Using Training Data to Drive Up Quality Metrics

SURVEY OF QUALITY ASSURANCE EXECUTIVES
Using Training Data to Drive Up Quality Metrics
SURVEY OF QUALITY ASSURANCE EXECUTIVES

The FDA’s Push for Data and Metrics

For the US FDA investigator, the single word that best sums up the facility inspection focus is “documentation.”

For Life Science executives, the single word that best sums up a continuous improvement program is “metrics.”

Fortunately, Quality Assurance (QA) teams will find that training data and performance metrics are able to satisfy both regulatory agencies and senior management. Training data plays an important role in elevating specific quality processes. For example, on our validated LMS, ComplianceWire®, our clients leverage employee qualification programs related to specific continuous improvement projects, such as reducing production error rates or improving CAPA timeliness.

Our recent Survey of Quality Assurance Executives reveals that QA teams are seeking to document “training effectiveness” to demonstrate the impact that training has on performance metrics. What’s more, QA teams are using data to assure compliance with regulatory agencies, improve efficiency and generate cost savings through better production methods.

FDA officials have made the connection between production improvements and the company’s ability to meet its regulatory requirements. As the agency states in their “Quality System” description:

“Typically, a quality system identifies problems with device quality through review of verification and validation data, inspection/test data, analysis of device history and service records, failure analysis, analysis of complaints, and review of other objective data.”

“In this regard, reduction in productivity is often an indicator of quality problems. Low morale and confusion are indicators of inadequate procedures, and/or training and poor management. Also, measurement of scrap and rework is an effective method of detecting quality problems and reducing costs. These are examples of sources that provide feedback to the quality system.”
Recently, and as a result of FDASIA, the FDA has clearly stated it’s good to establish metrics that will help define its risk-based inspection process. FDA officials have been seeking industry input as the Agency develops a new metrics program for measuring drug quality. According to an article in the publication IPQ, the FDA recently asked Pharmaceutical companies for metrics in response to potential drug shortages:

“What metrics do manufacturers currently use to monitor production quality?”

“What kinds of manufacturing quality metrics might be valuable for purchasers and prescribers when determining which manufacturers to purchase from or which manufacturers’ products to prescribe?”

“What kinds of manufacturing quality metrics might be valuable for manufacturers when choosing a contract manufacturer?”

The fact that the FDA is asking for the same indicators that a company uses to improve performance should help QA teams in their efforts to champion the use of statistical methods throughout the manufacturing and operational areas.

**Life Science Companies Use of Training Data**

Each year, UL EduNeering conducts a benchmarking study to identify trends and best practices from over 250 Life Science clients. A key finding of the December, 2012 study was the importance of leveraging training data to support performance and compliance metrics. To dig deeper into this subject, we conducted an additional survey in June, 2013.

We asked respondents which best practices were being incorporated into their training programs. The most cited answer (82% of respondents) was “Incorporate training into process improvement projects.”

This finding points to two compelling trends:

- QA teams need to consider influencing behavior to support metrics, and as such, should measure the value of “training data” when developing process improvement projects;
- This training data needs to make the correlation between training effectiveness and achieving performance targets on key quality measures.

Because training programs play such a critical role in continuous improvement programs, it follows that QA teams must be able to properly measure effectiveness.
Training Modality

In our survey, we asked respondents how their QA training programs were being measured. The most cited answer (89%) was “on-the-job” training, which would include observations of workers by their managers on key job skills.

<table>
<thead>
<tr>
<th>“How Are You Measuring Training Effectiveness?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessments and tests on key equipment use, operational procedures</td>
</tr>
<tr>
<td>SOP delivered electronically with assessment</td>
</tr>
<tr>
<td>On-the-job training, such as Mentoring Observations</td>
</tr>
<tr>
<td>Classroom Events: Trainer-led events that cover procedures, policies, etc.</td>
</tr>
<tr>
<td>Develop well-defined certification programs</td>
</tr>
<tr>
<td>Online courses, either developed in-house or off-the-shelf courses</td>
</tr>
</tbody>
</table>

Again, this answer suggests several trends:

- FDA investigators have asked organizations to demonstrate “training effectiveness” and QA teams are responding by adding the results of “observational” activities to their qualification programs.
- The online learning system must deliver a method to capture these “On-the-Job” activities as easily as they record classroom training, so that QA teams can measure the success of the training program, and help explain the role that training activities had in reaching the metric’s “improvement target.”
- Blended learning and role-based qualification programs support learning effectiveness goals.

Audit Findings Most Cited Source for Improvements

So where do most continuous improvement projects originate? We asked respondents which metrics or operational indicators are being used to monitor production quality and GMPs.

“Audit findings” was the most cited metric. Many QA experts have written about the importance of using performance metrics against audit findings, which have included both internal and regulatory audits/inspections. Audit findings are a “forward-looking” indicator that the QA team can use to proactively address issues that may eventually cause a product failure.

For example, Roger Janczack, QA executive at Abbott, noted in his 2012 article, *Meaningful Performance Metrics for Compliance*:

> The audit process is a periodic snapshot of performance by an independent inspector... Internal audits provide ongoing feedback on the health of the quality system... Functional area self-audits offer an excellent opportunity for most proactive measurement.

Given that many Life Science companies target areas for continuous improvement based on audit findings, they can help QA teams define the training objectives that will ultimately result in reduced audit findings over time.

<table>
<thead>
<tr>
<th>“Which Quality Metrics Are You Using?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPA Initiations</td>
</tr>
<tr>
<td>Production Output Goals</td>
</tr>
<tr>
<td>Product Error Rates</td>
</tr>
<tr>
<td>Employees in Compliance</td>
</tr>
<tr>
<td>Employees Performance Ratings</td>
</tr>
<tr>
<td>Audit Findings</td>
</tr>
</tbody>
</table>

CAPA Initiations were the second most cited answer. Possible CAPA metrics could include the number of repeat CAPA citations, the number of investigations that lead to a root cause analysis, and number of days needed to respond to a CAPA.

Other past surveys have demonstrated that training completions is another indicator for quality improvements. Jeffrey Macher, Professor at Georgetown University, in a 2011 presentation at the Pharmaceutical Quality Conference Conference, noted that “training” was the second most cited “area of focus” to address the “Cost of Poor Quality Improvement” (with Six Sigma being the most cited, based on a PDA/ISPE survey of quality teams). In other words, quality process may not be at the root of the problem, but rather, the education of the people executing on that process.”

Making Metrics Visible to Management

Communicating the value of the metrics and the impact on the business is also an important area for QA teams to consider.

We asked QA professionals which activities would have the most impact on building a “quality culture” within their organizations. The highest rated answer was “providing management visibility into quality metrics.”

![“Which Activity Best Drives The Quality Culture?”](image)

Clearly, QA teams need to provide senior management with real-time reports that align training and performance metrics.

No matter which metrics are being used, training effectiveness is the method for improving performance. If the learning system cannot generate data that demonstrates actual knowledge transfer, then the QA team gains no empirical evidence that the training program offered any value.

For example, a QA team was seeking to improve manufacturing yield by introducing new process technologies in multiple facilities. The production teams were trained on the new procedures and equipment. The QA team not only documented training completions, they also conducted “mentoring” activities to observe the operators, so they could demonstrate that they understand the new process, and carried out the procedures properly. The QA team used online assessments and on-the-job observations that are tracked by qualified trainers in the production environment. Only then can “training effectiveness” be demonstrated by the team.

TRAINING EFFECTIVENESS AS A STAND-ALONE METRIC

In addition to using “training effectiveness” as a tool for other programs, some companies track training completion rates and training effectiveness as stand-alone metrics. Senior management may demand timely completion of compliance training with employees. In addition, a company will need to measure training effectiveness through assessments and “knowledge checks” that are embedded into many “high-risk” activities.

Another way to measure training effectiveness is to assess learners at the start of the program with an “ungraded” knowledge evaluation form. This same form is assigned 90 days later to measure the learner’s improvements in retention. These results also demonstrate whether or not the learners applied the material to their day-to-day work functions. For example, one metric may be the aggregate score of line operators on questions related to equipment use.
Cloud/SaaS Tools for Capturing Training Data

In order for these continuous improvement programs to succeed, companies must invest in a learning system that can easily capture the data for analysis, and also integrate with document management systems, quality management systems and HRIS systems. In the areas of training effectiveness, the learning system must provide the ability to capture completion data and assessment data. That LMS should be 21 CFR validated and be designed specifically to meet the needs of QA and the Life Science industry.

More than 250 Life Science companies leverage ComplianceWire® to improve training effectiveness, while also reducing the administrative effort needed to capture these records for audit purposes.

What many QA teams have discovered is the “compliance cost” and the “quality cost” related to e-mailing an SOP or policy to all employees, or holding a “lunch and learn” to walk through revised SOPs. These “one-way” training activities lack the ability to capture electronic receipt or understanding, and as such any documented record that the employees had successfully grasped the contents and could apply them to their job function.

ComplianceWire facilitates a “multi-modal” training effectiveness program that starts with a base knowledge assessment, then an electronic SOP review, followed by mentoring activities, video-based learning (appropriate for equipment operation), refresher training, and finally, a post-training assessment to measure proficiency.

By combining these various blended learning activities into a single curricula, QA teams can ensure that all responsible employees comprehend and apply the information needed to comply with GMP-related SOPs and other critical information and documents.

The FDA, under FDASIA, is focused on assuring that individuals are qualified to perform their job. A role-based multi-modal curricula demonstrates that qualification.

Conclusion

As the UL EduNeering survey reveals, Quality Assurance teams are relying on metrics to fulfill regulatory obligations, gauge progress and proactively identify areas for continuous improvement. When QA teams are able to capture training data as part of a continuous improvement program, Life Science companies gain these benefits:

- Managers can measure training program effectiveness and learner satisfaction.
- Employees gain more visibility into their progress on all activities, from qualifications related to equipment operation to complaint handling procedures.
- Managers can add “employee training completions” as a quality and compliance metric.
- Training costs can be reduced by using technology to automate role-based training and qualification programs. Travel costs and filing costs are reduced, while records are easier to manage and SOP training can be performed through online delivery versus face-to-face meetings. Assessments and on-the-job training observations provide real-time checks on behavior change.
- Compliance executives report reduced audit findings and observations related to training and qualification.
About UL EduNeering

UL EduNeering is a business line within UL Life & Health’s 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®.

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, UL 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.