UL Compliance to Performance

Benchmarking Study

2016 Review | 2017 Forecast

Foreword

In this report, UL Compliance to Performance presents the results of our annual Compliance to Performance Learning Trends' benchmarking survey, as well as critical knowledge projects with more than 400 Life Sciences companies in 2016.

This report also shares the top priorities of companies in 2017, and this year "Improving Quality Culture" was cited most often. What's clear from the results is that improving culture impacts people, processes and systems. Quality Assurance and Learning teams, as well as Operations, HR and IT, are making process improvements and harmonizing systems as well as modernizing their learning management strategies.

What's more, regulatory agencies are also seeking to harmonize their efforts, as the MAPD Single Audit program for medical device companies underscores.

Finally, we share 2016 data compiled in ComplianceWire®, in which more than 42 million training completions were recorded in 2016, a 14% increase over 2015 completions.

Our benchmarking study has been conducted since 2008, and we believe these findings can help shape our clients' learning and compliance best practices for the coming year.

UL Compliance to Performance leverages this feedback to consider technology features, such as better tools to analyze data to improve learning and development, experts, who have years of Life Sciences experience, are sharing guidance directly to clients to accelerate the cultural change that leads to production efficiencies, cost reductions, a more engaged workforce, and ultimately, improved profitability.

The Shift to a High-Performing Culture

For our 2016 survey, we wanted to know how Life Sciences Learning & Development teams were planning to broaden their efforts to achieve regulatory compliance, but also improve workplace morale and achieve higher performance.

In 2016, our client interactions revealed a shift from "training effectiveness" to a strengthening of both quality systems and quality culture. Many clients have told us that quality culture impacts employee behavior and their interaction with their environment.

Consider manufacturing firms and the many technical skills within the operations environment. Addressing incidents with a formal skill-building program and process improvement program does require time, investment and resources, but clients agree that the long-term impact includes an improvement in quality metrics such as deviations, complaints and lot rejection rates.

In our survey, we asked for top "performance" focuses for 2017, and the top two cited were "Harmonized Systems" and "Improving Quality Culture." We believe that a "harmonized system" that combines compliance learning and competencies can impact quality culture.

For example, clients have told us that when production employees begin to understand both the upstream and downstream functions across the entire production cycle, they gain the context to better "own" their stage of the process, and then seek continuous improvement of that process.

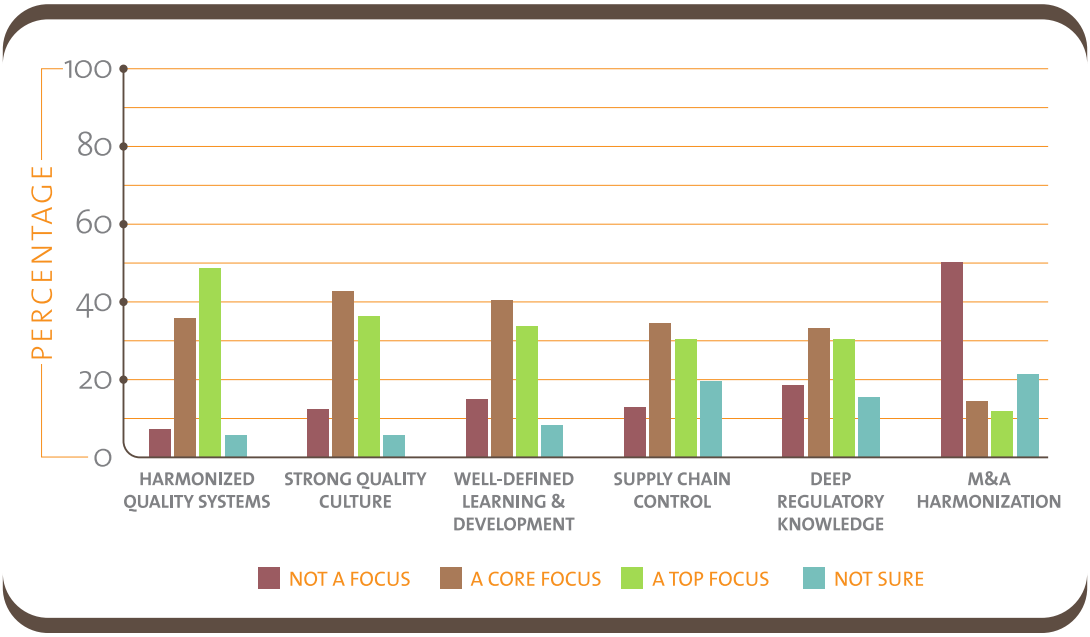
2016 Summary

The top learning priority was "Measuring Training Effectiveness," and US FDA and other global agencies continue to make the observations of "procedures not followed" on dozens of warning letters and 483s. SOP training continues to represent 65% of the learning activities captured in ComplianceWire.

Forecast for 2017

Many clients have told us that a learning strategy can be more critical than measuring training effectiveness. We believe that clients are seeking to embed best practices within their systems and processes, rather than make the attempt to measure the training effectiveness of individual programs within their production environment.

"Which statements represent a performance focus in 2017?"



Our Takeaway: A "Top Focus" for respondents in 2017 was "Harmonized Quality Systems" and "Strong Quality Culture."

Quality culture was defined in the following way: "we have a culture that's based on well-defined KPIs, and risk management best practices."

We believe that competency ratings can serve as performance indicators within the production environment.

The Competency Program's Impact on Quality Culture

In our survey, "Failure to Follow SOPs" was the number one training finding (for the second straight year). What's becoming clear is the typical SOP training exercise does not promote a continuous improvement mindset, and could actually stall the shift from compliance to performance. SOP training does not appear to change the mindset of operators who perform a task incorrectly because "that's how it's always been done." More organizations are seeking to move beyond SOPs and OJT checklists to help improve individual competencies.

A competency program has been shown to do more than just achieve audit readiness. A competency model empowers employees with the underlying knowledge to perform their jobs at the highest level of proficiency. As opposed to a training program, a competency model measures each individual's technical skills, and helps the individual strive for a higher standard. That's why competency programs have the power to reduce product failures, reduce work stoppages, and raise workforce morale over a long-term period.

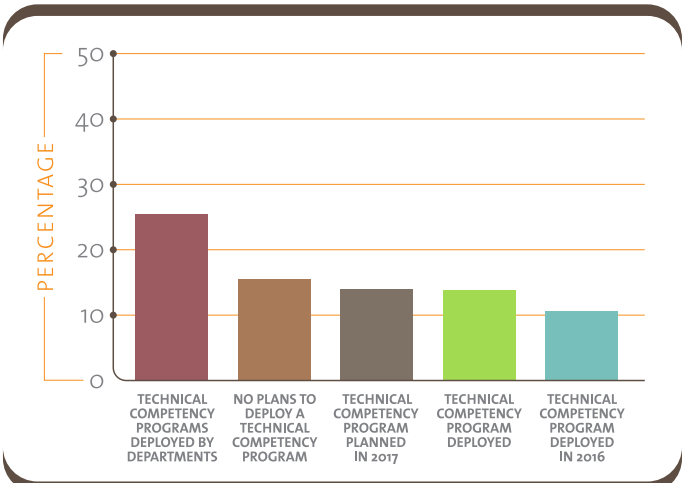
Goals of Competency Management Programs

Much like a leadership competency program, a "technical" competency program includes education, assessment tools, development strategies, and readiness ratings to improve technical skill performance. The program analyzes and tracks information about an employee's level of potential, performance over time, as well as retention risk.

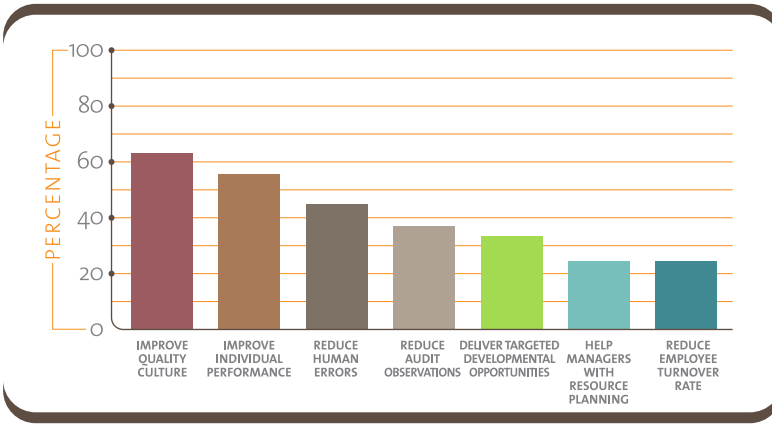
Nearly 40% of respondents indicated that an enterprise-wide "technical competency plan" was in place or would be in place during 2017. Another 26% of respondents indicated that individual departments had the ability to launch their own programs.

When we asked about the goals of the program, respondents cited "improve quality culture" most often.

"How does your organization manage technical (skill-based) competencies?"



"State the goals of your technical competency program."



"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." [1]

Source: Sonstein, S. A., Seltzer, J., Li, R., Silva, H., Jones, T. C., & Daemen, E. (2014), Moving from compliance to competency: A harmonized core competency framework for the clinical research professional, Journal of Clinical Research Best Practices. Vol. 10, No. 6.

Our Skills Development Framework: Improving Morale, Providing Opportunities

UL experts have developed a skills development framework that promotes a strong quality culture by increasing audit and compliance readiness, reducing failure incidents, and improving workforce morale by delivering advancement opportunities.

Assess each role within the area, and walk through the processes that each role interacts with.

Role and Importance: Enables companies to focus on specific skill sets, improves audit results when companies are asked for qualifications by role, and allows HR and department heads to identify potential recruits.

Define the skill levels and competency levels for each job function.

Role and Importance: Provides employees with the skill sets to advance along the "basic to expert path," and delivers more objective results for performance management.

Align similar roles, similar competencies, roles to competencies, and other relevant company scales.

Role and Importance: Allows for more targeted training, improves retention, and reduces over-training.

Develop role-based training programs, curricula, and technical competency models.

Role and Importance: Builds a competency management database that standardizes job functions and skill sets, while ensuring consistency and efficiencies across the organization.

Implement and deliver both training programs and technical competency programs.

Role and Importance: Ensures objective evaluation by integrating data from multiple sources. Results can be applied to performance reviews and part of an employee's advancement plan. Metrics may include a cohesive system of self-assessments, coaching/feedback, testing, performance demonstration, process metrics, e.g., manufacturing waste and rejections, and ongoing match-up of job descriptions with employee performance and training assignments.

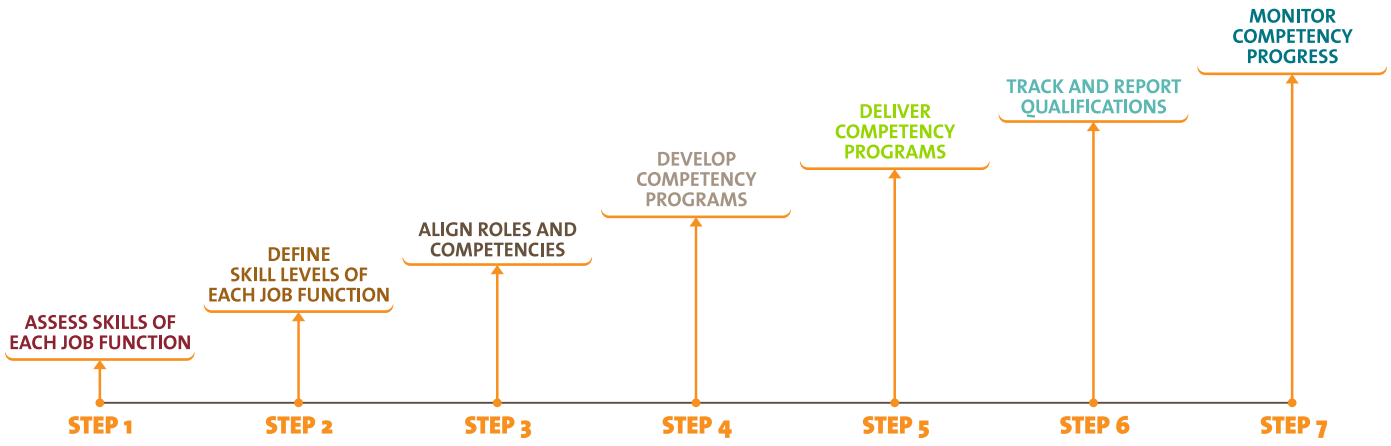
Track and report qualifications to these programs, identify skill and competency gaps, and drive training that closes these gaps.

Role and Importance: Puts predefined skill performance programs in place to improve manager coordination and consistency.

Monitor skill and competency development, evaluate if progress is on track, and adjust accordingly for each employee, team, unit, department, and physical location.

Role and Importance: Provide managers with ongoing progress reporting to ensure continuous discussions between managers and their direct reports.

UL Skills Development Framework



Addressing Global Expansion

In our survey, we learned that many global clients are seeking to expand their reach into the US for which FDA approval is required. Global clients need assistance in navigating and understanding the complexities of the ever-changing regulatory process. Clients are seeking to reduce delays or setbacks by gaining more knowledge about the changing regulatory landscape, and are seeking experienced advisors to ensure that their quality management systems, technology platforms, competency programs and product submission efforts will meet the rigor of FDA.

UL has a Readiness Assessment Solution that uncovers gaps in a company's processes, competencies and documentation. Our solution helps clients understand the status of their quality system and anticipate US FDA enforcement actions. For example, we conduct mock audits of our clients' quality systems, competency programs and records, and provide post-audit action and inspection awareness plans that prioritize corrective actions necessary to reduce non-compliance vulnerabilities in a sustainable way.

Top Ten Languages Used in ComplianceWire:

Language	Total Users	Users Added in 2016
Spanish (Latin America)	27,650	8,316
German	24,279	8,707
Chinese (Simplified)	18,748	5,540
Japanese	14,908	6,019
Portuguese (Brazil)	14,598	5,090
French (EU)	12,266	3,041
Italian	10,053	3,463
Dutch	7,904	1,410
Spanish (Spain)	5,424	2,940

Most Popular eLearning Courses in 2016

Top 2016 GMP Pharmaceutical Courses

1. Introduction to cGMPs
2. Principles of Good Documentation
3. Orientation to GMP Compliance
4. GxPs
5. Handling an FDA Inspection
6. Laboratory Safety
7. Principles of Aseptic Processing
8. Understanding GMPs for Facilities and Equipment
9. DEA Compliance
10. Change Control

Top 2016 Medical Device GMP/QSR Courses

1. Introduction to the Quality System Regulation (QSR)
2. A Guide to ISO 13485
3. An Introduction to ISO 13485
4. Complaint Management for Medical Device Manufacturers
5. Good Documentation Practices for Medical Device Manufacturers
6. Failure Investigations for Medical Device Manufacturers
7. Quality System Inspection Technique (QSIT)
8. QS Regulation 6: Acceptance Activities; Nonconforming Product
9. Design Control Regulations for Medical Device Manufacturers
10. QS Regulation 2: Quality System Requirements

Top 2016 Environmental, Health & Safety Courses

1. Hazard Communication
2. Bloodborne Pathogens — General Industry
3. Personal Protective Equipment
4. Fire Extinguishers
5. Hearing Conservation
6. Electrical Safety
7. Walking and Working Surfaces — Affected Person
8. Workplace Ergonomics: Factors to Prevent Injury
9. Lockout/Tagout -- Affected
10. Fire Prevention

Conclusion:

During 2017, we expect many clients to transition from compliance education to process improvement and competency management initiatives. For clients who have already started these initiatives, the results have been positive: improvements in quality, workforce morale, and overall productivity. UL Compliance to Performance is now delivering expertise and consulting to share best practices and guide clients on how to embed these best practices into their processes and systems.

To help our clients along their "compliance to performance" journey, UL Compliance to Performance will be providing these solutions in 2017 and beyond:

- Provide targeted expertise that addresses key challenges facing clients: entering the US market successfully, building a learning management strategy, improving audit readiness, conducting IT validation, and others;
- Deliver tools that provide visual analysis of their learning and compliance data so they can spot trends and make decisions on real-time completion data;
- Support our clients' need to address their performance management, goal management and competency management initiatives with proven applications used by dozens of world-class organizations.

About UL Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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