White Paper

Virtualized Infrastructure Leads to More Flexible Process Automation for Pharmaceutical Manufacturers

By Matthew Daniels and Michael Kalvaitis

With increased pressure to achieve faster drug approvals and decrease time to market, pharmaceutical manufacturers are being driven to make their entire infrastructure more efficient. Virtualization offers an appealing solution to pharmaceutical manufacturers to help accomplish that.

Virtualization has been mainstream in the IT world for the past couple decades. One of IT's biggest challenges is "infrastructure crawl," caused by servers that, by design, run one operating system and one application at a time, requiring many servers to meet the needs of complex organizations. These single-application servers typically use only a fraction of what the physical server can provide, wasting computing resources across the organization.

Virtualization, however, operates on the principle that more than one operating system and application (VM) can utilize the same physical hardware, or server host. This paradigm shift in hardware utilization greatly reduces the physical, power, and cooling footprint required to run an application and organization.

In recent years, these IT-proven technologies are finally reaching the plant floor. Pharmaceutical manufacturers are seeing potential in virtualization to reduce the risk of operations, create flexibility to grow, increase the reliability of the system, rapidly adjust based on market demands, and, ultimately, reduce the cost of doing business.

Challenges of a Traditional Infrastructure

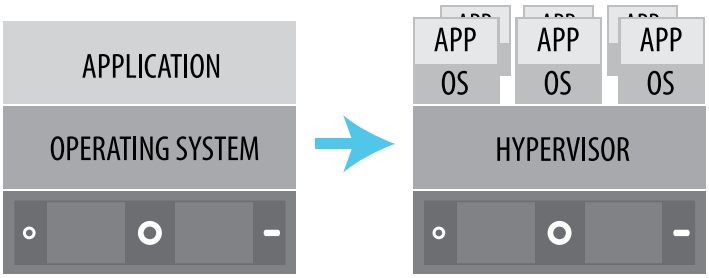
At a time when pharmaceutical manufacturers are trying to simplify their process, making it faster and more cost effective, a traditional computer infrastructure is doing the opposite. Every physical machine requires labor and expertise to install, maintain, and upgrade – a costly and time-consuming effort. Validation and qualification efforts increase the cost burden and, soon enough, one application or system becomes very expensive to operate. Further challenges present themselves when it is time to upgrade the hardware, especially when newer hardware cannot run legacy software required to operate the facility. Additionally, single-server application relationships increase the risk to the business when experiencing unplanned downtimes. Recovery and restoration processes could prove time consuming and potentially result in lost product.

For development, validation, and training environments, most manufacturers maintain offline systems, which are helpful but expensive to install, manage, and maintain when using dedicated hardware to each of the offline systems. Virtualization significantly reduces that hardware requirement, allowing multiple systems and software to share clustered resources.

A Virtual Infrastructure Versus a Traditional Infrastructure

With a virtualized infrastructure, it is much easier to develop, implement, and manage multiple systems, utilizing multiple operating systems at varying software releases. Installing old software on new hardware is no longer a problem, because the hardware platform is independent of applications and software. Most appealing, though, is the virtualization infrastructure reduces the amount of physical hardware [servers] required and minimizes the footprint.

A traditional infrastructure uses a 1:1 hardware/application ratio, where each server has one operating system running one or more applications. Virtualized environments offer a higher consolidation ratio, where multiple virtual servers (VMs) run on a single hardware server simultaneously. It uses a hypervisor – computer software and firmware that is responsible for running virtual machines while managing physical resources on the host (CPU, memory, and network resource). Virtual machine host servers maximize resource utilization, because resources are handled and scheduled through the hypervisor.



TRADITIONAL CONFIGURATION

VIRTUAL CONFIGURATION

One of the most significant benefits of a virtual environment is the ease of maintenance. Most maintenance activities can be performed live, while the system is running. Not only is it possible to migrate a virtual machine live, it is also possible to replace aging or malfunctioning hardware and balance server load and resources live.

This makes for a highly available environment. In the event of a server failure, a virtual machine will automatically migrate to another available host. It is even possible to configure the virtual environment to be fault tolerant, with zero downtime during a host failure.

A Business Case for Virtualization (Benefits)

While the upfront investment for a virtualized infrastructure could be higher than a traditional architecture based on the number of required systems, the longer term cost and reliability benefits make a virtualized environment highly attractive. A virtualized infrastructure significantly reduces the number of physical workstations that are required. That means fewer physical servers to maintain, and a smaller footprint, which saves space, cooling, and power in the data center. With virtualization also comes the flexibility to easily add and remove servers (VMs) and systems, support multiple software releases and operating systems on the same hardware, and reduce setup and decommissioning times. The system lifecycle is also extended, because legacy software can run on newer infrastructure. Ultimately, virtualization reduces lifecycle costs in hardware, facilities, and ongoing maintenance.

NEW ENGLAND CONTROLS

Some of the major benefits for moving the plant floor systems into a virtualized environment include:

- Business Continuity
  - Easier and faster backup strategy
  - Easier and faster disaster recovery
  - Higher availability of software and services by utilizing cluster features in the virtualized environment
  - Redundancy at every level of the infrastructure – power supplies, networking, hard drives, host servers
- Operational Flexibility
  - New hardware and servers are not required when deploying new systems
  - Reduced deployment effort and cost by utilizing templates (Rapid concept-to-deployment models)
- Cost Reduction
  - Reduced physical, cooling and power footprint
  - Simplified and centralized management
  - Reduced maintenance and lifecycle costs

Virtualization in the Life Sciences Industry

One example of a company that has implemented a virtualized infrastructure solution is Biogen, Inc., a Cambridge, Massachusetts-based biotechnology company specializing in discovering, developing, and delivering therapies to treat neurodegenerative, hematologic, and autoimmune diseases.

Like many companies who transition from a traditional, physical infrastructure to a virtual one, Biogen first started with a development system, where they could try out the technology before using it for their production systems. Biogen had four of Emerson's DeltaV™ automation systems dedicated for a particular area of manufacturing. For a traditional infrastructure of this size, they needed four of everything – network topologies, server infrastructure, workstations on the plant floor, etc., which led to a significant amount of cost for operation and maintenance.

In addition to the production systems, a development environment was used to test new code and functionality changes before implementing on the production system. New England Controls, a long-time partner with Biogen for automation solutions and technology, suggested to Biogen that their development system could be implemented, upgraded, and operated easier and more cost effectively using virtualization. Biogen was intrigued with the proposed solution, and they began working with New England Controls to scope out a virtualized system that met their needs. That effort was completed in 2011.

In the years after implementing the development environment, the Biogen automation team had become comfortable and experienced using a virtualized system. Ultimately, they decided to utilize the benefits of virtualization in their production environment.

Virtualizing the Production Systems

Transitioning the production systems was a significant decision. The entire Biogen Cambridge production system has about 60 workstations and 25 physical servers using eight (four redundant) DeltaV networks. This means that anytime they want to make changes to the system or conduct annual maintenance, they were required to do it four times or eight times, to duplicate the effort on the redundant control system networks. Biogen wanted to simplify their system, but they also wanted to minimize project risks. The plan was to start slowly, by virtualizing one production system at a time, starting with workstation-based computers and then moving to the server-class machines.

Their first task was to virtualize approximately one-third of their workstations, which was very low risk. If one workstation failed, an operator could simply move to another workstation.

Out of their 60 workstations, each with 500-watt power supplies, approximately 20 of those have been transitioned to thin clients that require only 30-60 watts that utilize remote desktop (RDP) and terminal services.

Following the success of the workstations, Biogen continued to proceed with one production DeltaV system at a time. The decision to virtualize the production system coincided with the installation of a manufacturing execution system (MES), Emerson's Syncade™ Suite. As a joint effort between the MES and automation teams, both Syncade and DeltaV became virtualized in a production environment, sized appropriately to meet the resource demands for the MES and DeltaV systems. Soon after the first DeltaV system was virtualized, the second followed suit.

In addition to having one-third of the workstations virtualized, Biogen has also transitioned nearly all of its servers to VMs at the time of this publication. (They plan to be all virtual by the end of 2015, except for a few remaining workstations on the plant floor.) Where they had 25 servers in a traditional setup, they currently have five server hosts in the virtualized environment.

Realized Savings and Benefits

One tangible benefit of transitioning to a virtual network has been the realized savings from reduced power consumption. One server can require 500 watts per hour, or 12 kilowatts (kWh) per day, or 4,380 kWh per year. According to the US Energy Information Administration, the average kWh cost for commercial use in 2014 in Massachusetts was $0.1492. That means it would cost $653 to run a server for one year. For Biogen, the transition from 25 servers to five servers delivers an annual cost savings of $13,072.

Management

There have also been other realized benefits, such as the ease of centralized management. The Biogen automation team can launch a management console at any time, from any place, and review the status, resource consumption and performance trends for any virtual machine within the environment. If an application is not performing well, a member of the automation team can quickly review the performance statistics and, if required, instantly provision more processing or memory power to the VM.

Upgrades and Maintenance

Upgrading the automation and MES systems is also a much simpler process. Previously, upgrading the traditional physical system was kicked off by the arrival of a tractor-trailer full of servers and workstations. Now, an engineer shows up to site with a USB drive containing all the new VMs required for the upgraded system. While one set of VMs gets turned off, the new set of upgraded VMs gets turned on. Maintenance activities required for the VM hosts are completely non-disruptive to the process control system. VMs are moved to alternate hosts while maintenance is performed and then moved back – all seamless while the VM is running and completely transparent to the end users and applications.

New Deployments

New systems and services are now easily and rapidly deployed. One major delay in implementing a new project is lead time for hardware and software deliveries. In a virtualized environment, the engineering team simply deploys the appropriate VM template and they are ready to go within minutes – not days and weeks.

Conclusion

While the Biogen virtualization effort is an ongoing process, it has been a great success thus far. It has simplified maintenance and management for the automation team, reduced hardware costs, reduced power consumption costs, and added a level of flexibility, reliability, redundancy, and scalability to the infrastructure that didn't previously exist.

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