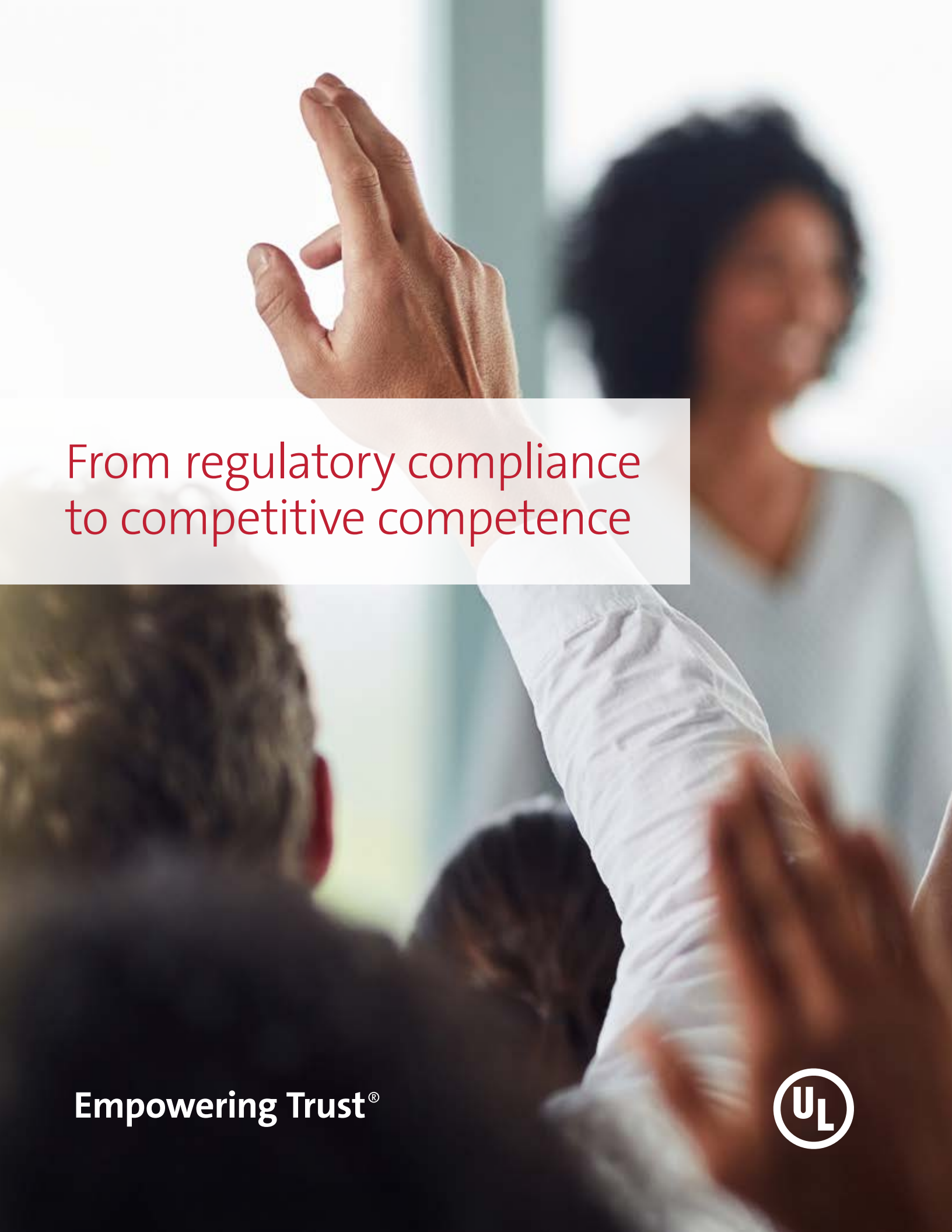

From regulatory compliance to competitive competence

Empowering Trust®

In this paper

- How forward-thinking companies are quickly moving from compliance to competency
- The shortcomings of current compliance training programs
- The impact of moving from compliance to competency

From compliance to competency

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The need to think beyond the standards

Although many organizations are able to obtain and maintain a high-level regulatory compliance, few have been able to translate regulatory compliance into a measurement of individual or organizational competence — moving from compliance to competency. This lack of movement could hamper organizations and impede progress. Within compliance-centric organizations, the focus tends to be on meeting minimum regulatory standards rather than moving beyond those standards.[1] Organizations that do not move beyond compliance are hindered in their efforts to build a workforce that is flexible, highly skilled and technically adept.[2]

For organizations to contend with the global pressures of changing labor markets, adhere to Current Good Manufacturing Practices (cGMP) and meet local and international rules and regulations, compliance is not enough. The days of simply using compliance measures as a checklist to ensure uninterrupted production appear to be coming to an end.

Why compliance Is not enough

Today, organizations with a skilled and agile workforce are top performers within their industry and have an undeniable competitive advantage. "An agile workforce is seen to increase productivity, profits and market share, to grow a business in a competitive market of continuous and unanticipated change and to enhance organizations' prospects for survival in an increasingly volatile and global business environment."[3]

Top-performing organizations know their workforce's skills and abilities and understand how to best utilize personnel based on their skill level to achieve higher levels of quality and maximum throughput. They have leveraged tools and techniques to ensure competency within a competitive global environment fixated on continuous improvement. When surveying organizations that have been unsuccessful at moving to the next level, the largest area lacking in a compliance-centric workforce is the ability to gauge and measure the technical skills and acumen of the workforce.

On a tactical level, this makes moving personnel from one job role to another difficult, time-consuming and uncertain. On a strategic level, long-term planning, workforce preparedness and employee-gap analysis become difficult, if not impossible. Being compliance-centric only leaves a huge blind spot within the organization.

Shortcomings in current compliance training programs

Often, the training program that brings an individual into compliance does not provide the technical skills needed for their role. Technical skill training tends to be highly separated from compliance training. This adds another level of difficulty, because management must then devise a method for tracking and monitoring an employee's competencies related to their current role as well as any future role assignments.

What is needed, then, are methods and tools to ensure employees are qualified for their current roles, and when gaps are discovered or created by market forces, managers can quickly react. This requires an intelligent and accurate view into workforce competencies. For organizations to remain viable and competitive, the status quo cannot continue.

In many manufacturing organizations technical skills are often overlooked, taking away much of their advantage. Technical skills require monitoring and active management because they most directly impact the product. The technical skills of an operator touch the work-in-progress and finished product multiple times and dictate how new products from engineering are manufactured as well as how long it takes to translate an engineered vision into a finished manufactured product. Technical skills can allow or inhibit quick changes to materials, production approaches or reactions to market forces. In short, technical skills are the lifeblood of a successful and profitable organization.

Why technical skills are not monitored or tracked

The reason technical skills are not monitored or tracked as closely as they should be is twofold: The first is that few tools are available to assist supervisors and managers on a daily, weekly or monthly basis to actively manage the ever-evolving needs of the production environment. Rarely does a supervisor have insight into the current technical competency level of the workforce today, tomorrow or in the future.

Second, most organizations do not know how to establish, monitor or manage their workforce's technical skills. Little training is available in this area, and the daily operational issues managers face tend to take the focus away from workforce competencies toward problem areas. Ionically, better management of the workforce's technical skills would eliminate many of the issue's individuals are facing on a daily basis.

Compliance to competency in practice

The need for change is so acute that organizations are being formed to specifically address this growing issue. In the field of clinical research, for example, a task force has been established to address the issue of competency as related to lead investigators.

In January 2013, the Multi-Regional Clinical Trials (MRTC) Center at Harvard University examined the need for clinical trial competency. From this examination, a group was formed called the Joint Task Force for Clinical Trial Competency (JTF). The group is currently working toward aligning and harmonizing the numerous focused statements relating to core competency for clinical research professionals into a single, high-level set of standards that could be adopted globally and serve as a framework for defining professional competency throughout the clinical research enterprise.[4]

The JTF's efforts have started the process of moving the clinical research enterprise from a focus on regulatory compliance to a focus on professional competency. This movement is based on the belief that the most effective method to ensure quality clinical trial design, conduct and compliance is to ensure that those responsible for the various aspects of a clinical trial are, in fact, competent.[5] This sentiment echoes throughout the compliance industry.

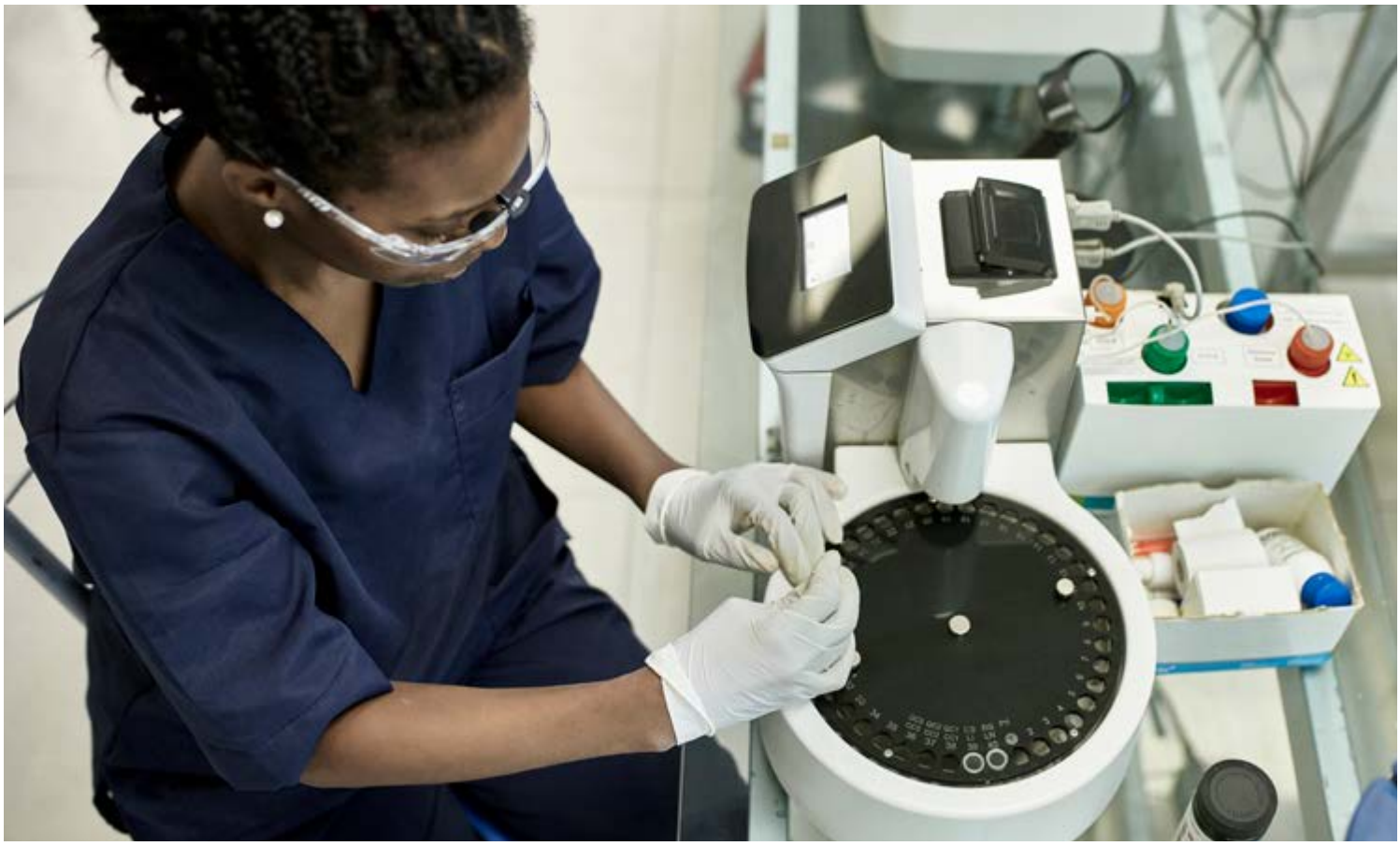
The mission of JTF's initiative is to bridge the large gap between "what to do" and "how to do it." These efforts are being accomplished by creating a universally applicable, globally relevant framework to identify competency domains and the associated cognitive skills necessary to conduct a high-quality, ethical and safe clinical trial. Similar efforts in the area of operational functions are needed and can have a dramatic impact on the organization if implemented correctly.[6]

The answer?
Operational skills management

The glaring lack of understanding around technical skills and related competencies define an employee's job function. This lack of understanding is heightened within compliance-centric organizations. Research on the use and implementation of workforce development models suggests that the use of intelligent and distributed systems and techniques offers responsive, flexible and multicriteria solutions.[7] For example, the JTF has found that, once the necessary competency is defined in the clinical trial setting, then it is up to the principal investigator, study sponsor and interested regulatory authority to ensure the study team member possesses the necessary competencies to carry out their tasks. If additional knowledge or skills are identified, appropriate training can be obtained.[8]

An equivalent process on the operational side of an organization is a model for defining and managing the necessary competencies known as "operational skills management." This approach involves identifying, preparing and retaining technical talent within an organization using a combination of training and skills-gap identification. Research has found that "training has a positive influence on the likelihood that firms undertake technical and organizational change."[9] Additionally, research indicates that, "when organizations bundle training programs together with human resource management practices that stress information-sharing, incentive-based compensations and greater attention to human resources selection, technological and organizational changes are more likely to occur."[10]

Operational skills management uses training, assessment tools, development strategies, readiness ratings and comparative profiles to improve technical employee performance. Think of it as a competency-based learning and development program. An effective operational skills management program analyzes and tracks information about an employee's level of potential and performance over time as well as retention risk.



An operational skills management program accomplishes a number of key goals for an organization

First: Merely undergoing the process of creating an operational skills management program forces an organization to define, assign value to and measure core technical competencies.

Sometimes, organizations implement a similar process for management or workers in other areas of the business, but technical competencies are a largely overlooked opportunity for gaining a competitive advantage. Many times, organizations can achieve a measurement of insight and advantage just by going through the process of defining technical competencies.

In this process, managers, supervisors and teams of employees define the competencies or qualifications for each critical job role through a process called competency mapping. Competency mapping is the process of identifying key competencies for a job and incorporating those competencies throughout the organization's various processes such as job evaluations, training or recruitment.[11] Technical competencies reflect technical skills expectations for an immediate, short- and long-term view of production. Once competencies are identified for each job, they are then assigned to specific roles.[12]

These technical competencies should be mapped to existing courses within the organization's Learning Management System (LMS). Whenever possible, organizations need to build on the foundation of their LMS to create an effective role-based technical-skills training infrastructure.

When technical-skill gaps are identified in the review process, those gaps can be mitigated by various means, such as on-the-job training, classroom or online instruction.

This systematic approach can drive business performance at many levels and provide insight to supervisors and managers about which skills are well-represented and which technical skills are still needed.[13]

Organizations can partner with well-established vendors to create and build programs to help them move from compliance to competency through an operational skills management program. Working with vendors familiar and comfortable with both compliance programs and technical skills provides opportunities for the best implementation of a successful program.

Second: Operational skills management programs often serve as a bridge between those who manage technical competencies and those who manage corporate or leadership competencies. While programs for managing corporate competencies are well-established and many competency models exist and contain universal components, technical skills are not always universally applicable. However, the language of and thinking behind competencies resonate with similar programs and can help garner support and resources when expressed in the appropriate language. The competency framework helps others understand the value and need for technical skills in a way that might not have been as obvious if presented in a different language or with a different approach.

Third: Operational skills management programs that properly define and measure necessary skills and competencies can be used to drive employee development, retention and business performance improvements. These programs help organizations to be staffed more cost effectively, especially during expansions or new market ventures. They also anticipate future redundancies and allow remedial actions to be taken, such as freezes, retraining and early retirements.[14]

The impact of moving from compliance to competency

An operational skills management solution allows for a dashboard-type view into the current state of a workforce's technical skills and offers the ability to quickly identify new and existing skills gaps. This provides a dramatic competitive advantage at every level of the organization. The sales organization can now pursue new customers knowing that manufacturing can gear up to demand, research and development can suggest new products knowing the workforce has the skills to manufacture them and production can accurately and confidently provide product-completion estimates.

When an organization starts to move its operational workforce from compliance to competency, "the categorization of competencies from novice to expert, or by professional role, can be a next step in this endeavor. Competency-based curricula or job descriptions can lead to standardization and elimination of redundancy in training requirements, standardization and accreditation of educational programs and better definition of career tracks and performance evaluations."[15]

The business impact of a competency focus

Focusing on competencies as opposed to a compliance-centric approach is not only ideal on a theoretical level, but it leads to tangible business results. One study found that two-thirds of firms achieved a competitive edge through developing and sustaining employee competencies as well as their ability to innovate, adopt new technologies and understand customers and their needs.[16] Additionally, the study found that competencies are a "forceful trigger and strong determinant for achieving individual and corporate goals and objectives. The responding executives, ranging from 75% - 85%, agreed that employee competencies are linked to business strategies, performance and results."[17] With findings like these, it is unsurprising that four-fifths of the sampled firms strategically linked employee competencies with productivity, profitability, business unit goals and objectives along with individual goals and objectives.[18] If organizations want to achieve an advantage in today's hyper-competitive environment, it is clear that few initiatives offer as much return-on-investment as focusing on the operational competencies of the technical workforce.

Moving from compliance to competency is becoming a requirement for top-performing organizations and improving their workforce's technical skills is emerging as a key driver in this transformation. Leading organizations have already begun to employ tools and processes specifically designed to ensure technical skills are valued and measured. The ability to measure, monitor and track technical talent within the organization is a critical step in moving away from a baseline of being merely compliant toward the competitive pinnacle of ensuring workforce competency. This affords organizations the ability to think strategically about technical competencies while making informed, data-driven decisions regarding workforce allocation and employee development. An operational skills management program can help your organization build the skilled and agile workforce necessary to gain a sustainable competitive edge.

CASE STUDY

Building a skills development framework

In a survey of UL's customers, more than 80% of respondents agreed that "competency management" programs that measured technical skills were important for "critical to quality" initiatives. We experienced this firsthand in 2014, as we assisted several customers in building measurable on-the-job training and mentoring programs.

We believe these projects underscore the need for our customers to formally map technical skill competencies for key job roles. As an employee progresses along a definedcompetency level, management can correlate this progress to compliance and business outcomes, e.g., reduced manufacturing cycle time, reduction in scraps, reduced audit observations.

In one particular skills-mapping project, our team worked with a pharmaceutical manufacturer to define a skills rating system for many manufacturing roles so employees could be better measured against this defined scale. Additionally, the company wanted their employees to be defined at a specific competency level for their role and gain opportunities to progress to new levels.

Conclusion

To accomplish this, we implemented a skills development framework to help the customer address both compliance and employee development challenges. Through this framework, we track to align with quality initiatives, so the end result is a stronger performing employee and improved quality metrics.

Skills development framework:

1. Identify each role within the manufacturing and operational processes
2. Define the skills and competency levels for each role, e.g., Basic, Intermediate, Advanced, Expert
3. Develop training programs that align to each skill and level
4. Track and report qualification for these programs
5. Assess each individual and rate them against the defined skill and level
6. Identify skill gaps and drive training that closes these gaps and drives an individual to a new level
7. Monitor skill development

ComplianceWire® is the best-in-class learning management system (LMS) designed specifically for highly regulated industries. Our team designed the platform to effectively and efficiently automate the creation, delivery, and reporting of role-based training, qualification and compliance programs for the life sciences industry.

This time-tested technology is used extensively by U.S. and global pharmaceutical, medical device and biologics companies as well as global regulatory authorities in the United States, China and India.

UL is a premier global independent safety science company that has championed progress more than 125 years. More than 14,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

Contact us today

To learn more about how to achieve enterprise-wide compliance, quality and performance goals with ComplianceWire® LMS, visit UL.com/compliancewire or call +1.609.627.5300 to speak with one of our LMS product specialists.

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