Server Consolidation in a Validated Environment

Pharmaceutical firms spend about five percent of revenue on information technology. But as drug development costs soar and blockbuster products are pulled from the market, IT managers are being asked to find savings. A good way to start is by consolidating validated applications onto virtual blade servers. Just be sure you have a change management process that meets the highest quality standards.

by
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With more than $35 billion in annual profits, the biopharmaceutical industry would appear to be in good health. But appearances can be deceiving. Despite investing $38 billion on R&D last year, the industry submitted 50 percent fewer applications for new molecular entities and biological license applications than it did in 1996, when it spent only $15 billion on R&D worldwide.

Indeed, Bain & Company estimates the current average cost to develop and launch a new prescription drug at $1.7 billion, double the cost 10 years ago. Unfortunately, the expected return on investment for a blockbuster drug has now fallen to five percent, far below the industry’s average cost of capital, says Bain, which recommends a wide variety of cost-cutting and restructuring initiatives.

Information technology is one area where biopharms can reap enormous savings and improve productivity at the same time. On average, biopharms spend five percent of revenue on IT. So a $40 billion industry giant invests about $2 billion a year, while a $2 billion tier-two drug maker invests about $100 million a year on IT. Do the math. Even a one percent savings on those line items is serious money.

How can biopharms wring huge savings from IT? One of the best places to start is by tackling a project that most of them have avoided: server consolidation.

Many pharmaceutical firms today have a vast array of underutilized servers, including NT, Unix, VMS, Linux and AS/400. A few years ago the Gartner Group famously estimated that corporate servers averaged 20 percent capacity utilization. But the reality is usually far worse. Welch Foods, for example, recently reported that its server utilization rate ranged between five and 10 percent prior to consolidation on virtual servers. Now its servers run at 60 percent of capacity.

Today, many companies are replacing their obsolete and underutilized servers with multi-processor rack-mounted blade servers that can stack to the ceiling and share resources like storage, power and network access. Moreover, by using virtualization software such as VMware ESX Server, each blade can be partitioned into many virtual servers, each running an application on its own operating system. The blade can be partitioned into multiple instances of the same operating system or into many instances of a variety of operating systems, from NT to Linux. With careful workload management, companies can achieve 85 percent capacity utilization and still have a buffer for development, testing, fail-over and spikes in demand.
Of course, it depends on the industry, the applications and other variables, but it is not uncommon for companies to retire at least 10 servers per virtualized blade. Welch’s consolidated its servers at a 15-to-1 ratio.

The cost-savings achieved by server consolidation can be staggering. Oracle Corp. reported that it expected to save $300 million by eliminating 4,000 underutilized servers. The US Air Force said it saved $100 million a year when it decommissioned 4,000 servers with 1,000 domains - that's $25,000 a year per server. Bayer Corp. reported that it will save $76 million over five years by eliminating 720 servers and 40 data centers.

Server consolidation delivers so many other financial and operational benefits that it is difficult to list them all, but some of the most significant include: reduced capital expense, fewer data centers, lower power consumption, improved systems management, increased service levels, and more streamlined change management.

Unfortunately, relatively few biopharms are willing to tackle server consolidation projects because so many of their systems and software must be qualified and validated to comply with FDA regulations. In some poorly managed projects this difficult and time-consuming process has been known to double the cost of the hardware and software. As a result, IT and business managers alike are reluctant to touch their validated systems. As long as the systems don’t fail completely, most managers figure it’s better to maintain them as they are for as long as possible.

Until recently that was probably a sensible decision. But recent advances make consolidating validated systems onto virtualized blade servers a lot easier and less costly than most people realize.

Consolidating servers in a validated environment does not have to be extremely expensive or time-consuming. Indeed, if you subscribe to good quality management practices - including a robust change management methodology - consolidating regulated servers should not be much different from

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**Roots of Server Sprawl**

Server sprawl is a serious problem in many large and mid-sized companies. In the 1990s, Microsoft’s Windows NT 4.0 server operating system became a viable alternative to more expensive Unix servers. Running on low-cost Intel microprocessors, these Wintel servers cost a third or less per user than comparable Unix systems. Unfortunately, the NT server operating system did not provide a logically separate or protected address space for individual applications - or even the operating system itself - so if one application crashed it took down the entire server. The more applications you ran on NT, the more likely it was to crash. So most IT managers ran only one application per box. Then, if the server crashed, it took only one group of users with it.

In time, the practice spread to Unix servers as business units racing to launch new applications feared that sharing a server with another group might slow them down. These decisions had fateful consequences. According to Gartner, companies that ran one application per box typically added three to five servers for things like production, development, testing and backup. If the application needed to scale, they might add 10 servers. The growth in servers and resources was geometric. Moreover, every new server required a new operating system, storage, disk, and network access.

The result? Today, many large companies are saddled with thousands of Wintel servers spread across the enterprise - some hidden in closets, others occupying expensive data center real estate. What started as a sensible money-saving and time-to-market solution has turned into a painful management headache that is costing large organizations millions of dollars a year, and middle market firms hundreds of thousands.
consolidating unregulated ones. At most it should cost about 30 percent more than a typical consolidation project. However, unless you follow a strict methodology, costs can easily soar out of control as you are forced to revalidate every application that you move.

Court Square keeps costs in check by applying the same Good Systems Practice™ (GSP) approach to every IT project, no matter how large or small. The GSP™ approach to deploying and managing information technology is based on the widely adopted IT Infrastructure Library (ITIL), the most comprehensive quality management system yet developed for IT environments. Under GSP, Court Square has optimized the ITIL framework to address the particular challenges of managing IT in an FDA-regulated environment, including 21 CFR Part 11 (electronic records and signatures) and Section 211, the GMP-based predicate rule governing software validation and systems qualification.

In the following discussion, we will describe how to consolidate regulated servers onto virtualized blade servers using VMware ESX Server. As a consulting firm, Court Square does not endorse any particular technology. However, VMware is the market leader in providing virtual servers for x86 processors running a variety of Windows, Linux, FreeBSD 4.9, and Netware operating systems. With its bare-metal architecture, ESX Server is the most robust and secure solution for these platforms, and the most appropriate choice for such enterprise software consolidation projects. Other vendors, including IBM, Hewlett Packard and Sun Microsystems provide virtualization solutions for their proprietary versions of Unix, including AIX, HP/UX and Solaris.

1. Prioritize your project goals:
What do you most want to achieve by consolidating your validated servers? Do you want to maximize cost savings, optimize service levels, dramatically improve security, or create a fault-tolerant system with telco-style reliability? Does your IT department develop and test many new applications each year? Each of these involves trade-offs and will influence the way you design and manage your new infrastructure.
2. Audit your current infrastructure:
Find out how many qualified and validated servers you have. Document their hardware and software profiles. Determine if all of you external hardware components will work with your new systems. If not, find suitable replacements. Quantify the capacity utilization of each server you are replacing so you can determine how many blades you will need to purchase and how many virtual servers you will need to create. Check to see if you have enterprise licenses for the operating systems you intend to consolidate that allow you to move them to a virtual environment without penalty. Determine whether the applications you will consolidate are CPU dependent, memory intensive, disk dependent or require large amounts of bandwidth. This is important because it will determine which applications you group together on the same servers. Good workload balancing means you do not group like applications together. By carefully balancing the applications you have on each server, you can achieve the highest possible capacity utilization.

3. Design your new infrastructure:
Whether you are consolidating NT, Solaris, HP/UX, VMS, AIX, Linux - or all of the above - you need to ensure that your new blade server infrastructure is provisioned so you can achieve a capacity utilization rate of approximately 75 to 85 percent. Key elements to consider in your provisioning plan include, bandwidth, power, cooling, storage, CPU cycles, and data center real estate. If you consolidate enough servers onto blades, you may be able to close one or more data centers. Of course, your target utilization rate will vary depending on the goals you established in step one. You should keep some capacity in reserve to meet spikes in demand and to have adequate development and testing platforms. Depending on your needs, VMware provides sophisticated management software - VirtualCenter and VMotion - that enable on-the-fly provisioning, continuous consolidation, and zero-down-time maintenance and fail-over.

4. Qualify the new infrastructure:
Title 21 Section 211 of the Code of Federal Regulations requires documented evidence that an infrastructure component will perform
according to specification. Infrastructure components include the blade server hardware, network, storage, power and cooling systems. In addition, the VMware host server and the virtual containers in which the guest operating systems and applications will reside must also be qualified. Unlike some virtual machines that run atop an operating system, VMware ESX Server interfaces directly with the server hardware - CPU, memory, network interface, and disk storage - and should be qualified as an infrastructure component. Qualifying a virtual server such as VMware ESX Server requires more testing than a single logical server, in part because it can be partitioned into many containers, each of which will host an operating system and application. It is important to develop a test plan with scripts that output to qualification documents addressing these unique functions. Reliable change management procedures that address the requirements of 21 CFR are critical to keeping costs in check. By using standardized processes and templates, and carefully documenting the qualified server build, you can replicate additional server builds by documenting changes. In Court Square's Good Systems Practice methodology, this is known as Qualify Once - Install Many.

5. Move the validated systems to the newly qualified infrastructure:
Moving a validated application to the new infrastructure cost-effectively requires a GSP-qualified change
management procedure like the one you used to qualify multiple virtual servers and blades after the first Qualified Build. If you intend to move the validated application and its original operating system to the virtual server, then all you need to do is take a backup image of the two and install them on the appropriate pre-qualified VMware ESX Server container. Remember to follow your workload management plan and avoid grouping like applications on the same blade and virtual servers. By following standardized change management procedures you will test only the minor changes - such as software patches - that you made during this process. These changes will be captured in your standardized documentation and will preserve the application's validated status. If, however, you move a validated application to a virtual server with a different operating system from the original, you will need to revalidate the application.

Server consolidation in a regulated environment is a serious undertaking with many pitfalls for those who lack standardized procedures. A quality management approach like the ITIL-based Good Systems Practice outlined here is critical if you want to minimize risk and control costs with a repeatable process. By combining blade servers, virtual machines and a quality management practice that includes strict change management procedures, you can begin to manage your validated systems just as you do your other IT assets.

There are many validated systems that you can consolidate - including Linux, VMS, AIX, HP/UX, Solaris and others - but in many organizations, Wintel servers are the low-hanging fruit and the best place to start. The sooner you get going, the more cash you can drop to the bottom line.

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