SECTOR ANALYSIS

Healthcare and Life Sciences:
Using Technology to Support Innovation and Cost Savings

WORLD QUALITY REPORT

2011/12

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HEALTHCARE AND LIFE SCIENCES

Using Technology to Support Innovation and Cost Savings

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This is an extract from the *World Quality Report* 2011-2012 which presents findings from a global survey completed online by over 1,200 CEOs, CFOs, CIOs, IT directors and managers, and quality assurance (QA) directors and managers around the globe. The goal of this report is to examine the state of application quality and testing practices across different industries and geographies.

The full report can be accessed at www.capgemini.com/testing or www.sogeti.com/testing.

The Healthcare and Life Sciences sector includes companies in the Pharmaceutical industry such as R&D, operations and production facilities, medical device manufacturers, as well as stakeholders in the public health sector. The industry itself is highly competitive, and the current state of IT investment clearly reflects this. The complexities associated with bringing new medicines or devices to market create a tremendous cost overhead. Today, IT plays a critical part in every aspect of the Pharmaceutical industry's operations, and Healthcare companies remain on the cutting edge of the technological innovation. During the economic downturn, Pharmaceutical companies were forced to curb their IT budgets, but not investing in information technology is simply not an acceptable alternative. To remain at the forefront of innovation, Healthcare businesses are finding ways to do more with less.

Today, many of the large Pharmaceutical companies are taking inventory of their IT systems as they are attempting to globalize and standardize their IT portfolios. They are working on reducing the number of applications as a measure to reduce costs. This, however, is proving to be an exceptionally difficult exercise. Naturally, it is hard to find packaged applications that provide the exact functionality that custom systems were precision-built to support. Additionally, most Pharmaceutical companies have multiple subsidiaries around the world that are used to their own, specific ways of working, and it is not easy to consolidate a large number of older, heavily customized applications into a single standardized system. Application modernization initiatives also require large initial investments, and by the time the new global system is operational, it can consume considerable IT resources. Plus, there is no guarantee that all divisions of the company will be aligned with the global requirements and will be successful in overcoming inertia and resistance to change.

Despite the large investment required for modernization and the obvious challenges, application consolidation and modernization are a necessity for today's Pharmaceutical companies. Their operations and processes are becoming more globalized; take, for example, the process of clinical trials. Traditionally, clinical trials took place close to the company's facilities, but the cost of running these complex programs locally has escalated so dramatically in recent years, that companies are increasingly looking to move parts of, or even the entire process, offshore – to locations such as China or India. In order to support this migration, pharmaceutical companies need modern IT infrastructure capable of handling sensitive data in a timely, secure, and cost-efficient manner. As a result, even in times of recession, making investments in centralized, consolidated and updated IT systems is absolutely critical for Healthcare businesses.

Quality is considered one of the most important factors in the Healthcare industry. Application functionality, usability, and performance are essential to the core operations of Healthcare companies, but even more critical are data integrity, availability, and security. One of the fundamental requirements of the Pharmaceutical industry is to ensure that computerized systems provide reliable data. Data integrity lies in the core of the regulations issued by government bodies such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA), and company policies around data security are subject to local government and industry reviews and audits. Similar to the Financial Services industry, where even a small discrepancy in each individual transaction can add up to large errors, even minor inconsistencies in pharmaceutical data can skew the results of a clinical trial or other important events. More importantly, data errors in the Pharmaceutical

industry can have a catastrophic impact on people's lives – with patients not receiving the right treatment or even harming people in the worst-case scenario.

Detailed guidelines govern all aspects of data security in the Pharmaceutical industry. Specific regulations such as FDA 21 CFR Part 11 or EU Annex 11 are designed to address the issue of electronic records and electronic signatures used in critical computerized systems. Our survey confirms that most pharmaceutical companies have adopted a lifecycle approach to application and data security where security is addressed throughout the system design, development, and QA phases (see Figure 29). Working in a regulated environment places additional demands on QA skill sets. In addition to knowledge of applications, platforms, and quality tools and practices, QA team members are required to have domain expertise and experience in regulatory compliance.

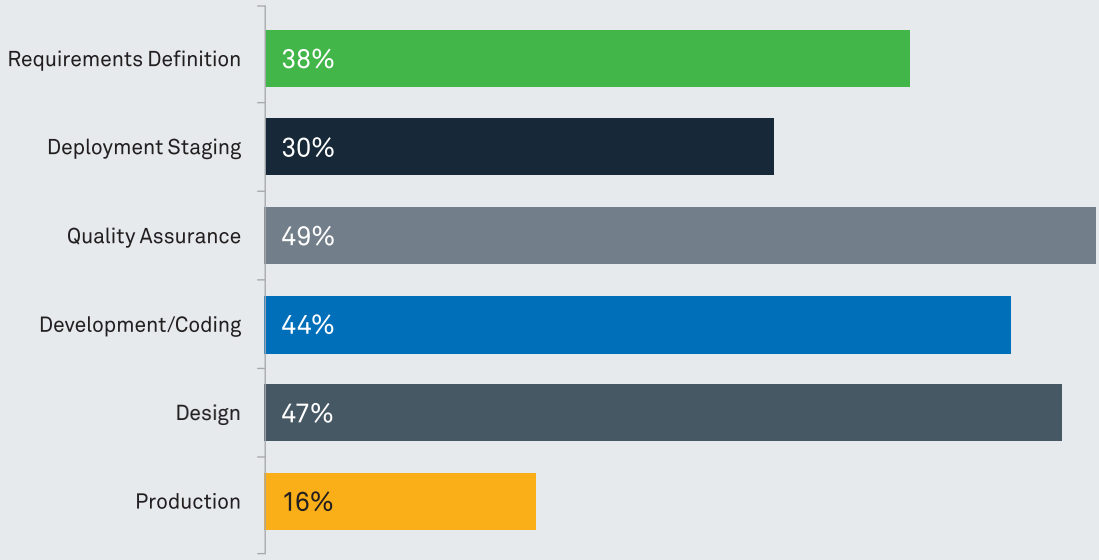
Data security and integrity concerns also play a key role in selecting new technologies – such as cloud computing. Although a majority (81%) of survey respondents state that at least some of their applications are on their way to being migrated to the cloud within the next two years, security is listed as the number one risk for using the cloud. Given the sensitive nature of some of the information handled by Healthcare companies, we expect that the systems being moved to the cloud will mostly be ERP packages supporting Logistics, Human Resources, or Finance functions. The most mission-critical production applications such as the IT systems that control core manufacturing processes are unlikely to be hosted in a cloud environment. Similarly, any information containing patient data is almost certainly going to remain housed within on-premise data centers due to country-specific privacy regulations.

One area that is likely to benefit from cloud technologies is application testing. The majority of surveyed pharmaceutical companies (73%) say that they use external contractors or third-party vendors for QA-related activities. Nearly two thirds of Healthcare survey respondents indicate that a portion of their testers are working in a nearshore or offshore facility. Having testing environments available on the cloud and using SaaS-based testing software licenses can significantly improve collaboration between the offshore providers and in-house project teams.

As the economic situation continues to improve, the level of IT investment among Healthcare companies will improve, as well. However, the new wave of spending will no longer be intended for maintaining a company's complex legacy applications. Pharmaceuticals will instead direct their IT resources to support innovation, modernization, and globalization. Application quality, security, and compliance will continue to be important disciplines for this sector due to the sensitive and highly regulated nature of their business, and Healthcare companies will always look for new ways to increase the efficiency of their QA operations.

FIGURE 29

IN WHAT PHASES OF THE APPLICATION LIFECYCLE DO YOU ACTIVELY PARTICIPATE IN APPLICATION SECURITY ASSURANCE ACTIVITIES (SELECT ALL THAT APPLY)?



Contacts

We value your comments and ideas. We welcome you to contact us in relation to any questions you might have concerning the 2011-2012 *World Quality Report*.

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Together, Capgemini and Sogeti have developed innovative, business-driven QA and testing services, combining best-in-breed testing methodologies (TMap® and TPI®) and the global delivery model, Rightshore®, to help organizations achieve their testing and QA goals. Capgemini and Sogeti have one of the largest dedicated testing practices in the world, with over 8,200 test professionals and a further 12,500 application specialists, notably through a common center of excellence with testing specialists developed in India.

More information is available at:
www.capgemini.com/testing
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