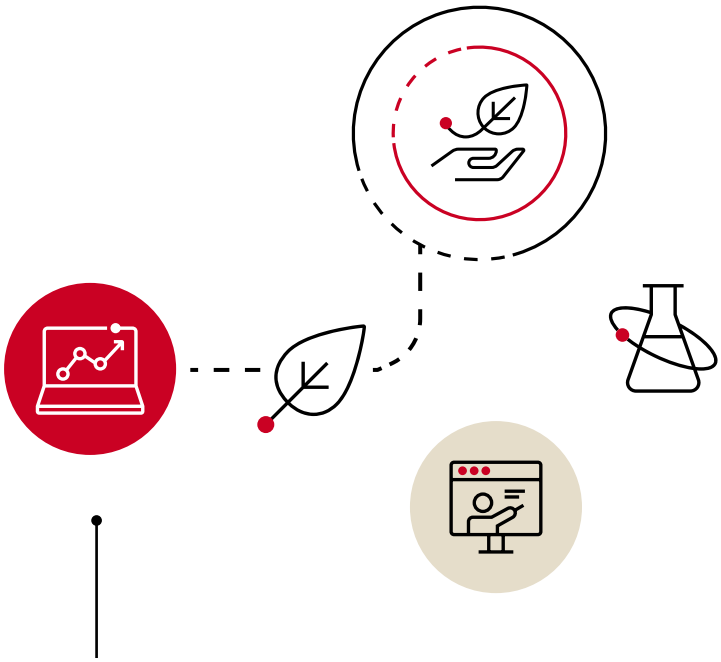

Why life science companies change learning management systems

Haroon Zikria
Senior solutions architect

Mark D. Lee, Ph.D.
Head of research and analytics

UL Solutions

Safety. Science. Transformation.™

For enterprise software buyers, the decision to rip and place software is never easy. It seems everyone has a horror story to tell about a new system implementation gone wrong. The many thousands of capital expenditure (CAPEX) dollars; the delays and their commensurate cost overruns; the promises of new functionality and capabilities that never materialize; the hundreds of hours of productivity lost while users got the hang of the new system, and on and on. Like jumping out of a perfectly good airplane, ripping out a stable, functioning, fully paid-for system and embarking on a new system implementation project can violate every visceral instinct for self-preservation. Studies suggest that the failure of human resource information systems projects, for instance, costs organizations in the United States alone at least $100 billion (USD) a year[1]

So how can a salesperson be so bold as to suggest a rip and replace? In the case of learning management systems (LMSs) for the life science industry, there are several cases — some smart and some unwise — that prompt organizations to embark on a rip-and-replace project.

Organic growth and expansion

Healthy companies grow. They expand in terms of headcount, revenue and product development, which requires specialized systems to support them. With these occurrences, the U.S. Food and Drug Administration (FDA) ratchets the scrutiny on the training. As companies grow, the burden of managing training qualifications manually or on spreadsheets can become overwhelming. Rudimentary electronic systems or limited functionality modules within another enterprise system will come up short sooner rather than later, and that means risk. That is the point at which a new LMS moves from "nice to have" to critical. The UL Solutions ComplianceWire® team is a frequent participant in this type of expansion. ComplianceWire® is a highly configurable system proven to accommodate small businesses and top 10 global pharmaceutical companies alike. Our customers include drug innovator companies, contract manufacturing organizations (CMOs), clinical research organizations (CROs) and any number of life-science-adjacent businesses that come under the scrutiny of global regulatory authorities because they know how to make, sell or support life science products that could place human lives at risk. Businesses choose ComplianceWire® as a proven solution familiar to regulatory authorities and the industry as a whole, with over 3.6 million current users and many more during its longer-than-20-year history.

[1]*Durmic, Nermina. (2020). Information systems project success factors: Literature review. Journal of Natural Sciences and Engineering, 2. DOI number: 10.14706/JONSAE2020218.*

Mergers and acquisitions

Within the life science industry (pharma, medical devices, biosciences), mergers and acquisitions happen all the time. As a result, organizations seek cost efficiencies by consolidating IT systems. The opposite may happen when a company splits or divests from a larger company. Companies need to decide what to do with their IT infrastructure and the data it contains. Sometimes that means buying a new version of the same system or moving to an entirely new one.

Rudimentary electronic systems or limited functionality modules within another enterprise system will come up short sooner rather than later.

Many organizations utilize different systems to provide training to their employees. Some have separate systems to store user and employee information, the organization's policies and procedures, and content, e.g., e-learning, videos. They may also have other required systems for manufacturing, such as a human resource information system (HRIS), manufacturing enterprise system (MES), laboratory information management system (LIMS), electronic document management system (EDMS), etc. Typically, the acquiring company prefers to use its existing systems and decommissions the acquired company systems. Some reasons for this are contractual obligations, more familiarity with their existing systems and minimizing their costs. One of the main systems affected is the LMS, and the result may be to use either their LMS or the acquired company's LMS. Some of the larger Fortune 500 companies may use multiple LMSs for different needs, e.g., quality, HR, clinical, but this typically isn't the case for small to mid-size companies.

These types of situations can go either way for ComplianceWire®. For large, well-established organizations that are not already our customers, there is a chance the decision about which LMS to keep can turn on factors other than full evaluation of the options. Companies are reluctant to go through an evaluation or change systems because if their current setup is working well, change can bring risk. Sometimes the systems integration and rationalization process in a combined company can take years. If an evaluation is based on system functionality, life science companies often recognize the superior economy of ComplianceWire® because it is validated out of the box, complies with important regulations like FDA 21 CFR Part 11 and EU Annex 11, and allows ready responses to the questions auditors and regulatory bodies might ask during a plant or clinical site visit.

Regime change

Change is constant. This is true in corporations in terms of management, structure and organization. When change occurs, it sometimes affects systems currently in use. New management may bring new ideas and strategies to improve outcomes in products and procedures and create new efficiencies.

The change in management can affect the current LMS by either replacing it with a new LMS and/or adding another LMS to meet the organization's specific needs. Newly arrived managers often have biases about which system will best lead to their desired outcomes. Although change is unavoidable, choosing a validated LMS for life science is critical and sometimes not well understood by people unfamiliar with the unique requirements of regulated industries like pharmaceuticals and medical devices.

Friction over the LMS can develop because HR typically favors learning systems that focus on employees' career growth and aspirations. Offering topics that learners want to learn about and allowing them to choose their courses is called "pull learning". In contrast, in life science organizations, quality and operations teams often decide what employees need to know and give them little leeway. Telling learners exactly what and how much they need to learn is a more traditional approach called "push learning". Their differing perspectives may lead the two groups to fear for their jobs and the organization's direction. HR doesn't understand why the quality and operations teams want to change an LMS that has been functioning successfully. And quality and operations may be concerned that losing control of the LMS will result in a system that doesn't suit their purposes and may lead to mistakes, lost time and lower quality. ComplianceWire® can help smooth the regime change processes. Customers who have used this system know its power, ease of use and life-science-ready features and often come back to it when dealing with another LMS change. In many cases, even when ComplianceWire® is a second LMS in a company, its ease of administration, role-based training and easy integration with other critical quality systems pay dividends in the form of reduced administrative positions, improvements in audit readiness and response, and reduction in IT support and validation needs.

Modern interfaces and ease of use

Sometimes, from either the learner's or the administrator's perspective, or both, the organization's LMS is nonintuitive and requires click after click to access basic functions. The incumbent LMS, however well it works, is certain to reach a point of diminishing returns when it is chronically difficult to navigate. It steepens the learning curve for new users, and it creates a drag on the system's adoption and users' enthusiasm for learning. With time and growth, the costs of lost productivity can become a serious problem. The need for an LMS with a user interface that evolves with today's rapidly changing software and technology landscape becomes apparent. What's more, a clunky, static user interface that is clearly outdated raises questions about how much the vendor is investing in its product.

ComplianceWire® has an active Customer Advisory Board, and we work hard to meet our customers' demands for an easy-to-use, aesthetically pleasing and fully functional user interface that meets their specific needs.

The incumbent LMS, however well it works, is certain to reach a point of diminishing returns when it is chronically difficult to navigate.

Regulatory compliance

An important trigger to a rip and replace is regulatory compliance. An LMS that falls short in meeting FDA 21 CFR Part 11 functional requirements results in precious time, resources and dollars wasted on validation and revalidation with each new release of software. An LMS that cannot produce its operational qualification (OQ), installation qualification (IQ) and performance qualification (PQ) procedures upon request represents a large hidden expense of the incumbent system that, by itself, often justifies purchasing a new LMS. ComplianceWire® is often the best choice when regulatory compliance is the new system driver.

Audit response

There are two types of organizations within life science: those that are currently being audited and those that will be soon. One common area that is audited is training. Auditors want to know who is qualified — and, more importantly, who is not — for their designated role. An LMS must be able to generate reports quickly and easily for an auditor. The information contained by those reports must be clear and concise, identifying who trained on what and when. These reports must also include an electronic signature of the individual's training record. When an LMS doesn't offer these functionalities, or makes it difficult to achieve the desired outcome, a change in the LMS is imminent. Again, this is a factor that heavily favors a system like ComplianceWire® that was designed around life science requirements and makes audit response simple and intuitive. Our professional services teams know from decades of experience what auditors are looking for, and that is baked into the reporting and the configuration of the system.

There are two types of organizations within life science: those that are being audited and those that will be soon.

Cost

Cost is an obvious consideration. But what is often less obvious and dangerously unquantified is the cost of not having certain critical features and functionality. Many software buyers will select the lowest-cost LMS option at the expense of some of the key components discussed in this paper. But buyer beware: Like anything else, you get what you pay for. This path frequently results in spending more money later to fix what a poor buying decision broke. Careful evaluation is required to understand and quantify the total cost of a system's operation. Often the licensing is not the only cost, but it is the cost that garners the most attention in the selection process.

More and better functionality

An LMS must provide the necessary functionalities for learning based on the learner's role or required corporate training. Training must be assigned, captured (with electronic signatures), tracked and reported on for the internal organization and for external audits required by government agencies, customers or third parties. A quality LMS will provide easily digestible reports and dashboards that translate the results of training. The right LMS will make these features easily accessible and configurable.

As stated before, the requirements of a growing life science company will quickly test the limits of a paper-based or low-functioning LMS. Evidence of your personnel's qualifications must be able to be produced at a moment's notice. An inability to do so in the face of the fast multiplying of documentation, procedures and policies makes for an obvious trigger for a rip-and-replace. The need for change becomes evident when the functional deficits of an LMS require workarounds or manual completion of tasks outside the LMS. Compliance managers run the risk that critical functionalities may be compromised or omitted completely.

The need for change becomes evident when the functional deficits of an LMS require workarounds or manual completion of tasks outside the LMS.

The “one hand to shake” paradigm

Within an IT ecosystem, systems must communicate with other systems via integrations. Depending on the resources an organization’s IT department may have, single-vendor solutions could provide an attractive option. The “one hand to shake” paradigm champions the cause of maximizing efficiency by consolidating vendors, contracts, purchase orders, etc. This presents a powerful case for change.

But as is often the case, perils can present themselves only after it is too late. Often the feature set of bolted-on submodules pales in comparison to pure-play solutions. Additionally, each submodule is often the domain of a different suborganization within the vendor, with different contacts for each component. Finally, many “integrated” systems aren’t really all that integrated. They are cobbled-together collections of acquired pieces whose seams are clearly visible and that do not interact very well. A recent study comparing integrated versus solutions in IT systems concluded that sacrificing functionality for the ease of dealing with one vendor partner can often short-change organizations by saddling them with less useful applications that require more human resources to operate than planned[2].

Many “integrated” systems aren’t really all that integrated. They are cobbled-together collections of acquired pieces whose seams are clearly visible and that do not interact very well.

---

[2]*Hennessey, T. (2021, January 3). The great IT debate: Best-of-breed or single suite? Supply Chain Brain. https://www.supplychainbrain.com/blogs/1-think-tank/post/32357-the-great-it-debate-best-of-breed-or-single-suite.*

Summary and conclusion

Rip and replace has outlived some of the ugliest aspects of its bad reputation. Cloud, or browser-based, software delivery has changed the game. Costs — both CAPEX and OPEX — have come down significantly. The instability that resulted when new software was installed on new hardware and then integrated into a corporate network is no longer as commonplace as it once was. And—as the moniker suggests—"best of breed" software is usually just plain better, with better functionality, which mitigates the need for expensive customizations.

While these factors and more have served to embolden software buyers to replace their LMS systems, substantial risk remains. It comes down to the mechanics of any other sound purchasing decision. Are the right people involved? Are the right questions being asked? Does the business have sufficient budget and institutional will to change? Is the procurement process thoughtful and coherent? Are the selection criteria tightly aligned with the goals of the business? When questions like these are answered well, a solid, well-reasoned business decision usually follows.

UL.com/Solutions

PLC23CS904817