



WHITE PAPER

NAVIGATING THROUGH THE CLOUD(S) IN LIFE SCIENCES

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HIGHLIGHTS

For 'Cloud' Solution Providers

- Lachman Consultant Services, Inc. (Lachman Consultants) is one of the premier consulting firms in the Life Sciences Industry and is well versed in the critical compliance matters that drive industry decision-making in the area of GxP compliance relative to the handling of electronic data.
- Lachman Consultants can help your clients perform a GxP compliance assessment without the need to access your physical infrastructure.
- Industry-specific GxP standard operating procedures (SOPs) must be available for your current and prospective life science customers. Lachman Consultants can help you develop these SOPs, along with the thought leadership content you need to earn the trust of life science decision-makers.
- Your system should be audited for life science GxP compliance. Lachman Consultants will help identify any gaps, assist your clients in closing those gaps, and validate the systems once all recommended steps have been implemented.

For Life Sciences Companies

- If you are worried about meeting GxP compliance regulations using cloud software, platforms, or infrastructure, Lachman Consultants can help bolster your team to ensure you do it right.
- Lachman Consultants can help you identify the proper way for your firm to integrate cloud solutions and create an action plan to ensure compliance. Lachman Consultants will show you how it is possible to comply with GxP audit requirements without touching a server or reviewing software code.
- If you already utilize cloud solutions (it's likely that you do), Lachman Consultants can assess your policies, procedures, and practices, identify your compliance gaps, and help you fix those gaps.

OVERVIEW

Whether we embrace it or not, the Data and Application economy is upon us. Every business is, in some respects, a digital business, and in the digital realm things change FAST.

The term 'cloud' as a technology concept has been in use since at least 1997¹, but even as recently as 2009 companies like IBM were just introducing it to prospective clients. Fast forward 7 years, and it is now the preeminent way computing power and information are shared, and the next evolution is already underway in the form of the 'Internet of Things' (IoT).

¹ NetCentric attempted to trademark the term 'cloud consulting' in 1997, although it had previously been used by telco engineers for decades as shorthand in conjunction with distributed computing power. See Regalado, A. "Who coined the term 'Cloud Computing'" October 21, 2011. <http://www.thebusinesstechnologyforum.com/2011/10/who-coined-the-term-cloud-computing/>

According to a 2015 Accenture survey of global business executives, 72% surveyed expect to see broad adoption of industry platforms that integrate data with digital business partners². Hybrid clouds in particular will see enormous growth, with expected growth from \$25B in 2014 to \$85B in 2019 (a 27% CAGR)³

The adoption of cloud solutions is a response to these solutions' power to rapidly solve existing and new business challenges. The value of the cloud is pretty clear for global businesses, and most companies are working hard to leverage its value.

Admittedly, life sciences companies are behind the curve, often because of the complexities of regulatory compliance and the relatively slow evolution of the FDA and other global regulatory agencies in response to technological change. **In this context, companies that can take advantage of cloud opportunities may develop strategic and competitive advantages.**

CLOUD APPLICATION IN LIFE SCIENCES

In today's highly competitive environment, life sciences companies must drive efficiencies to achieve the margins desired by their board or investors. Pricing pressures are constantly increasing as value-based healthcare models replace fee-for-service and lower cost generics grow in popularity.

IT and data systems have been ripe areas for finding this efficiency in life sciences. Specifically, R&D, compliance, and distribution functions can gain tremendously from the integration of cloud - based IT and data solutions. The impacts of developing these efficiencies through cloud solutions typically include **better cost controls, faster time to market and, in the long run, reduced regulatory friction.**

A short list of likely benefits includes the following:

- ❖ A move from a capital expense model for software to an operating expense model, thus improving the balance sheet;
- ❖ Far easier methods to manage information flow between partners, suppliers, distributors and licensees, speeding decisions and reducing mistakes;
- ❖ Reduction in manual processing, non-standard systems, and 'work-arounds', improving GxP compliance and reducing the risk of regulatory friction;
- ❖ Improving visibility up and down the value chain, helping to avoid counterfeit products, serializing data, improving demand planning and inventory management, and gaining pricing insights.

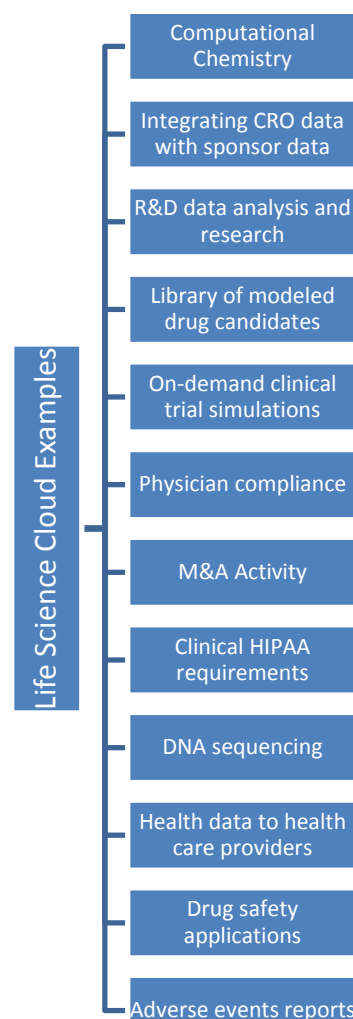


Figure 1: Examples of Cloud Solutions from Lachman Consultants' Clients

² Accenture Technology Vision 2015 Survey: <https://www.accenture.com/us-en/insight-technology-vision-2015.aspx>

³ Hybrid Cloud Market – Global Fore cast to 2019: <http://www.marketsandmarkets.com/PressReleases/hybrid-cloud.asp>

If you are an 'IT person', it is more likely you are comfortable with the upside of cloud solutions and are interested in tapping into the benefits described above. Your QA colleagues, however, probably have hesitations about implementing a cloud solution, and for good reason.

Cloud solutions are a double-edged sword for QA. There are tremendous benefits, but also legitimate concerns about how GxP compliance requirements developed a decade ago can be met in a cloud environment.

It can be done.

Lachman Consultants has worked with numerous life sciences companies in ensuring that cloud solutions are optimized for GxP compliance. Figure 1 contains a few select examples from those clients of functions entrusted to cloud solutions.

Before we discuss solutions, it's important to better understand the challenges.

THERE'S A CLOUD HANGING OVER OUR HEADS (BUT IT'S A GOOD THING)

CLOUD BASICS

Let's start with what 'cloud computing' is. At a basic level, it turns computing power and data storage into a utility. Using water supply as an analogy, as opposed to investing in digging and maintaining a well you instead connect to existing infrastructure, turn on the spigot, and adjust volume and temperature to your needs. You can use as much as you need, when you need it, and pay by the use. Due to economies of scope and scale, your water supply is much more reliable and much, much cheaper as a utility than as your own asset.

The variations of cloud solutions have evolved to map to what companies require. Today's variations are categorized as Software as a Service (SaaS), Platform as a Service (PaaS), and Infrastructure as a Service (IaaS).

Types of cloud models

Private: Infrastructure owned and maintained by company.

Public: A 3rd party provider provides services off-premise with access through the internet.

Hybrid: Utilizes public cloud infrastructure in combination with privately owned or managed computing assets.

Figure 2: Types of Cloud Models

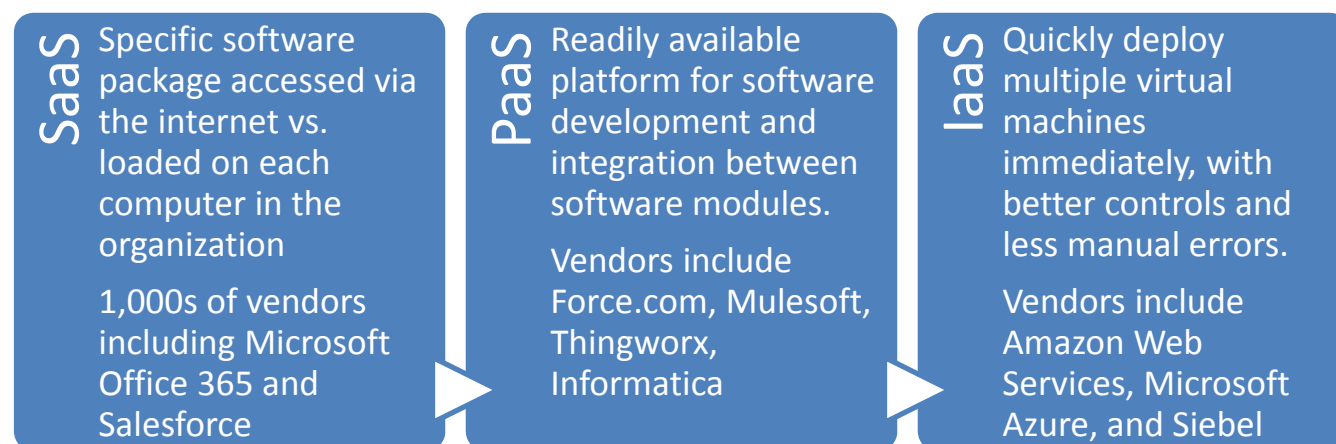


Figure 3: Variations of Cloud Solutions

These cloud variations (Figure 2, Figure 3) have brought the cost of development down and have allowed companies the opportunity to pick and choose software and hardware to rapidly solve specific business issues, rather than hope to customize an enormous legacy ERP system over the course of months or years. The model and variation chosen is driven by budget, the need for integration, and the need for control.

The growth of cloud opportunities has generated a litany of service providers that fit very specific niches. With each service provider comes a need to store, integrate, and analyze the data produced in a way that is compliant with regulatory requirements.

It is important to note that this ecosystem of service providers continues to develop quickly. If the life sciences industry follows the path of other industries, the next evolution of cloud computing will see the integration of data from millions of machines and devices in a GxP environment.

Dubbed the “Internet of Things” (IoT), data from any object (thing) that can be measured could be captured, logged, and analyzed.

In a life sciences manufacturing environment, examples would include the remote monitoring of manufacturing equipment or the monitoring and control of pharmaceutical serialization through distribution channels.

If done well, such a scenario automatically provides data throughout the testing and manufacturing process across manufacturing plants, providing real-time awareness of non-compliant actions. If done poorly, it will create new challenges for compliance including issues with device interoperability, data integration and integrity across devices and systems, privacy of that data, and incorrect analysis of the volume of data provided.⁴

THE REGULATORY BASICS

There is always a great deal of fear and misunderstanding of how to maintain regulatory compliance with new technologies. In the last 15 years, technology has migrated from hardware & instruments (easy to see and audit) to software (with code that can be reviewed) to a ‘black box’ cloud infrastructure. So how is it possible to audit in a cloud environment when the service provider may not allow audits of their premises? Further complicating matters, in a distributed and shared virtual server environment, data may not actually reside in any one specific data center, let alone on a specific machine.

Migrating services to cloud solutions does contain a significant degree of regulatory risk, if done incorrectly. Although operations are outsourced, the responsibility and accountability for GxP compliance remains with the life sciences company.

The reality is that it becomes difficult for a company to understand whether it is in compliance or not without proper planning with compliance experts. As an example, the FDA has already stated it will continue to enforce all predicate rule requirements including requirements for records and recordkeeping. FDA GxP regulations are currently under review and these revisions may shed additional light when released in late 2016, but likely not enough to keep up with technological advances.

'Internet of Things' applications

- Gain real time visibility into manufacturing plants for equipment availability and utilization
- Proactively maintain equipment based on logged events and information derived from these logs
- Ensure compliance at all times and be able to respond in real-time to exceptions
- Minimize waste by monitoring equipment used for serialization throughout distribution channels

⁴ Pharmaceutical Manufacturing Driven by the Internet of Things:
http://www.tcs.com/resources/white_papers/Pages/Pharmaceutical-Manufacturing-Internet-of-Things.aspx

Fear of Regulatory Deficiency Impacting Profitability

Regulatory warning letters for cloud-specific GxP violations are currently rare, but the expectation is that these will become increasingly common as the FDA/EMA/MHRA and other global regulatory agencies clarify guidelines in response to the growth of cloud-based solutions in life sciences.

For reference, regulatory deficiency notices and warnings have significant impact on costs and time (Figure 4). This is amidst an increase in GxP inspections by major agencies. For example, the EMA reported conducting 50% more GxP inspections in the first half of 2015 than the same period in 2014.

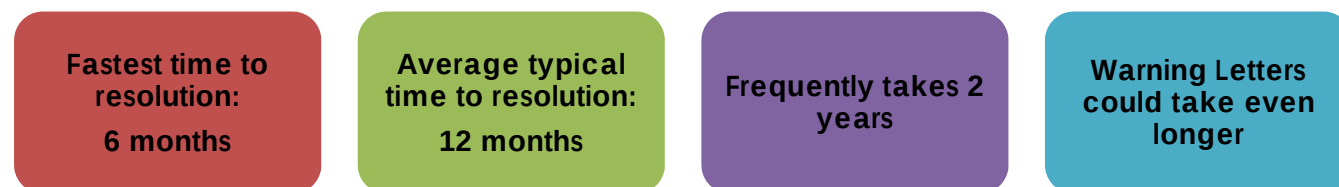


Figure 4: Lachman Consultants estimates of timelines to resolve regulatory deficiency notices (FDA Form 483)

With the change of payment structures in the US and the rapid growth of the generic pharmaceuticals market, economic and regulatory pressures in the life science world are increasing. In this environment, time to market has become even more critical to shareholder value creation and sustainable profitability than ever before. However, speed without precision leads to compliance issues, which throws cloud computing into the spotlight.

The potential speed and ease that a functional cloud solution brings is enticing, as long as compliance risks can be understood and managed. With the frequency that GxP issues are being cited in regulatory deficiency statements, compliance fears arising from poorly understood cloud risks are holding companies back from implementing cloud solutions that could very well maximize speed to market and net margins in the long run.

STRATEGIES TO THRIVE

Of the thousands of life science companies across the globe, it is unclear how many utilize cloud services or are GxP compliant with the cloud services they do utilize.

It is also unclear how many operate in a way that ensures compliance with current and future regulatory agency expectations for cloud computing. Our experience in this market tells us this number is painfully low.

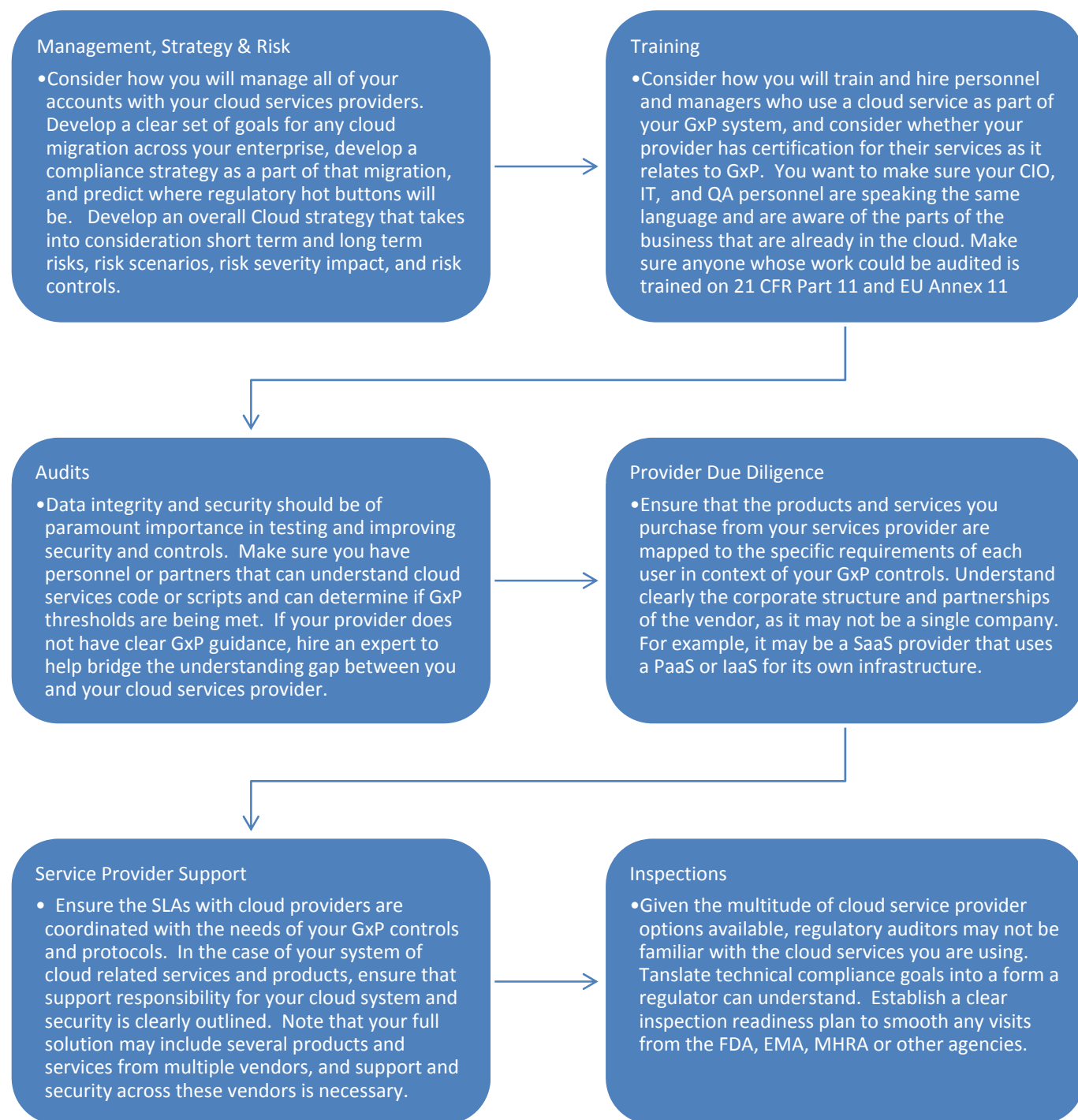
Regardless, what does this mean for YOUR organization?

The decision on how to approach regulatory compliance is a strategic one, and varies based on the size and state of your company. It's a risk/reward decision. However, given the strategic complexities and challenges that life science companies will increasingly face, a well-constructed cloud computing strategy will be a **sustainable competitive advantage** in balancing speed with precision.

Quality is an investment, and cloud computing done right can create a sustainable competitive advantage.

We have found that those companies which have accepted that **quality is an investment**, rather than an accounting cost center, are those that should expect to stay competitive in a tough marketplace. Investing in a system of accurate, effective, and sustainable compliance will protect profitability and shareholder equity in the long run, as well as serve to maintain brand equity amongst customers.

This requires a mindset shift away from being overly fearful of the winds of regulatory demands to proactively seeking ways – like cloud solutions - to drive quality. With this in mind, we offer a few strategic tips to ensure your company thrives in this new era of cloud computing.



WE CAN HELP

To better understand your risks and adequacy of cloud products and services, contact us. We will explore how your company can gain or retain a sustainable competitive advantage through our cloud computing compliance services.

Lachman Consultants offers the following services to the life science industry with respect to the implementation of cloud computing and compliance with Part 11/Annex 11 requirements:

AUDIT

Preparation for inspection or as a proactive quality step

TRAINING

Ensuring lab, data, and auditing personnel can apply GxP principles

ENHANCEMENT

Upgrade procedures and policies, address inspection observations or regulatory deficiencies identified in audits

SUSTAINABILITY & CONTROLS

Ensuring adequacy of staffing, internal and external audits, metrics and continuous improvement

To start the conversation, contact

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