Compliant. Connected. Complete. ™

master™
CONTROL

Introduction
FDA regulatory requirements and ISO quality standards mandate companies to execute and document employee training. (21 CFR 211.25 and 820.25) These requirements ensure employees understand how to perform their duties within company and industry guidelines. Well-managed training programs minimize the risk of non-compliance and improve product quality. This paper identifies the basis for the requirement and examines the associated challenges for meeting the requirement and the shortcomings that lead to general system failures. A new approach for meeting and going beyond the tracking requirements is presented.

Why Track Training?
The fundamental requirement for training
Implementing and tracking employee training is a sound business practice that allows companies to know:

- Employees are properly trained to correctly perform their tasks.
- Tasks a specific employee can perform.
- Employees can competently perform specific tasks.

Without this fundamental information, organizations:

- Create products with poor quality
- Create products at a much higher cost due to inefficiencies, scrap, rework, etc.
- Eventually fail, based on financial losses due to systemic failures or legal repercussions.

The fundamental requirement for tracking training
The auditor's mantra is: "If it isn't documented, it didn't happen." While entire chapters and books have been written to address the ISO Certification requirements, suffice it to say that to attain ISO certification, auditors require documented proof of a planned and systematic training process.

Moreover, tracking and documenting training is a **legal** requirement with regulated companies, including those regulated by the FDA, for the purpose of **ensuring** product quality. Simply, the stakes are too risky when dealing with ingested or injected products; therefore, the FDA legally mandates documented proof of required and completed training.

Tracking Training – How hard can it be?
After accepting the fact that training tracking is required, most people presume that it is a relatively easy process to implement. A common question is: "How hard can it be?"

The key information required to track training is:

1. Understanding what training is required.
2. Understanding what training has been completed.
3. Comparing those two facts to identify any gaps.
4. Using that information to close the gaps.

And for the most part, the presumption is accurate. Assuming that one knows the training requirements for a specific job, tracking training for an individual is not exceedingly complex. If anything, it may be considered tedious. This is an unfair presumption because the requirement is not to just track training for an individual, but for an entire organization. Therein lies the challenge.

Integrated
Quality Management

MasterControl Training helps manage the training process and integrate it with other processes
critical to regulatory compliance, such as CAPA, change control, audit, and customer complaints

Tracking Training – The challenges.
The most significant challenges when tracking training for an organization are:

A.   The Daunting Volume
        The sheer volume of tasks that must be handled when tracking training in a typical organization is
        challenging. The gargantuan volume of tasks are based on the following factors:
        •   There are many types of training, such as:
                •   Corporate Requirements
                        •   Company orientation
                        •   Safety
                        •   Environmental
                        •   Quality System
                        •   GMP
                •   Job-specific requirements.
                •   Machine-specific requirements.
        •   There are 100's to 1000's of specific job functions or tasks.
        •   There are 100's to 1000's of employees.
        •   These employees work multiple time shifts and typically at multiple locations.
        •   There is relatively high attrition in a manufacturing environment.
        •   And finally, re-training requirements means most training has to be repeated annually.

        In a medium-sized company there may be a million or more training tasks that should be
        completed on an annual basis for employees that work at different times and in different locations.

B.   The Follow-up Nightmare
Whether there are 1,000,000 training tasks or as few as 10,000, there is a significant communication challenge known as the "follow-up nightmare." The first step is identifying what training tasks need to be completed by whom. The next, and probably more challenging step is communicating the training requirements to the affected Trainees.

The problem is exacerbated because two-way communication is required. The Training Coordinator needs to communicate to the organization the tasks that need to be completed, and needs to receive communication from the organization when the tasks are completed. Furthermore, the initial communication is followed with reminders and escalations to only those that are delinquent in completing their training tasks.

C.   Organizational Struggles
Most organizations struggle as they encounter significant challenges with ownership and accountability when tracking training. These challenges stem from the delicate balance that exists between the training coordinators, who are responsible for tracking training, and the employees who are responsible for performing the tasks. By assigning the responsibility to track training to an individual, the organization implies that it is that individual's problem, not the organization as a whole, and certainly not the employee's.

This challenge is exemplified in the common method for handling training requirements and records. Because of the sensitive nature of the documents, they are typically stored in a secure location, accessible only by requesting permission from the owner. Therefore, if an employee wishes to review completed or upcoming training, the individual must physically go to a different location and request "viewing rights" from the owner. Unintentionally, the organization has created a barrier and inhibits its employees from participating in the training tracking.

D.   The Last-minute Audits & Inspections
Organizations typically receive advance notice of upcoming audits or inspections, but these notices may be only days or a small number of weeks prior to the audit. When the notice is received, the organization must decide whether to redirect its resources to prepare for the audit. In most cases, heroic efforts are required to continue the priority tasks during the day and address the audit preparations in the evening hours. As a result, the organization expends extra resources to produce less than desirable results to prepare for last minute audits and inspections.

E.   The Document Dependency
The mantra, "if it's not documented, it didn't happen," signals organizations' document dependency, but the dependency is rooted more deeply than a simple mantra. All successful manufacturing organizations view quality as a critical objective that saves money, improves customer loyalty, and improves time to market. Quality in manufacturing organizations is a function of:

- Creating the correct process design.
- Documenting the processes.
- Training personnel to refer to the documents and perform the processes.
- Executing with perfect (or near perfect) process repetition.
- Managing and documenting changes because materials, products, design, and the processes themselves are ever-changing.

As a result, manufacturing organizations pursuing repeatable quality are document-centric.
It follows, then, that the vast majority of training in these organizations is based on documents.
Before an employee can be trained on a particular procedure, the process for that procedure is
documented. In effect, the employee is trained on the document.

Industry sources confirm this tight connection between documents and training. Organizations,
consultants, and auditors agree that 90% of training in a manufacturing organization is triggered
based on new or changed documents.

Tracking Training – Alternative Solutions to Address the Challenge.

Tracking training is not a new problem. This section explores two approaches that organizations have tried and introduces
a third approach. All three approaches are evaluated based on their ability to address the challenges cited above.

The Paper Approach

The "Paper Approach" is a very common method used today to track training. The following scenarios describe this
approach:

- All training requirements for each position or task are documented on a physical piece of paper.
- All training records for each person are recorded on a physical piece of paper.
- All training certifications, resumes, accreditations, etc. are recorded on a physical piece of paper.
- All employees have a manila folder that organizes all physical pieces of paper.
- The manila folders are stored in a secure filing cabinet in a secure room.

While there are some advantages to using a paper-based system, most do not work. Tracking training on paper is feasible
only for the smallest companies. When organizations exceed approximately 100 employees, the paper-based approach
begins to fail.

Advantages

- The cash outlay for paper is obviously very inexpensive, however, the true costs lie in the time and resources
  spent trying to maintain the system.
- Paper is essentially a "clean slate" from which anything could be tracked, so one could argue that this
  approach provides the ultimate flexibility.

Disadvantages

- The primary disadvantage is the inordinate amount of time and effort that must be expended to manage and
  maintain a paper-based system.
- Even with extraordinary efforts, the paper-based system fails to meet the challenges addressed below.

Challenge #1 – The Daunting Volume

Without question, there are situations when a paper-based approach works well in high-volume environments. Raw
scalability is limited only by storage space required to store the documents. However, the paper-based approach fails when
used for tracking training because of the following change scenarios:

A. The organization determines it needs a new corporate training requirement. If there are 1000
     active employees, 1000 training requirement documents will need to be printed. These new
     training requirement documents will then be added to the 1000 folders.

B. The organization updates its corporate handbook. All 1000 employees require training. Training
     records for 1000 employees need to be inserted into the folders.

C.   The organization has 300 standard operating procedures (SOP), and work instructions. Approximately 33% of the SOPs are changed on an annual basis. If each employee was only affected by one of these changes (gross underestimation) that would result in 100,000 updated training records that need to be created.

Challenge #2 – The Follow-up Nightmare
To illustrate the Follow-up Nightmare, each of the three scenarios described in The Daunting Volume sections requires at least two touch points. The Trainee has to be informed of the Training Requirement. Then, the Trainee has to inform that the Training is completed. The number of touch points increase significantly when reminders and escalations are considered. The primary problem here is a communication issue. Simply put, the Paper-based approach provides no assistance for resolving this communication issue.

Challenge #3 – Organizational Struggles
The Paper-based Approach abdicates trainees from viewing the training problem as theirs. Rather, they view the person that owns the folders/papers as owning the problem. The Paper-based approach leads to significant problems with buy-in and accountability and perhaps more threatening, organizational struggles between departments with competing objectives.

Challenge #4 – The Audits & Inspections
The Follow-up Nightmare is magnified when scurrying to prepare for an upcoming audit or inspection because the training data is not current.

Challenge #5 – The Document Dependency
The Paper-based Approach is a standalone island of paper that doesn't connect to an organization's document control system, whether it is paper-based or electronic. Document changes magnify the problems associated with the Paper-based Approach by creating a higher volume of training records. Higher volumes intensify the Follow-up Nightmare by creating additional work for training coordinators that leaves the organization in a poor position to host an audit or inspection.

The Hybrid Approach
The Hybrid Approach is also a commonly deployed method for tracking training. The following scenarios describe this approach:

- Computer-based tools are used to help track the training data. Such tools include:
- Excel spreadsheets for creating "training trackers" that document each person's required training and completed training.
- Customized Access databases that serve roughly the same purpose as the Excel spreadsheets.
- All training requirements for each position or task are documented in the computer.
- All training records for each person are recorded in the computer and typically on a physical piece of paper. The paper is still required for approval signatures.
- All training certifications, resumes, accreditations, etc. are recorded on a physical piece of paper and may be noted in the computer system.
- All employees have a manila folder, that organizes all physical pieces of paper.
- The manila folders are stored in a secure filing cabinet in a secure room.

The Hybrid Approach leverages the computer where possible, but in most cases is still dependent on paper as the official tracking mechanism. Meaning, when an audit is performed, the auditor is typically shown the paper-based information as the official record. The computer software simplifies the process of creating and updating the documents, but is insufficient in providing a complete system and therefore must be used in combination with paper.

Advantages

- Basic computer tools, such as Excel, require limited investment. Often, the use of these tools reveals the limitations that lead to building an Access database. While the Access software does not require a significant investment, the internal "pet project" quickly escalates and gains a life of its own. In the end, the investment in building and maintaining the custom software is no longer an advantage.
- Like paper, a blank spreadsheet or database is extremely flexible. Conversely, this means every data entry, report, etc. has to be custom built.
- Basic computer tools do not support approvals, workflows, and electronic signatures. As such, these tools are limited to tracking training data as opposed to helping organizations control training information.

Disadvantages

- The primary disadvantage of the Hybrid Approach is the maintenance required to manage and synchronize two systems. The computer-based tools certainly ease the pain of creating and tracking some information, but significant time is still required to keep the paper-based system updated.
- Even with extraordinary efforts, the Hybrid Approach fails to meet the challenges addressed below.

Challenge #1 – The Daunting Volume
The Hybrid Approach faces the same daunting challenges as the Paper-based Approach because most, if not all, training records are based on paper to capture the official signatures of the Trainee and the person that verified the training.

Challenge #2 – The Follow-up Nightmare
The Hybrid Approach may simplify the process of identifying the affected Trainees, however, it does not address the communication challenges. Notifications of required training and communication of completed training still occurs via email, phone, or face-to-face communications and still requires the transmittal of signed documents. The training coordinator still faces the nightmare of knowing who has responded to the notifications, who has completed, etc.

Challenge #3 – Organizational Struggles
With the Hybrid Approach, Trainees do not perceive the training-tracking problem to be theirs. Similar to the Paper Approach, the Hybrid Approach centralizes the location of the data and assigns a responsible party. In other words, the Excel spreadsheets or database are still centralized with a training coordinator who acts as a gatekeeper. These computer solutions are not off-the-shelf software that can be placed into end user hands, and as a result, lead to significant problems with buy-in and accountability.

Challenge #4 – The Audits & Inspections
The buy-in and accountability problems lead to stale data that must be corrected (as much as possible) prior to the audit. The Hybrid Approach requires a heroic effort to attempt to update the paper-based records and create reports that are based on the updated information.

Challenge #5 – The Document Dependency
Like the Paper Approach, the Hybrid Approach is a standalone island that in no way connects to an organization's document control system, whether it is paper-based or electronic. Document changes only magnify the problems associated with the Hybrid Approach by infusing more Volume, which worsens the Follow-up Nightmare, which heightens the organizational struggles, and leaves the organization in a poor position to host an audit or inspection.

The "Training Control" Approach
The "Connected" Approach utilizes a computer software application that not only addresses the training tracking needs, but also provides "Training Control." More than passively tracking training data, a Training Control solution actively:

- Supports a distributed model that requires Trainee participation.
- Continually performs gap analyses between required and completed training for all Trainees.
- Automatically assigns training tasks based on the gap analysis.
- Allows Trainees to view their Training Tasks and training records as part of their day-to-day activities.
- Supports Trainees electronically signing when training tasks are completed.
- Synchronizes changes between documents (e.g. SOPs) and their associated courses.
- Automatically triggers required training based on linked document changes.
- Provides reporting of real-time data based on current status of all training tasks.
- (Maybe mention escalation).

Advantages

- The Training Control solution meets all training tracking requirements, but more specifically, addresses the most significant challenges that cause common solutions to fail. These advantages are discussed below.

Disadvantages

- The specialized Training Control Approach requires a larger up-front investment than either the Paper or Hybrid Approaches. However, this investment is quickly recovered based on the efficiencies gained and overall reduced training costs.

Challenge #1 – The Daunting Volume
The Training Control Approach leverages the computer to automatically perform gap analysis and assign tasks. Based on the power of the computer, the specialized solution scales to handle more training tasks than people can effectively handle on a manual basis.

Challenge #2 – The Follow-up Nightmare
The Training Control Approach transforms the Follow-Up Nightmare into nirvana (Whoa dude! ;-) because it addresses the communication challenges. The system automatically assigns training tasks to the affected Trainees when training is required. The system allows Trainees to sign-off when training is completed. Follow-up responsibilities are drastically reduced and those that remain are simplified via the use of reporting on real-time data.

Challenge #3 – Organizational Struggles
The Training Control Approach is designed with a distributed model that encourages and requires participation from Trainees. Each Trainee receives training tasks and views them by clicking on "My Tasks." Each Trainee views their upcoming and completed training records by clicking on "My Training Folder." With this naming convention, the system invites each Trainee to participate in the system, significantly improving both buy-in and accountability.

Challenge #4 – The Audits & Inspections
The Training Control Approach allows an organization to be audit ready in a moment's notice because it provides real-time training data. At any point in time, the Training Coordinator can view reports to represent the current status of training tasks for the entire organization.

Challenge #5 – The Document Dependency
The Training Control Approach morphs the Document Dependency into the Document Opportunity. Changes to documents can trigger the corresponding training tasks, either automatically or with optional human intervention. The impact of this capability cannot be underestimated. If industry sources are correct, this means that 90% of training in a manufacturing organization can be automated since it is triggered based on documents.

MasterControl Training - The "Training Control" Solution

MasterControl Training is a solution that addresses not only the standard training tracking requirements for an organization, but also resolves the challenges that cause other approaches to fail. MasterControl Training is one module in the MasterControl Integrated Quality (IQ) suite that enables organizations to control their documents, training, and quality processes.

By providing Training Control, MasterControl Training delivers the following benefits to organizations:

1. Realize substantial efficiency gains by going beyond "passive tracking" and implementing active Training Control.
2. Reduce training-related costs and improve timeliness by automating the 90% of training that is triggered by documents.
3. Increase employee retention by improving overall participation with skills development.
4. Dazzle both customer and regulatory compliance auditors with reports and a solution that clearly illustrate Training Control.
5. Improve corporate communications and culture by enabling the distribution of critical corporate communications with accountability.
6. Improve the bottom line by improving product quality through more effective Training Control.

Conclusion

To improve and ensure product quality, regulatory and certification agencies require organizations to track employee training. The Training Control Approach meets and exceeds the standard training tracking requirements and eliminates the challenges that cause other approaches to fail. Implementing a training control solution minimizes the risk of non-compliance and improves overall product quality.

About MasterControl Inc.

MasterControl Inc. has been at the forefront of providing quality management software solutions since 1993. Hundreds of companies worldwide use MasterControl to help ensure compliance with FDA regulations such as 21 CFR Parts 11, 210-211, 820, 606; ISO quality standards such as ISO 9000, ISO 13485, ISO 14000; and Sarbanes-Oxley Act requirements. In addition to providing off-the-shelf products, MasterControl also offers comprehensive technical and customer support, including product training, implementation, and validation services.

For additional industry white papers about automating quality and regulatory processes, visit www.mastercontrol.com, or call, 800-825-9117.

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