



Compliance in the Cloud? Finding the Silver Lining for CSV

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Moving to the cloud used to be a daunting proposition. Issues such as reliability, data security, availability and scalability had many life sciences companies reluctant to take advantage of this “new” technology.

Not anymore.

An increasing number of life sciences companies are turning to cloud technology for the tremendous benefits it offers -- reduced costs, increased flexibility, improved security and ease of implementation. That does not mean that the cloud is the perfect solution for everyone. Depending on a company's IT infrastructure, the cloud can still represent a challenging – and sometimes painful -- approach. But when done correctly, and with the right partner, the cloud can be the optimum framework for maintaining a host of solutions, including validation and compliance testing.

This paper will discuss the benefits and potential pitfalls of cloud technology adoption and hosting for today's life sciences companies in the arena of computer systems validation.

The Industry is Changing

Talk to the CEOs of most pharma and life sciences today and two major challenges continue to vex them – the ability to do things faster (and remain competitive in the marketplace) and the overriding necessity to control and/or reduce cost.

For life sciences companies, cost reduction is increasingly critical – especially when the estimated cost of bringing a new drug to market can easily exceed the \$1B dollar threshold. (You also need to factor in a long product development cycle and a time-sensitive patent period of 20 years to understand the full impact). Cost is also borne out in PwC's 21st annual CEO survey ^① (which included responses from 70 pharma and life science companies). Their report highlighted that today's healthcare consumers have even greater expectations when it comes to gaining more value for their money.

In this increasingly digital world, one would expect that more companies are willing -- and able -- to overcome their reluctance in leveraging new technologies to address these issues. But even with the heightened interest in automated technologies such as artificial intelligence (AI) and robotic process automation (RPA), moving to the cloud has been an arduous and long process for the life sciences industry.



But there is good news on the horizon. According to a recent study ^② by Straits Research, “cloud computing in the pharmaceutical industry market is projected to experience record growth over the coming years as regulatory issues are expected to resolve amid settling security fears. In the future, the market is expected to witness the creation and management of a colossal amount of data, and a marketplace that is increasingly intertwined and globalized.”

^① PwC 21st 1st Annual CEO Survey, "Preparing for Disruption," published 2018

^② Cloud Computing in Pharmaceutical Industry Market: Information by Type (SaaS, IaaS & PaaS), Deployment Type, Application (PMS, EMR, Online Sales) and Regional Outlook - Forecast Till 2026, published April, 2019

Why Change?

When cloud hosting platforms first started popping up, life sciences companies (like many industries) took a wait-and-see approach. After all, many of these companies had already invested in their own internal systems, with dedicated teams building and managing both the infrastructure and the software applications in-house.


Those initial decisions seemed sound then, and for many companies, they still do.

- ➔ For some, it's about maintaining control of the systems and the process.
- ➔ For others, it's a trust issue. "Who knows the business better than we do?"
- ➔ And for others, it's just tradition. "It's the way we've done business for years. Why change something that works?"

But the challenges of operating and maintaining these sophisticated internal systems are increasing exponentially. Competition from new entrants is forcing life sciences companies to become quicker and more nimble. "Doing more with less" has become the new mantra. And every industry continues to look at cutting more costs out of the equation.

Just consider what a current on-prem system costs a company, both monetarily and operationally:

- ☰ While infrastructure and application ownership come with control, it also comes at the additional cost of infrastructure and application management, with dedicated resources to manage that operation.
- ☰ Infrastructure and application management in the life sciences world demands dedicated resources with specific expertise in validation and compliance.
- ☰ Scaling and change management of on-prem systems are additional workloads that need to be managed by internal team members.
- ☰ While on-prem ownership allows for patch, upgrade and change control, the burden of managing validation, user acceptance testing, and qualification remains with the internal team as well.

 On-prem also requires more traditional perpetual license arrangements, which incur higher up-front costs, in addition to annual support and maintenance costs.

The question may be more about affordability than cost. Is your organization able to afford the upkeep of your internal operation, along with the dedicated resources to carry out all the required support activities? More importantly, can you afford not to take advantage of cloud technologies that can truly drive change and innovation in your company?

The Benefits of Cloud Hosting

There are many reasons that cloud computing has continued to gain acceptance and momentum across many industries. Here are just a few of the key benefits.

Lower Cost of Ownership

It's true that the monthly/annual licensing fee for an on-prem compliance solution can appear to be reasonable and affordable. But when you add in the costs associated with hardware assets, maintenance and upgrades, data security and disaster recovery (among others), the cost can become prohibitive very quickly. Recent studies have shown that total ownership for cloud-based solutions can be up to 77 percent cheaper than an on-premise arrangement.

Think OpEx vs. CapEx

When considering a cloud-based solution, companies should also investigate the advantages of the OpEx pricing structure. OpEx allows expenses to be distributed equally over the lifetime of the system. Those "savings" can then be utilized for other capital expenditures such as research and product development.



The Ability to Scale – Rapidly

In the increasingly competitive pharma world, it has become imperative that life sciences companies are able to adjust and adapt to the marketplace in a timely fashion – not just in terms of months or years, but in terms of weeks, sometimes even days. The companies that can deploy new IT solutions or scale core IT applications/infrastructure – rapidly – will be the winners in the marketplace.

Increased Security

In an FDA-regulated industry such as life sciences, data security is tantamount. Which is why many life sciences companies originally rejected the cloud-based approach. The concern centered on the ability of a remote user to access the company's data and sensitive information. But cloud technology has come a long way and most cloud service providers add an extra level of security through the use of data encryption.



Increased Productivity

Wouldn't it be wonderful to enable staff to actually work on the tasks they were hired to do – and be able to allocate the necessary time for them to do it? By off-loading the burdens of internal management of IT infrastructure and application management (not to mention administration), internal teams are able to eliminate onerous – and often trivial tasks – while freeing up time for their dedicated roles and responsibilities.

Greater Connectivity

Cloud computing makes connectivity and collaboration (as well as communication) a simple and easy process, both internally across departments and externally across regions and countries. Utilizing prescribed access points and security features, team members are able to access and share information across the breadth of the cloud-based platform. This enables “one version of the truth” across the organization while ensuring consistency in both the management and maintenance of the data.

“If you change the way you look at things, the things you look at change.”

Dr. Wayne Dwyer

Leveling the Playing Field

Cloud computing technology is currently being used by life sciences companies of all shapes and sizes. But in today's competitive world, the cloud can be considered the equalizer for small-to-medium size life sciences companies that want to play with the "big boys". Burdened with smaller budgets and limited resources, the SMB players can now compete directly with the larger organizations, taking full advantage of the cost-effectiveness, scalability and reliability of new hosting platforms.

Choosing the Right Host Provider

In the world of cloud computing, choosing the right host provider is critical. There are special reasons for this. Here are some questions you should be asking a prospective host provider:

? Do they understand the regulatory environment of the life sciences industry?

Most major hosting providers serve a wide range of companies and industries. Very few have the proper understanding of the specific regulatory requirements that govern the life sciences industry. Neither their support teams – nor their infrastructure or services offerings – are designed with regulatory qualification requirements in mind.

? Do they understand FDA-specific compliance requirements and audit protocols?

Most major hosting providers do not understand all the nuances of hosting a validated compliance application on their system. This becomes very important when it comes to understanding the requirements and ramifications of an FDA audit.

? Who's in control?

Most hosted applications today are controlled by the vendor – not the customer. This means the ability for the customer to dictate the schedule for a system patch or upgrade release is essentially non-existent.

? Do they offer validation documentation?

Most major host providers do not supply qualified documentation – that task is left up to the customer. This can significantly increase both the up-front cost, as well as on-going implementation and maintenance costs.

Reach for the Sky

It isn't hard to see why life sciences companies were reluctant to embrace cloud technology five to ten years ago. Security and reliability issues were top of mind. But like most new technologies, cloud computing has grown up and matured over the last few years...and is poised for tremendous growth.

We've discussed the many benefits of the cloud. Scalability. Agility. Affordability. Speed. Collaboration.

And one could argue that newer cloud hosting providers are able to offer an even higher quality product by enhancing and streamlining the qualification of the infrastructure and maintaining the validated state of the applications being hosted. For some on-prem systems, that process could take from four to six months. With the cloud, it can be reduced to days.

And cloud-based systems enable instant connectivity and collaboration, so life sciences companies can enable quick communication amongst internal quality management, as well as outside partners, suppliers and other key stakeholders. The result – greater visibility, quicker analysis and lower risk.

Isn't it time you looked at the silver lining of the cloud for compliance?

About Tx3 Services

Based in Blue Bell, PA, Tx3 Services is a regulatory compliance technology company that offers computer systems validation, 21 CFR Part 11 solutions, and compliance consulting services for the pharmaceutical, biotechnology, and medical device industries. The mission of Tx3 is to provide its clients with industry-specific IT solutions that combine best-in-class technology with their extensive Life Sciences expertise, enabling them to meet regulatory requirements in a more efficient and cost-effective manner.

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