A Tale of Two C's:
From Compliance to Competency

THE NEED FOR SOMETHING DIFFERENT

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A Tale of Two C's: From Compliance to Competency

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The Need for Something Different

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 hampers organizations and impedes progress. Within organizations that are compliance-centric, the focus tends to be on meeting minimum regulatory standards, not on 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 check-off list to ensure uninterrupted production are ending.

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 the skills and abilities of their workforce and understand how to best utilize personnel based on their skill level in order 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 are not successful 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. At the tactical level, this makes moving personnel from one job role to another difficult, time consuming and uncertain. From the strategic level, long-term planning, workforce preparedness and employee gap analysis become difficult, if not impossible. Being only compliance-centric 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 his or her 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 and any future role assignments.

What is needed are methods and tools for ensuring employees are qualified for their current roles and that when gaps are discovered or created by market forces, managers can quickly react. This requires having 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 either not managed or so poorly managed that it does not provide much of an advantage. The primary reason that technical skills require monitoring and active management is because these are the skills that most directly impact the product. The technical skills of an operator "touch" the work-in-progress and finished product multiple times. The technical skills dictate how new products from engineering are manufactured and how long it takes to translate an engineered vision into a finished manufactured product. Technical skills allow or inhibit quick changes in materials, production approaches or reaction 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 could 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 continuingly shifting needs of the production environment. Rarely does a supervisor have vision 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 the technical skills of its workforce. Little training is available in this area and the daily operational issues facing managers tend to throw focus away from workforce competencies toward fighting a myriad of fires. Ironically, better management of the technical skills of the workforce would eliminate many of the fires those individuals are "putting out" 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 of 2013, the Multi-Regional Clinical Trials Center at Harvard University hosted a meeting of representatives from pharmaceutical companies, contract research organizations, academic institutions, clinical research sites and professional societies to look at the need for clinical trial competency. Out of this meeting, a group was formed called the Joint Task Force for Clinical Trial Competency (JTF). The group is currently working toward aligning and harmonizing the many 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 efforts of the JTF 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 this JTF initiative is to bridge the large gap between "what to do" and "how to do it." This is being accomplished by creating a universally applicable, globally relevant framework to identify the 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]

Compliance to Competency
THE ANSWER?
Operational Skills Management

There is a glaring lack of understanding around the technical skills and related competencies that 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 solutions that are responsive, flexible and multi-criteria.[7]

For example, the Joint Task Force for Clinical Trial Competency 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 that the study team member possesses the necessary competencies to carry out his or her 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 called, "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 stressing information-sharing, incentive-based compensations and a high attention on 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. It can be thought of 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, 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 and measure core technical competencies. Sometimes organizations have put a similar process in place 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 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 various processes (i.e., job evaluation, training, recruitment, etc.) of the organization.[11] The technical competencies reflect technical skills expectations for an immediate, short- and long-range view of production. Once competencies are identified for each job, the competencies are then assigned to specific roles.[12]

These technical competencies should be mapped to existing courses within the Learning Management System (LMS) of the organization. Whenever possible, organizations need to build on the foundation of their LMS to create an effective role-based technical skill 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 what skills are well-represented and what technical skills are 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 to manage 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 competencies and the thinking behind them resonate with similar programs and can help garner support and resources when couched 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 so obvious if presented with 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. This program can help organizations to be staffed more cost-effectively, especially during expansions or new market ventures. It can 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 technical skills of a workforce, and provides the ability to quickly identify existing and new skills gaps. This provides a dramatic competitive advantage at all levels of the organization. The sales organization can 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 estimates of product completion.

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 good on a theoretical level, but it leads to tangible business results. One study found that two-thirds of firms achieve a competitive edge through developing and sustaining employee competencies in addition to the ability to innovate, ability to adopt new technologies and the ability to understand the customers and their needs.[16] Additionally, it was found that competencies are a "forceful trigger and strong determinant for achieving individual and corporate goals and objectives. The responding executives ranging from 75 to 85 percent agreed that employee competencies are linked to business strategies, performance and results."[17] With findings like these, it is not surprising 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 competences of the technical workforce.

Conclusion

Moving from compliance to competency is becoming a requirement for top-performing organizations and improving their workforce's technical skills is emerging as the key driver in this transformation. Leading organizations have already begun to employ tools and processes specifically designed to ensure that 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 to 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.

The following Case Study is an excerpt from our *ComplianceWire Benchmarking Study; 2014 Results – 2015 Forecast*.

Download the complete white paper for more insights and to learn how to move your organization from Compliance to Competency.

ComplianceWire®
BENCHMARKING STUDY
2014 Results | 2015 Forecast

Life & Health

CASE STUDY:
Building a Skills Development Framework

In a recent survey of UL EduNeering clients, more than 80% of respondents agreed that "Competency Management" programs that measured technical skills were important to "critical to quality" initiatives.

We experienced this first-hand in 2014, as we assisted several clients in building measurable on-the-job training and mentoring programs.

We believe these projects underscore the need for our clients to "map" technical skill competencies formally for key job roles. As an employee progresses along a defined competency level, management can correlate this progress to compliance and business outcomes: reduced manufacturing cycle time, reduction in scrap, reduced audit observations, etc.

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

To accomplish this, we implemented a "Skills Development Framework" that could help the client address both compliance and employee development challenges. Through this framework, "knowledge gaps" are tracked, and aligned with quality initiatives, so that the end result is a stronger performing employee, and improved quality metrics.

Skills Development Framework:

1 Identify each role within the manufacturing and operational process

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 to 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 and track progress
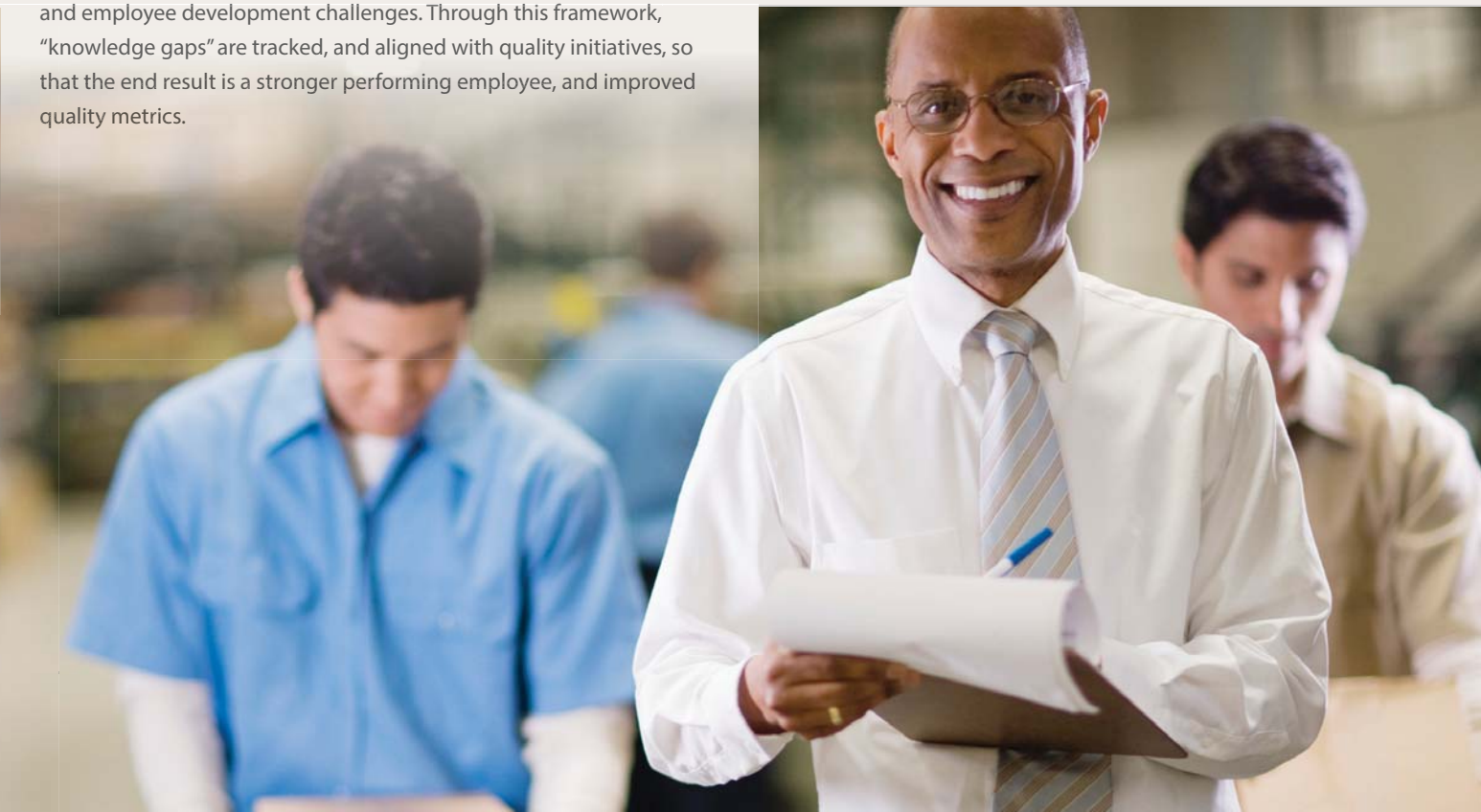
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About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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