing unprecedented numbers of investigational new drug (IND) applications, most of which were for new cell and gene therapy products. This new trend in public health discoveries enunciates how fast science and technology are progressing.

The FDA soon recognized it was becoming an inhibitor to progress as the agency's current IT infrastructure was unable to keep up with the pace of innovation. Through a program called the Technology Modernization Action Plan (TMAP), the FDA began migrating its entire IT infrastructure to the cloud.

"As technology advances, the FDA must keep pace with the increasing complexity of rapidly developing technology and continue to modernize and evaluate our programs and processes, ensuring they continue to be efficient, consistent and scientifically rigorous," said Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health (CDRH).[1]

Advancing technology continues to increase demand for more innovative and sophisticated products. Still, innovation isn't only about what you can make, it's about what you can make possible. For instance, given the increasing capabilities and computing power of cloud technology, the life sciences industry is actively designing and developing cloud-specific products, processes and services.

"The majority of life sciences companies have acknowledged the benefits of [cloud] technology: 64% of companies already apply cloud structures in their IT environments or plan to do so. Cloud technology is one of the top priorities in enhancing internal efficiency." – KPMG International, 2017.[2]

In highly competitive industries, companies relentlessly pursue their core mission through forward thinking and harnessing the best resources available. That said, in the face of heightened customer expectations, globalization, increased regulatory scrutiny and demand for value, companies across all industries are re-examining their operational IT infrastructures in favor of the cloud.

Benefits of Cloud Adoption

Every organization has some version of an initiative to improve efficiency and effectiveness embedded in its business model. The technology resources companies have at their disposal in this Industry 4.0 era have significantly redefined the dynamic of business strategies, operations and the workforce. The following trends illustrate the realities and opportunities companies in all sectors are currently facing.

Scalability on Demand

Processes such as running extensive database queries, gathering and organizing data from multiple sources and producing lengthy reports need to be completed quickly while the information is still current and actionable. When critical decisions need to be made quickly, it's important to have all eyes reviewing data, providing input, making adjustments on the fly and seeing results in real time.

This scenario defines a new organizational paradigm where the collaboration of cross-functional teams is mission-based, transparent and aligned with a clearly defined outcome. Pursuing this outcome-driven approach calls for a company culture that fosters modernization. At the core of this culture is an IT infrastructure that can readily adapt to new technologies, changing workflows and departmental integration.

Scalability in an On-Premise Environment

- Predicted and actual infrastructure needs rarely align. Adding more hardware and storage capacity as needed isn't always feasible.
- During peak operating times, departments may have to compete for bandwidth as well as deal with system latency, stalled data queries and unpredictable server performance.
- Sharing data often involves distributing spreadsheets or using portable storage devices.
- Stakeholders up and down the supply chain don't have data until it comes to them, resulting in fragmented, inconclusive and delayed business insights.
- Unstructured data is unused due to lack of technology needed to quickly compile and analyze it.

MasterControl Cloud

- Agile ecosystem with maximum system uptime.
- Able to increase bandwidth on demand.
- Rapidly adapts to new trends, business changes and updated strategies.
- Enables gathering, processing and analyzing complex data sets in a fraction of the time it would take in an on-premise infrastructure.
- Allows data to be securely shared across all business units — error-free and in real time.

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Mobility

Data from a 2017 LogicMonitor survey revealed the top reasons why enterprises migrate to the cloud: IT agility (62%), excelling at development and operations (DevOps) (58%) and mobility (55%).[3]

If this survey was conducted during the COVID-19 pandemic, the mobility response would most likely rank higher on the preference scale. Almost overnight, working remotely shifted from an employee option to a mandate as countries across the globe began to impose social distancing.

Companies had little time to determine if employees could:

- Securely access organizational systems and databases from outside the company's IT environment.
- Keep data and other proprietary information secure with employees using various mobile devices for remote access.
- Interact and exchange data with third-party companies outside the firewall.

Some might argue that this is all possible in an on-premise architecture through a virtual private network (VPN).

Mobility in an On-Premise Environment

The surge of online activity during the COVID-19 lockdown showed that company VPNs have limited bandwidth and can experience outages, which:

- Disrupts business operations.
- Causes costly production delays.
- Forces employees to use risky workarounds, such as transmitting data over unsecure networks to get their work done.

MasterControl Cloud

- Operates on a single, fully integrated platform.
- Enables connectivity with your IT applications and enterprise business systems.
- Allows accessibility from virtually anywhere.
- System and data access are tightly controlled based on users' access rights.
- Continually monitors and tests solutions for performance — immediate action is taken as needed.

"We're a small company with teams located on each coast. But our interaction and review processes are a lot easier because our system is cloud based. Otherwise, we would have to have a VPN. That's another hassle we would need to maintain, and we don't have a lot of resources for that." – *Balaji Sudabattula, vice president of quality and regulatory affairs, BraveHeart Wireless*

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"All of the information is in the cloud. I typically access it from a browser on my desktop. But I have the capability to access what I need from my phone."
– *Ted McAleer, vice president of business development, BraveHeart Wireless*

"We are finishing configuration and beginning the training. We could not do that remotely without it being in the cloud." – *Jon Thompson, Closure Systems International Inc.*

Data Analysis

A bold, yet realistic prediction is that the future is in data — specifically, the real-time processing and analysis of it. Data is abundant, multi-structured and fast moving. This enables companies to use data analytics to create predictive insights rather than rely on instinct or educated guesses for:

- Defining important metrics for creating goals and courses of action.

- Making decisions regarding production and supply chain processes.

- Detecting compliance patterns to take corrective actions before they become a detriment to productivity.

- Implementing strategies for effecting change, controlling change and systematically adapting to changes.

Interest in more sophisticated decision-making capabilities is on the rise. Thus, advanced analytics is rapidly becoming a mainstream competency for creating strategies and business value.

Data Analysis in an On-Premise Environment

- Legacy IT infrastructures commonly consist of complex, disparate systems that lack the computing power needed to process and analyze data while it is still relevant.

- Unstructured data that is transcribed into a usable format is prone to errors and omissions.

- Survey data from Forrester cites that between 60% - 73% of all data within an enterprise goes unused.[4]

MasterControl Cloud

- Agile infrastructure with immense data storage capacity enables companies to centralize enormous amounts of data for more efficient and real-time data management and analytics.

- Cloud architecture shortens the distance data needs to travel, which minimizes delays in returning requested data.

- Customers determine how data is downloaded and used and who has rights to access and modify it.

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Technology Validation

If your company is regulated by the FDA or other global regulatory bodies, validation of electronic systems is required for compliance. Software defects have contributed to a significant number of compliance violations and even product recalls. Validation requires extensive amounts of time, effort and resources, which is the reason companies tend to postpone technology updates. As a result, companies miss out on valuable new features and functionality, and they increase their security risk.

In the past, the FDA has advocated least burdensome and risk-based approaches to validation, using a risk assessment to determine the potential of the system to affect product quality and safety. However, the agency has not prescribed specific validation methods or provided guidance on how a company should define or calculate risk. Consequently, companies have often completed more testing than was necessary.

Validation in an On-Premise Environment

- Requires developing a detailed plan that includes defining the scope and time frame of the project as well as scheduling time and resources needed to complete all the tasks.
- Involves manually writing user requirements, protocols, test scripts, etc.
- Requires validation and subsequent documentation of the installation qualification (IQ).
- Requires running tests to validate the operational qualification (OQ).
- Commonly takes 30 days or longer to complete the validation.

MasterControl Cloud

MasterControl's cloud platform includes our unique Validation Excellence Tool (VxT)™.

- Designed in collaboration with former FDA officials.
- Completes the validation steps for installation qualification (IQ) and operational qualification (OQ).
- Allows customers to leverage internal testing completed by MasterControl.
- Provides the necessary information to understand and prioritize testing requirements based on the actual risk of software adoption or upgrade to specific critical business processes (CBPs).
- Slashes 336 hours from project preparation and reduces the actual project validation execution to 20 hours.

"A full validation without the VxT would be months because you're doing a lot of the work that the VxT does for you. The VxT allows me to go in and set criticality levels on the line items, products and things that are changing." – *Robin Joyner, system administrator, Wellington Foods*

"The reason we chose to go cloud is because the IQ and the OQ are pretty much taken care of by MasterControl, so it's not something we need to worry about. Also, being in the cloud, we are able to upgrade more frequently." – *Sue Wallace, global quality system and consumer data analyst, WD-40 Company*

"I will not go back to standard validation. It requires writing your own protocols and evaluating all the risks and rating them from high to low. You might catch things, or you might not. It's much easier when something has already been scripted and done for you." – *Pete Raghubans, quality assurance manager, EpiBone*

Security

Cybersecurity incidents are on the rise. Currently, there is a ransomware attack on businesses roughly every 14 seconds. By the end of 2021, that number is expected to jump to every 11 seconds.[5] These statistics suggest that the attack surface of IT systems and data continues to expand as companies develop more technology-based products. Organizations cannot let their guard down with infrastructure and data security.

Security in an On-Premise Environment

- Uses a single, strong firewall. However, if intruders manage to get through the firewall, they have access to the company's entire network, systems and data.
- Legacy systems and software are high risk for security vulnerabilities. Breaches can go undetected for months or longer.
- Difficult for internal IT teams to monitor, detect and prevent outside threats while overseeing other pressing IT administration needs.

MasterControl Cloud

- Cloud infrastructure has multiple security levels, which includes multifactor authentication and authorization.
- The infrastructure includes network and system security measures, making it difficult for intruders to gain access to critical processes or data.
- Security measures are implemented and maintained by skilled cloud and cybersecurity experts.
- ISO 27001:2013 certified – focuses on the implementation, maintenance and continuous improvement of an information security management system (ISMS).
- ISO 27017 certified – focuses on information security aspects specific to cloud computing and assists with the implementation of cloud-specific information security controls.

"When companies, especially small ones, say that on-premise is safer than cloud, what I would ask is, how can anyone with a small IT department think it can do a better job of keeping a platform secure than a provider like MasterControl that's set up to protect the system? People must be realistic about their belief that on-premise is safer."

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Automatic Upgrades

Technology upgrades are inevitable for many reasons. IT infrastructure components, i.e., operating systems (OS), servers, software, applications, etc. eventually become obsolete, expire from their vendor support cycle and become incompatible with newer components. Unfortunately, the longer you delay upgrades, the more costly and time-consuming they become. Aside from implementing new tools and improving productivity, upgrades are necessary for improving resiliency and strengthening your security posture.

Upgrades in an On-Premise Environment

- Need to schedule far in advance and coordinate with IT teams and administrators.
- Involves arranging for vendor to access test and production servers in order to troubleshoot and resolve any issues before beginning the upgrade.
- Requires planning around critical production and business timelines.
- Often requires prolonged downtime to complete all the upgrade, testing and validation procedures.
- Unpredictable in terms of time, effort and costs.

MasterControl Cloud

- Updates are more frequent, predictable and easier to complete and validate.
- Releases always include the latest security functionality and protocols.
- Your users always have the latest features and enhancements.
- Your software is stable, reliable and high quality.

"I no longer have to tell users that the system is going down for a day because we have to do a patch. We automatically get the patch every Wednesday night, and I don't have to go through the headache of taking the system offline, planning out when we're going to get the update and then implementing the new features."
 – *Matt Seitz-Paquette, North America quality specialist, Fagron*

"The biggest benefit of being in the cloud is we have the latest, greatest updates to the entire system." – *Robin Joyner, system administrator, Wellington Foods*

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Focus On Your Priorities

It's our commitment to ensure that your MasterControl system maintains an optimal level of performance, security and reliability, so your organization can focus on innovation, growth and delivering value. MasterControl's fully connected cloud environment elevates your efficiency, which helps you achieve more in less time and with less effort.

Over half of our customers have migrated to the cloud. They are immediately recognizing the advantages as well as seeing how legacy technology inhibited progress. To remain competitive long term, now is the time to implement the technology that will ensure success.

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About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality and compliance software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organizations digitize, automate and connect quality and compliance processes across the regulated product development life cycle. Over 1,000 companies worldwide rely on MasterControl solutions to achieve new levels of operational excellence across product development, clinical trials, regulatory affairs, quality management, supply chain, manufacturing and postmarket surveillance. For more information, visit www.mastercontrol.com.

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