

Cloud Computing Apps: Always Ready for Any Compliance Storm

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When faced with a difficult business problem, good managers evaluate all of the variables before preparing a solution. They consider timelines, costs, resources, quality, and more. Unfortunately, this logical approach just doesn't work when it comes to solving the life sciences' compliance conundrum because the variables are always changing. In fact, the only variable in the compliance equation that is constant *is* change.

How do you solve a problem comprised of endlessly shifting sands? It's like herding cats – each time you respond to one regulation, a new rule emerges or an old one changes. Even the brightest chief compliance officers struggle to concoct the right combination of training, tools, and technology that will keep their organizations compliant...and, maybe more importantly, safe from the fury of state and federal agencies.

“A lot has changed over the last few years,” said the Chief Compliance Officer at a leading biotech organization. “The #1 concern was always criminal liability, but now we're becoming just as concerned with civil and state penalties, as well as how we are perceived in the court of public opinion. Compliance today is a very complex challenge for the industry.”

Key bills strengthening the FDA's enforcement powers, as well as strategic staff appointments have also added to the aggressive regulatory climate. In fact, the FDA has requested a \$3.2-billion budget for 2010, representing a 19% increase over last year. “Drug companies that do not have a compliance strategy in place may soon pay a very high price,” said Deborah Autor, director of compliance at the FDA's Center for Drug Evaluation and Research (CDER) at the 2009 FDLI conference in Washington, D.C.

Desperate, drug companies turn to technology but they hit a brick wall with their aging client/server systems that are incapable of efficiently handling the rapid pace of change characteristic of modern-day regulatory compliance. With each new rule or area of emphasis (such as the recent increased attention paid to off-label promotion), life sciences companies need to add new functionality to their CRM or SFA systems. With these traditional applications, the build/upgrade process lasts an average of 12-18 months followed by a deployment roll-out lasting another several months. So, by 2013, a company might be compliant with 2010 rules – and, by then, the rules would have changed again...maybe more than once.



Add to this the fact that time is money. The cost to go through such an arduous upgrade process is equally as painful, amounting to anywhere from \$2 to \$6 million (only to be obsolete before even being fully deployed).

It's quite a pickle – spend the millions on compliance strategies or risk millions in fines if non-compliant. But things are looking up. Today, there's another dramatically less expensive, infinitely faster option – and it's the only option designed to keep pace with the government's rapid rate of regulatory change. It's a multi-tenant SaaS CRM system built in the Cloud. With it, you're always ready.

Cloud Computing Model Built for Change

Multi-tenant Cloud computing applications are uniquely designed to be able to change (like compliance rules) as frequently as the weather. Unlike any other available technology, applications running in the Cloud allow for rapid, behind-the-scenes upgrade cycles for their users. System changes necessary to support regulatory compliance requirements can be made and pushed out to customers through regular upgrades – for free. Done right, none of these application changes will affect a company's data files or previous customizations.

Here's how: Multi-tenant SaaS applications in the Cloud are built to serve multiple customers from a single, shared instance of an application, yet the architecture provides a boundary between the platform and the applications that run on it. These applications are designed with logic that is independent of the data it controls. So, instead of hard-coding data tables and page layouts, admins define attributes and behaviors as metadata that function as the application's logical 'blueprint.' Administrators then have the ability to configure their organization's instance of the application to meet their specific needs – whether that means changing product detail priority, issuing a new aggregate spend indicator level, or any other regulatory compliance change.

The speed, low cost, and ease of such an upgrade with a Cloud Computing application is simply not possible with other technologies such as client/server applica-

tions. For organizations running client/server systems, upgrades mean years of waiting for new functionality; massive data migration initiatives to upgrade; reloading of software onto remote users' hardware; and, even retraining of all employees that use the system.

In contrast, most Cloud applications release new features and functionality to all of their customers – regardless of whether there are five or 5,000 users – multiple times per year. Even if federal regulations or guidelines change tomorrow, users in the Cloud will be prepared to comply well ahead of impending deadlines without ever having to suffer through the traditional upgrade process. Similarly, mobile users also benefit from Cloud technology upgrades. As all upgrades are pushed to customers via the web, mobile devices are also upgraded seamlessly when the users sync – it takes just seconds.

Compliance officers are getting more and more involved in the selection process for new CRM or SFA systems because of their potential impact on compliance. Increasingly, companies have more extensive reporting requirements through corporate integrity agreements with the government, in addition to federal and state regulations. So a system that offers an attractive business package and also supports compliance needs will be an appealing option.

Finally there's a reliable way to handle changing variables in the complex compliance equation. Move to the Cloud and you'll always be ready for unexpected compliance storms. Even better, you'll be ready to capitalize on the much-anticipated sunny days ahead.

About Veeva Systems

Veeva Systems is the leader in multi-tenant SaaS-based solutions for the global life sciences industry. Veeva's customers range from the world's largest pharmaceutical companies with thousands of users to emerging biotechs commercializing their first products. Veeva customers achieve the fastest time to value through the deployment of fully functional applications that are flexible, simple to deploy, inexpensive to operate, and provide a superior user experience. Veeva is a privately-held company headquartered in Pleasanton, CA. For more information, visit www.veevasystems.com.