

# **THRIVING IN A HIGHLY REGULATED ENVIRONMENT**

Compliance Powers Mandatory Learning

sumtotal<sup>37</sup>



# THE CHANGING AND CHALLENGING LIFE SCIENCES MARKET

Pharmaceutical, biotech, and medical device organizations operate in one of the most highly regulated environments in the world. At the same time, the entire life sciences industry continues to experience massive amounts of change as its primary purpose shifts from disease treatment to disease prevention. The end result is that all market players, including your own organization, will face even greater and more complex compliance demands in the future as your business processes become further automated, data-driven, and focused on targeting the needs of individual patients.

The pharmaceutical industry is built on continuous innovation, where long-time incumbents must become more agile to compete effectively with a mix of fresh startup market entrants and new entities formed through the mergers and acquisitions of long-time rivals. Increasingly, ad-hoc collaborative partnerships are forming as a way for two or more organizations to share the high cost and risk burden of bringing a new medication or a new medical device to market.

In all of these endeavors, your organization relies heavily on access to the expertise of a highly trained workforce whose learning skills require constant updating. For instance, the large number of acquisitions and divestitures in your industry may result in your organization suddenly onboarding new employees and gaining access to new products and technologies. You will need to quickly educate staff on all changes and be consistent in the new learning you provide. Consistency is also important, in how you communicate this information to your employees.

## THE TOP THREE CHALLENGES FACING PHARMACEUTICAL, BIOTECH, AND MEDICAL DEVICE ORGANIZATIONS LIKE YOURS ARE HOW YOU WILL:

1. Ensure the complete compliance and validation of all your systems, including learning management and talent development.
2. Maintain continuous innovation so that your organization can quickly and safely bring new products to market.
3. Educate your employees, such as sales teams, so they are always fully up to date on the cutting-edge developments at your organization.

# COMPLIANCE POWERS MANDATORY LEARNING

With an average annual compound growth rate of three to six percent, the global pharmaceutical market is on track to exceed \$1.5 trillion by 2023. However, the average cost of researching and developing a new drug is approximately \$985 million. While technologies like artificial intelligence may start to help organizations reduce their huge R&D costs, the industry is coming under increasing public pressure to cut prices as the market becomes more patient-centric.

Failure to comply with any aspect of regulations, such as those from the U.S. Food and Drug Administration (FDA), can have very costly consequences for an organization, potentially to the tune of millions of dollars. Your organization may be subject to substantial fines, you may be prevented from manufacturing or from marketing your new drug, or you may even face legal action. Additionally, you may incur remediation costs as well as sustaining significant damage to your organization's current standing in the industry and its public reputation.

Adhering to regulations and being able to document and demonstrate that compliance must be a part of every action your organization takes, including all of the processes relating to how you deliver mandatory training to each of your employees.



# THE INTERSECTION OF LEARNING MANAGEMENT, TALENT DEVELOPMENT, AND COMPLIANCE

As soon as your organization onboards a new employee, you will start that individual's training program to ensure that they already have, or can quickly acquire, the required skills to carry out their assigned role with your organization. To verify regulatory compliance, for instance, in adherence with Part 11 of the FDA's Title 21 Code of Federal Regulations (21 CFR Part 11), you also will be securely maintaining training records. These records will document the learning progress of your new hire, in terms of course and exam completions in line with your standard operating procedures (SOPs).

It is critically important to maintain a consistent alignment between learning and compliance so that you are always providing your employees with the latest version of the available training. For instance, whenever you make a change to your standard operating procedures, that change must be immediately reflected in the related training, and all relevant employees must then retake that element of the training so that they're fully up to date on the latest SOPs.

One way to help your employees deal with learning that is directly tied to your regulatory compliance is to make that experience more engaging, both in terms of the initial training session and any reinforcements later on. The key is to use a mix of learning mediums from the traditional instructor-led training to on-demand and micro-learning.

Consider how you might use augmented reality (AR) or virtual reality (VR) learning when the emphasis is on the learner having access to a safe environment where they can make and learn from their mistakes with zero consequences. At the same time, your organization will be able to harvest a significant amount of learning data from an AR or VR training session about how an individual employee performs on a given set of questions, problems, or tasks.

You can expect that your organization will encounter increasing regulations on how your employees handle and use patient data, which will translate into additional learning you will need to provide. As more and more information can be collected from wearables and other smart devices and sensors, for example, during clinical drug trials, your organization will need to document and demonstrate compliance with patient privacy. Consider another area where compliance is set to be a factor in new training courses you will have to provision: how your employees can safely share patient data to collaborate with their peers internally and externally with your partners.

# ATTRACT AND RETAIN EMPLOYEES BY OFFERING LEARNING FOR LEARNING'S SAKE

Pharmaceutical organizations, alongside other life science disciplines, are looking to attract many more employees, expecting jobs in their sectors within the United States alone to increase by 7% from 2018 to 2028. This pressure on hiring means that pharmaceutical organizations need to offer a more engaging employee experience, including learning and talent development opportunities.

Among pharmaceutical and life sciences CEOs, 60% are concerned about the availability of digital talent in their existing workforce, with 57% sharing they were already finding it somewhat or very difficult to attract digital talent. While turnover rates are lower at pharmaceutical organizations than other industries, losing a trained employee can have a major negative impact on the organization. Providing a more flexible working environment is one way to both attract new hires and to retain existing staff, including the ability for employees to access all training and career development at their own convenience and via the device of their choosing.



Estimates suggest that the average time to fill a nonexecutive position in the life sciences industry is **105 days**, equivalent to a loss of \$52,500 as that job remains unfilled.

Your organization, which has traditionally focused its learning program predominantly on mandatory training, is now also looking to offer employees access to learning for learning's sake. You will offer this type of training from onboarding throughout an employee's tenure with your organization. This commitment to talent development can help boost your appeal to new younger hires as well as encourage experienced employees to stay with your organization.

Much of this newer type of learning is geared towards upskilling and is centered on an individual employee's personal learning path. The content often focuses on empowering employees to improve their soft skills such as communication, collaboration, and future leadership. Your organization is also looking at just-in-time training, so that employees can quickly access learning assistance to check information and shorten their time to productivity. Virtual reality training can play a role here, enabling employees to quickly refresh their knowledge of how to run a particular process or to operate a piece of machinery.

You must also offer employees learning across a growing number of modalities to encourage self-directed learning, again with the aim of increasing employee retention. This includes showing individual employees what their career path looks like at your organization and highlight the skills that they will need to gain in order to keep moving along that pathway. Ultimately, you want to help develop agile, productive, and engaged employees who can learn at the same speed of change, impacting your organization as it operates within the fast-moving life sciences industry.

**The goal** is to provide short bursts of engaging, high-quality learning, which employees can consume at the time and via the device of their choosing. This learning will also be a regular weekly activity, perhaps taking 25 to 30 minutes out of each 40-hour work week. Over the course of one year, those weekly sessions could total as much as 26 hours of learning. To help with employee engagement, your organization may consider using socialization and gamification to encourage employees to share what they're learning with their peers.

# USE COMPLIANCE TO HELP YOUR ORGANIZATION THRIVE DURING TIMES OF MASSIVE CHANGE

What's becoming clear is that you need to be able to rethink all aspects of talent development, so that your organization can adapt and act more nimbly in the face of sudden major market and industry shifts.

Being able to automatically and securely deliver necessary training to individual employees and track that the training has been successfully completed is even more vital when your office-based staff have suddenly become mostly remote workers. This challenge is particularly acute across the pharmaceutical and life sciences sector where employees have been office-based or facility-based. You must still be able to demonstrate through your training records that your employees are licensed to operate and that they are immediately alerted to any changes in procedures and the subsequent requirement for any retraining.

Given the highly regulated environment in which you already operate, you may feel that your organization is well positioned to adjust to change. Alternatively, you may see massive sudden change as an opportunity to revisit all aspects of how you deliver and track mandatory training. You may look at how to further ramp up virtual learning, as well as expand your custom content for mandatory training and what would be required to validate that additional training.

Instead of continuing to hire people for specific pharmaceutical jobs, your organization might look to match skills with a particular task or project. This may mean less reliance on filling full-time permanent positions and more emphasis on hiring part-time and contingent employees. This approach clearly makes the issue of compliance more complex and in need of a solution that easily, clearly, and securely documents training. At the same time, you may want to develop your full-time employees to work in a similar project-based way, so that may mean that you focus more on encouraging them to gain skills that they can then easily transfer across different roles across your organization.

# YOUR TRUSTED AND EXPERIENCED LEARNING AND TALENT COMPLIANCE PARTNER

We at SumTotal have decades of experience in learning and talent compliance and in working with pharmaceutical, biotech, medical device, and clinical research organizations around the world. Seven of the twelve largest pharmaceutical manufacturers use our SumTotal solutions. Our customers include Abbott, AbbVie, Biogen, Daiichi Sankyo, Dr. Reddy's Laboratories, and Toshiba Medical Systems.

We understand compliance and the specific regulations for good practice (GxP) for the healthcare industry, which are core areas of functionality that we have consistently focused on since our early days as an organization.

## WE PROVIDE FEATURES TO MEET THE PARTICULAR NEEDS OF YOUR ORGANIZATION, BOTH TODAY AND IN THE FUTURE, WHICH INCLUDE:

- E-signatures
- Audit trails
- Course management
- Training and compliance certification
- Reporting and tracking in uneditable form
- Off-the-shelf learning compliance content
- Deployment options and upgrades at your pace to adhere with validation requirements
- Onboarding
- Career planning
- Talent assessment
- Performance management

SumTotal provides an end-to-end solution to meet all of your learning and talent development needs. With learning at the heart of our solution, we have built a unified suite around our award-winning Learning Management System. We infuse learning throughout the employee lifecycle to ensure success for your organization.

SumTotal solutions are used by companies of all sizes and industries, including airlines, financial services, healthcare, manufacturing, and pharmaceuticals. SumTotal is committed to continuous innovation with a focus on consumer-grade user experience and robust mobile capabilities to drive employee engagement.

SumTotal Systems believes that learning-centered talent development is the heart of HR and HR Technology, and that building a culture of learning is critical to business growth and sustainability.

Learn more at [sumtotalsystems.com](https://sumtotalsystems.com).



**ARE YOU READY TO TAKE  
YOUR ORGANIZATION'S LEARNING  
AND TALENT COMPLIANCE TO THE  
NEXT LEVEL?**

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# ABOUT SUMTOTAL

SumTotal provides a unified, comprehensive Learning and Talent Development suite that delivers measurable impact across the entire employee lifecycle. With SumTotal, organizations can build a culture of learning that is critical to growth, success, and business sustainability. SumTotal's award-winning technology provides talent acquisition, onboarding, learning management, and talent management solutions across some of the most innovative, complex and highly regulated industries, including technology, airlines, financial services, healthcare, manufacturing, and pharmaceuticals.

Skillsoft and SumTotal are partners to thousands of leading global organizations, including many Fortune 500 companies. The company features three award-winning systems that support learning, performance, and success: Skillsoft learning content, the Percipio intelligent learning experience platform, and the SumTotal suite for Talent Development, which offers measurable impact across the entire employee lifecycle.

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