Pharmaceutical MANUFACTURING
WHITE PAPER

Cloud Software's Silver Lining

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Often criticized for its cautious pace when it comes to new technologies, today's pharmaceutical industry is finding itself with little choice but to embrace the future.

In order to globally manage product quality and stay compliant on multiple regulatory levels, while also growing financially, the pharmaceutical industry needs to change its business model and leverage new technologies. Pharma simply can't face current business challenges without updated tools; chief among these tools in need of updating are IT solutions. When it comes to IT solutions, many pharma manufacturers have found themselves painted into a corner with costly legacy on-premise software.

Traditional software models in pharma involved the purchase of multiple commercial off-the-shelf systems, installed on internal systems. Then, in order to meet the complex, specific needs of the pharma industry, these numerous systems were cobbled together internally by onsite IT staff. Adding to the confusion, most systems were heavily customized.

While some level of customization is both expected and needed, it is not uncommon for pharma manufacturers to use hundreds of complex custom software applications to orchestrate manufacturing operations on the plant floor. Custom applications are often developed in-house, designed to work hand-in-hand with the legacy enterprise system.

Savings realized from adopting cloud-based ERP can be invested into other areas of the pharmaceutical enterprise.

What this means for pharma are multiple disparate systems, heavily customized, relying on legacy software that is often out of date.

There is a large amount of complexity and cost involved with upgrading legacy on-premise solutions. Additionally, software systems must be certified, which can be a time-consuming endeavor that involves internal and external resources. As a result, pharma organizations often are reluctant to invest in new applications and/or new software releases.

Companies sink more and more time and money into simply maintaining legacy solutions, leaving them unable to capitalize on new features that could help their business.

ERP GETS A BAD RAP

These frustrations have led to several misconceptions about software's culpability in an already complex pharmaceutical enterprise.

Past negative experiences with enterprise resource planning (ERP) systems that held the promise of manufacturing integration have taught pharma that the costs associated with implementing and maintaining ERP systems can quickly spiral out of control. The off-the-shelf prices of high-end ERP tools plus the costs of training, customization, and upgrades – not to mention the downtime associated with any of these tasks – cancelled cost savings and complicated an already highly regulated industry with high stakes.

According to a 2016 Nucleus Research study, the average total cost for setting up on-premises ERP systems – including software, hardware, consulting, personnel, and training – is about $8 million.[1]

Industry horror stories don't help ERP's case. In the late 90s, FoxMeyer Drugs, once the fourth-largest pharmaceuticals distributor in the United States, went as far as to sue both its ERP vendor and the integrator, claiming that a botched implementation drove the company to bankruptcy. While the lawsuit (settled in 2004) may have been an anomaly, historic ERP failures are not.

In 2008, a Gartner Group study of ERP implementations concluded that between 20% and 35% of all ERP implementations fail, and up to 80% exceed time and budget estimates.[2]

Additionally, the historic disconnect between the plant floor processes and the office-based systems that ERP was originally designed to manage – and the struggle to implement the two – have given birth to the misconception that perhaps ERP systems are ill-suited for modern manufacturing environments. In a recent report, Blueprint for Digital Success, PwC makes its opinions on ERP fairly clear. "Existing ERP systems do not have full capabilities to handle the more sophisticated data trends, analytic methods and algorithms that need to be used to provide the more advanced business intelligence and foresight that will be needed in the Industry 4.0 era."[3]

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CLOUD MOVES IN

Fortunately, today's ERP software is not the same ERP software that manufacturers struggled with 20 years ago. Growing acceptance of cloud-based software in the pharmaceutical industry is playing a key role in this evolution. According to PwC, "the cloud promises a new way to address ERP's most notorious challenges."[3]

Industry analysts believe that by 2018, almost one dollar in every three generated by the enterprise software market will come from

cloud subscriptions.[4] According to an Allied Market Research report, the global cloud ERP Market (worth $21.1 billion in 2015) is forecast to reach $41.69 billion by 2020.[5]

In 2009, software giant SAP – a company that built its empire based on on-premise ERP software – announced its plan to offer cloud-based ERP. Now a market-leader in cloud-based solutions, SAP has 125 million subscribers to its cloud solutions.

Cloud-based ERP solutions alleviate the heavy cost-burdens associated with on-site maintenance, upgrades and updates. With the right systems integrator, cloud-based ERP systems can be up and running in a matter of weeks. According to PwC, the total overall cost of ownership for a cloud-based solution can be 50 to 60 percent less than for traditional solutions over a 10-year period.[6]

Cloud software grants companies the agility and scalability needed to be successful in a new era of doing business.

PHARMA IN THE CLOUD

The realization that pharma's software struggles – multiple disparate systems, heavily customized, relying on expensive, outdated legacy software – can be rectified with the adoption of cloud-based systems is not new to the industry. Cultural struggles, regulatory concerns and validation challenges initially caused the pharmaceutical industry to proceed slowly, but the paradigm is now shifting as pharma recognizes the urgent need for a new business model.

Validation

After overcoming its initial fears surrounding security of cloud-computing, the pharmaceutical industry has turned its attention to validation challenges. The FDA mandates that companies validate computerized systems per 21 CFR Part 11, but considering this guidance pre-dates the common use of cloud-based ERP, compliance has caused confusion. The FDA's silence on how to apply traditional concepts of validation, auditing, and Part 11 compliance to a cloud-based model caused the industry to hesitate. However, an important new draft guidance, "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under Part 11 – Questions and Answers," was released this summer. This draft guidance attempts to clarify regulatory expectations for using electronic systems, including electronic records, cloud computing and mobile technology, in clinical investigations.

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Still, it is difficult to validate a system that's constantly being updated with new features. Despite that fact that the burden of maintaining cloud-based applications has shifted to the software vendor, pharmaceutical companies still maintain regulatory responsibility. Here we see numerous ERP system integrators stepping up to the plate, providing add-on "validation packages" that review new release functionality, determining if re-certification is needed and validating processes when required. Additional features such as digital traceability through eSign, validation of signatures, and process controls to enforce SOP, help companies meet compliance requirements with significantly less complications and costs.

Quality

The pervasive use of outsourcing and multiple suppliers in the

pharmaceutical industry means that quality management now extends beyond a company's manufacturing floor. Cloud-based ERP software dramatically increases connectivity with all players across the quality supply chain and aids in collaboration.

Cloud-based software enables pharmaceutical manufacturers as well as their multiple suppliers, vendors and contract manufacturers to access analytical and operational data together in real time, immediately gaining insights into trends and risks. Some cloud-based ERP solutions, such as SAP Business ByDesign, can be configured to hold as many required data fields as a company needs to ensure employees are not missing any critical data or skipping any regulatory steps.

Enhanced quality assurance functionalities included in modern ERP systems provide end-to-end capabilities and help to build quality directly into pharma's product design and processes.

Scalability

In order to respond quickly to changing market demands and inventory needs, the pharmaceutical industry requires scalable solutions.

Whereas on-premise software has limited capacity, cloud capacity can be upgraded to meet a company's changing needs. This means that pharmaceutical companies won't "outgrow" their ERP software. When a company's data storage needs or number of facilities change – as often is the case in an industry where mergers and acquisitions are common – its software can grow with them. Project teams can be quickly scaled up or down. With minimal effort, pharma manufacturers can quickly adjust cloud-based ERP solutions to meet their current needs.

Additionally, the material resource planning (MRP) functions offered in some cloud-based ERP platforms, such as SAP Business ByDesign, can bring measurable improvements to forecasting and inventory management. Advanced functions make it easier for employees to monitor supply and demand and manage inventory accordingly.

NEXT-GENERATION ERP

Changing business requirements

have pushed pharma's current IT solutions and tools to their limits, and without the right IT infrastructure, it will quickly become too expensive and burdensome to develop and manufacture drugs.

ERP software, however, has reinvented itself in the cloud. Truly the next-generation of business software, modern ERP is a digitization catalyst, allowing pharma manufacturers to capitalize on all the benefits of enterprise software, without the traditional costs and challenges associated with software implementation. Savings realized from adopting cloud-based ERP can be invested into other areas of the enterprise, allowing the pharmaceutical industry to pursue new innovative opportunities.

REFERENCES

1. Banks-Louie, Sasha (April 4, 2017). 10 New Reasons to Move ERP Into the Cloud. *Forbes.*
2. *Address Five Key Factors for Successful ERP Implementations.* (Aug 29 2008). Gartner Inc.
3. *Blueprint for Digital Success.* (April 13 2016). PwC Global.
4. *Information Technology (IT) Spending on Enterprise Software Worldwide, from 2009 to 2021.* (2017) Statista.
5. *ERP Software Market by Deployment and Function - Global Opportunity Analysis and Industry Forecast, 2013 – 2020.* (March 2015). Allied Market Research.
6. *ERP in the Cloud – Is it Ready? Are You?* (2013). Strategy&, PwC.