Is Software-as-a-Service in Your Future?

By John Avellanet, Managing Director, Cerulean Associates LLC

My February column on virtual computing and 21 CFR Part 11 compliance brought a slew of questions, comments, and inter-esting discussions from readers (a copy of the article, “Virtualization and Validation,” is available here on the Pharmaceutical Processing site or in the article library on my website). In the discussions and questions, one theme repeatedly came up: deciding on computer software you access over the internet rather than installing and maintaining software directly on your computer. Software you access over the internet is known as “hosted” software or “software-as-a-service” (SaaS) because it is hosted by someone else and then given to you as a service. Commonplace out in the broader marketplace, especially small to mid-sized businesses, software-as-a-service is not widely used in the biopharmaceutical or medical device industries, as a result, the ins and outs of SaaS and selecting a SaaS vendor is not well known. After a number of inquiries for advice from readers, I decided to contact a friend of more than twenty years, Alex DeBlois, who now lives out in Seattle, Washington area. Alex is a former SaaS supplier executive (he’s now with a company called Seven Simple Machines, www.7simplemachines.com), and so Alex was free to speak with candor about the pros and cons of SaaS in the biopharmaceutical arena.

**Doing Business with a Software-as-a-service Supplier**

The first point Alex made is that in any business, certain departments are more receptive than others when it comes to adopting software via the internet: “Sales and Marketing is number one, followed – in no particular order – by Finance and Personnel departments, customer service, order intake or supply chain, etc. Most shipping and receiving groups already use software-as-a-service when they access the web portals of the post office, UPS, FedEx, and other shipping services.”

If you’re debating about SaaS for your company, your Sales and Marketing force may be a natural fit to pilot the software and Marketing teams often embrace SaaS due to the following:

- **A tight focus on specific functionality (“When you get SaaS, you are only paying for the functions you need, not the other 90% of the functions in most software that you will never use”)**
- **Ease of integration with other systems like order entry, billng, shipment tracking and so on.**

Depending on the business needs, your teams may also benefit by using a software-as-a-service model.

- **Desires departmental flexibility: Team needs some level of control over the software they use to run their operation, and SaaS (hosted) software can allow for a degree of customization that out in the broader marketplace is not available with locally installed software.**
- **Looking for a product you can pay for as you go: When you purchase software, you pay for the product up front. With SaaS, you typically pay for the product on a per user/month basis.**
- **Moving to a SaaS model allows for a quicker return on investment:** Alex explained, “Although there are up-front costs in migrating to a SaaS platform, the company can start hearing the return on investment almost immediately. The company can choose to implement the SaaS platform in a phased manner, which means that the company doesn’t have to invest in a single shot.”
- **Technological skills are no longer a barrier to adoption:** Alex suggested may not be good candidates for software-as-a-service adoption: new product development (including preclinical and clinical), manufacturing, and quality or regulatory operations.

Over the years, I’ve learned that quality and regulatory affairs departments tend to be conservative when it comes to anything new (a colleague of mine tells a wonderful story of how his company was about to purchase what everyone felt was the perfect computer system to manage their chemical compounds and inventory, but as they were running through the final specifications, the vendor happened to mention the phrase “uses cutting-edge technology” when the regulatory affairs vice president was in the room and presto, the deal was off). While that is a bit extreme, I have seen the conser-vatism play out in the following manner when something new is broached, the regulatory personnel look to the regulations for guidance. Unfortunately, as I pointed out in my speech at the National Institutes of Health in late April, the regulations tend to be more than a decade behind the realiti-ty of technology today, and as a result, the regulations are silent on questions involving current technology capabilities. Regulatory silence is then interpreted as “no” (e.g., better to do nothing). However, this can be more than made up for when you factor in the zero to very low infrastructure and maintenance costs over those years. Given that such a large percent-age of any computer department’s budget is strictly for main-tenance, the savings can be substantial.

Additionally, the adoption of innovation in pharmaceutical firms is beyond the scope of this column, but as I stated in my previous article, “When you factor in the zero to very low infrastructure and maintenance costs over those years. Given that such a large percentage of any computer department’s budget is strictly for maintenance, the savings can be substantial.”

The next step would be to examine SaaS vendors with custom-izations to meet your needs, which is why the information in this article has given you some good insights on where you may want to explore options.

**Building the Business Case for Software-as-a-Service**

Beyond tackling the objections, building the business case for SaaS adoption somewhere in your organization requires an analysis of the financial aspects or total cost of ownership. Alex suggested three areas where vendors have a role to play: cost, security, and performance.

**Cost**

Vendors often offer varying degrees of usage of their software based on whether a person is connected to the internet at that moment or if that person is off-line. A sales representative out in the field could input all the or data, then simply upload it via an internet connection at home. If technology packages are hosted (installed and maintained by someone else) and given to you as a service, then a key consideration in selecting a SaaS vendor will be the degree of functionality allowed away from the internet.

There are three areas within biopharmaceutical companies that Alex suggested may not be good candidates for software-as-a-service: new product development (including preclinical and clinical), manufacturing, and quality or regulatory operations.

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**Security**

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**Performance**

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**Qualification of a SaaS vendor is a large topic, and the how-to’s are beyond the scope of this article. However, two resources for any audit team is to use the software-as-a-service model.**

Carnegie Mellon’s Capability Maturity Model® Integration (CMMI) and the TickITplus schema (www.tickitplus.org). Both of these models beyond tackling the maturity and quality controls of a software development and service organiza-tion. There is also a third option – but one that is relatively new – and that is for the software vendor to be certified in ITIL 2000®: IT Service Management.

**Final Thoughts**

Software-as-a-service is not for everyone. I would like to think this article has given you some good insights on where you may best be able to adapt SaaS in your organization for the most value and least risk. I welcome your feedback and questions, as well as any suggestions for future topics to address. Are you ready?

**About the Author**

John Avellanet is the founder of the FDA regulatory intel-ligence and lean quality systems compliance program for executives and business owners, SmarterCompliance™. He is the author of more than 90 articles, books, and book Best Practices in Biotechnology Business Development, and a frequent speaker with FDA officials. He can be directly reached through his independent advisory firm, Cerulean Associates LLC, on the web at www.ceruleanllc.com.