# KEEPING UP IS GETTING HARDER

HOW AN LMS CAN SIMPLIFY MANUFACTURING COMPLIANCE

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How an LMS can Simplify Manufacturing Compliance

From creating products by hand to the Industrial Revolution to Industry 4.0, there is no question that the manufacturing sector has grown and changed by leaps and bounds. In fact, without manufacturing we wouldn't have the very products that make our lives easier – from light bulbs to cars to the iPhone.
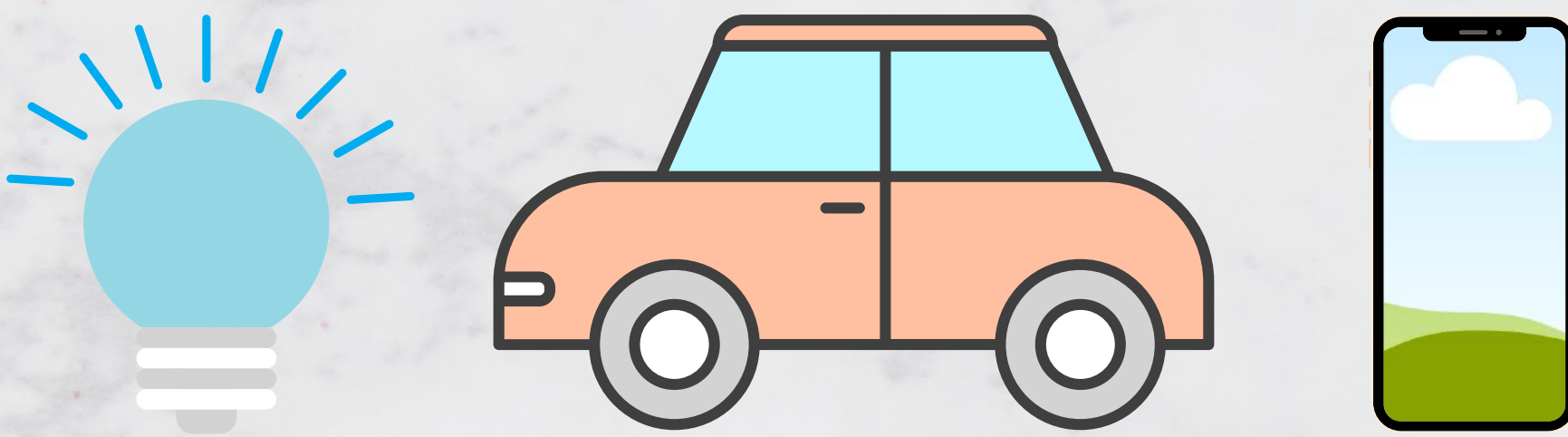
But, while the industry is trying to manage the fast pace of product innovation and delivering to the masses, they're being bombarded with more and more regulations that make it nearly impossible to keep up.

In the early days of the Industrial Revolution, working conditions were extremely dangerous. For example, children as young as 5 years old were operating machines that weren't equipped with safety covers or fences. Iron workers worked in temperatures of 130+ degrees every day and accidents on the job happened regularly (Industrial Revolution Working Conditions, n.d.).

 In 1833, The Factory Act was established, restricting the hours children could work and setting certain standards in factories. And so began the era of regulations (e.g. 1947 ISO standards, 1970 OSHA) – from employee safety to environmental protection and more.

Regulations have helped make the workplace safer but aren't without some disadvantages.

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Since 1981, the federal government has issued at least one manufacturing-related regulation each week (Gray, 2017) – with the Environmental Protection Agency (EPA) issuing most rules that impact industrial production across the US.

In recent years, it has been estimated that there are 297,696 restrictions on operations as a result of federal regulations (Gray, 2017).

The sheer number of rules is crippling for any industry, but especially for manufacturing.

The strategic goals of most manufacturing companies are to produce competitive products, operate profitably, and grow their business in an environment of increasing globalization and elevated product development costs. This is challenging already; but in certain sectors such as medical device and biotech manufacturing, the task is even more overwhelming due to the additional burden of dealing with the various facets of manufacturing compliance originating from the FDA, EPA, and SEC among others.

What's more, the costs of staying in compliance is staggering and more than any other sector, manufacturers bear the highest share (Cost of Regulatory Compliance, n.d.). Each year, they spend around $190 billion to comply with economic, environmental, and workplace safety regulations as well as regulatory compliance taxes. (Mecco, 2019)

$190 Billion

Manufacturing spends more on compliance than any other industry

And, if that weren't enough, non-compliance will cost even more.

A study from Ponemon and Globalscape reports that it is 2.71 times more costly for an organization to not comply with mandates. The average cost of compliance is $5.47 million versus an average of $14.82 million for noncompliance. (Merkulov, 2018)

Today, we are experiencing the 4th Industrial Revolution or what some call 'Industry 4.0' which is expected to bring with it a massive productivity boom that hasn't been observed since 1970. (Suri, 2018)

But, can the manufacturing industry keep up?

One thing is for sure, without a solution to efficiently combat ever increasing regulations, production lines are sure to come to a screeching halt and innovation will slow significantly.

This white paper will address specific training challenges of the manufacturing industry and provide a solution to simplify processes in order to create a highly efficient compliance system.

Why is compliance so problematic for manufacturing?

Training plays in integral role in staying compliant for the manufacturing industry. However, it's plagued with challenges that are difficult to overcome without assistance.

Manufacturers are faced with very demanding compliance and regulatory requirements. Not only do they typically employ a high number of employees, facilities are often widely dispersed across multiple locations and operations are highly interactive and regulated — involving multiple processes and people.

Not to mention, globalization of the market and the accompanying international standards they must abide by (e.g., ISO 9001, ISO 13845, IEC 61215 and IEC 61646).

As a result, delivering compliance training is much more difficult and complex. And, not every LMS can support the depth of data running through the system.

In other industries, there could be 20 SOPs to maintain as compared to hundreds or even thousands of SOPs a manufacturing business upholds.

At this level, many manufacturing companies start to have trouble finding a specific SOP, they aren't sure if they're working off the most up-date-date version of it and struggle to keep track of what employees read it or not.

And, this is just the tip of the iceberg.

They also must provide comprehensive reporting to the 'powers that be'. Without impeccable versioning and auditing capabilities they're left to answer for discrepancies in what is required versus what has been done – and this could lead to a very costly mistake.

Highly regulated industries, like manufacturing, continue to struggle with a myriad of regulations and then consequently having to make those changes to internal processes and practices.

But, no matter how difficult staying in compliance can be, not complying is catastrophic.

- Business profitability declines as a result of fines relating to compliance breaches
- Productivity lowers because of temporary shutdowns in production — unable to fulfill orders and money lost
- Employees, whose families are dependent on their salary, are burdened because of layoffs and unemployment
- Company reputation is damaged, or could be permanently destroyed, by non-compliance
- Public safety is jeopardized when product recalls happen as a result of not following regulations

A lot is at stake when manufacturers are unable to maintain compliance.

People get hurt, the environment suffers, and businesses are no longer able to focus on competitiveness and growth opportunities.

Don't end up being a manufacturing statistic. Keep the 'conveyor belt' moving forward by choosing an LMS that can streamline processes, minimize costs and, most importantly, help your business stay compliant.

How the right LMS can simplify compliance for the manufacturing industry

The right LMS should be a business's rock and 'best friend' among the rigors of compliance. The words 'simple' and 'compliance' don't normally go together, but they can.

Learn more about the specific qualities an LMS should have in order to keep up with the pace of highly regulated industries, like manufacturing.

Centralized Content Management, Version Control and Automation
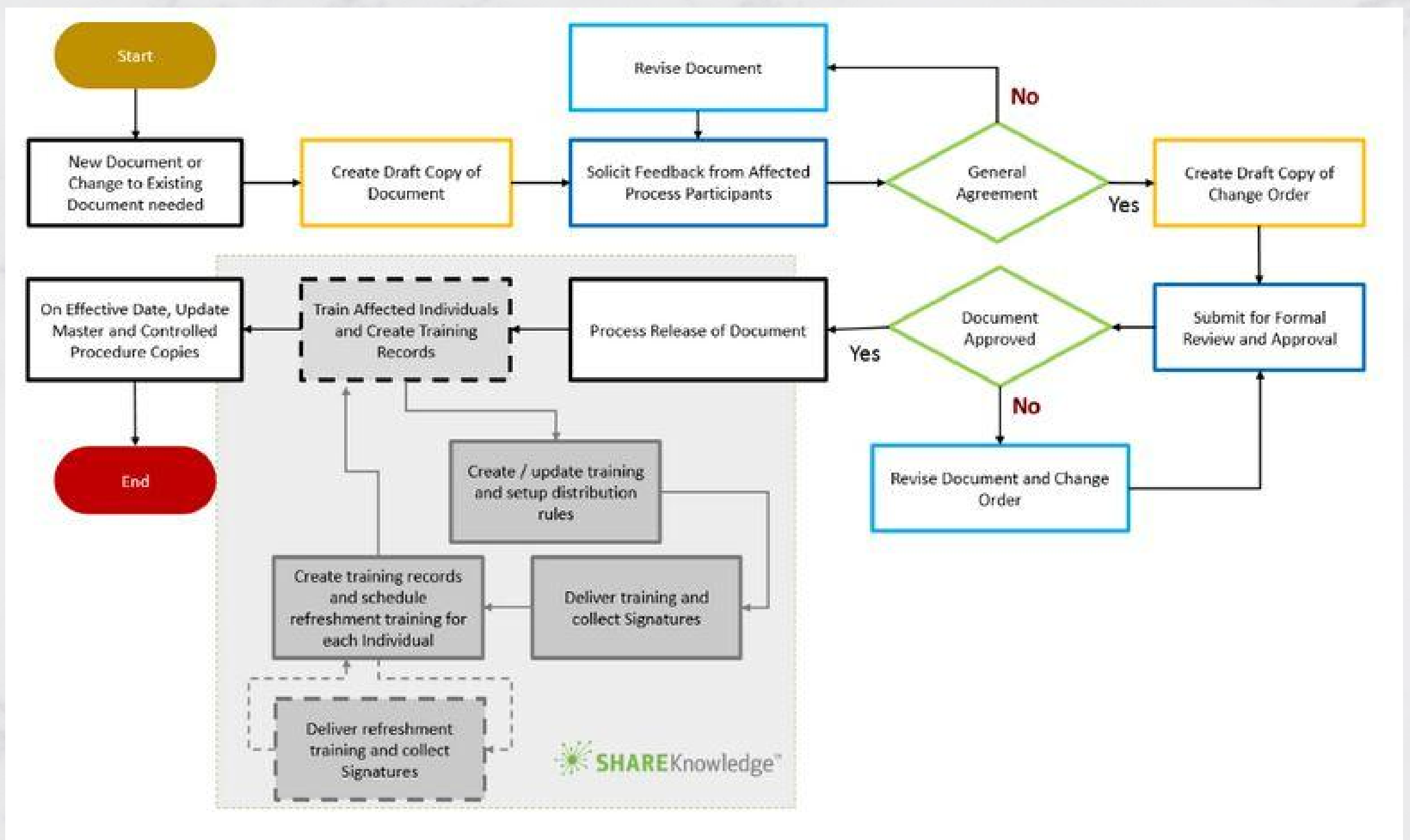
How is it possible to simplify anything when content is dispersed everywhere? It's not. A centralized content management system is a must when it comes to compliance.

Content management and how it works with an LMS will be a key feature to consider when evaluating training solutions.

So, whether it's integrated with an LMS or works as part of it, there should be no issue with finding a piece of content, knowing if it's the most current version or who was the last person to make changes.

Traceability also plays an important role in compliance.

At the drop of a dime, any administrator should be able to find out if an SOP or other compliance related material is up to date. There shouldn't be any discrepancies.

An LMS should quickly and efficiently help answer questions like,

- Who did what, when, and why?
- What change was made?
- Why was it made?
- Who requested it and who approved it?
- When did the change happen?

Maintaining a high level of complex content means version control is more important than ever. So, an LMS that is specifically designed for these situations, ensures a clear chain of liability and the security of fulfilling compliance requirements.

Human error also makes staying in compliance tough so automation will be a key piece of the compliance puzzle.

Automation does the work, so processes are streamlined and efficient.

For instance, every time an SOP is updated it should automatically revise courses throughout the entire system.

When there is a synergy between content management, versioning and auditing, staying in compliance isn't the regulation monster it used to be. In fact, common compliance gaps that happen with some LMSs are now closed, leaving a business with an airtight solution.

Reporting & Dashboards

It's not enough to just do the motions to stay in compliance, it must be demonstrated with comprehensive reporting.

Reporting can be a major hang up for companies that don't have a system in place that can handle the depth of information required by regulators.

So, an LMS that can satisfy the needs of manufacturing must not only be able to dive deep into specific data sets but also present it in an easy, understandable format.

Customization makes it possible to slice and dice the information in a variety of ways. And, when automation is added into the mix it makes the process even more efficient.

While there is a time and place for extensive reporting, it's also crucial to see a snapshot of compliance in real-time with the use of dashboards. This enables a business to be more fluid and make changes as necessary rather than finding out too late to correct the problem.
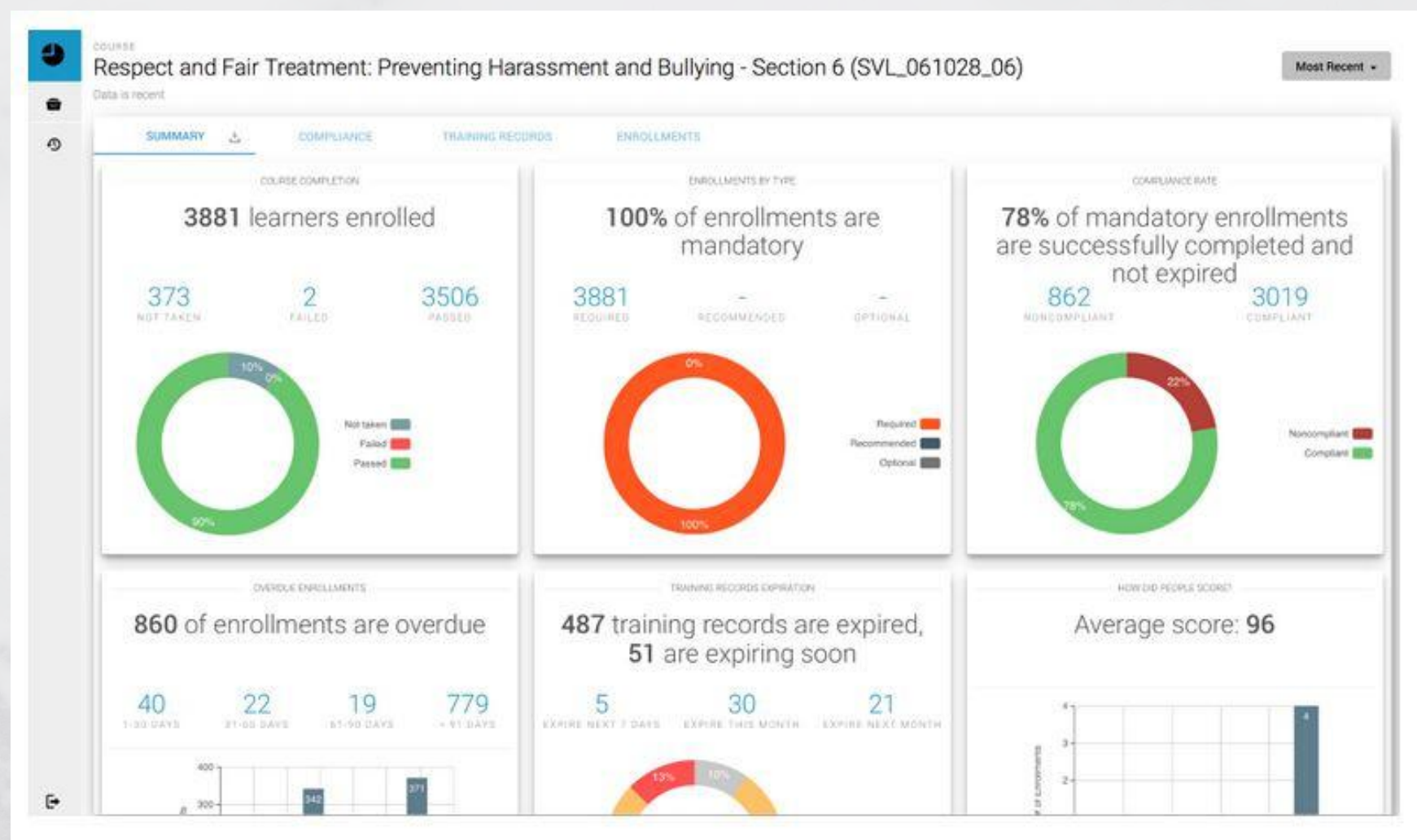
Instead of performing periodic audits, which can be time-consuming and a hassle, businesses can monitor the parameters of training that indicate compliance or non-compliance with regulations.

But reports aren't going to help at all if there are issues with creating or getting them into the hands of the right people.

Staying in compliance is difficult as is, so pulling a report shouldn't add to the stress. It should be quick and easy and the right people, not just the administrator, should have access to do so.

Mobile Training

In the case of manufacturing, there is an added level of difficulty when it comes to ensuring that all employees receive required training. This is because many of them are not in traditional offices but out in the field or on the factory floor.

An LMS that offers mobile training helps simplify compliance immensely.

Worker safety is generally the highest priority. The U.S. Occupational Safety and Health Administration (OSHA), for example, requires documentation that workers are protected against hazards such as electrical shock, chemical exposure and injury by industrial equipment. And, it's also required to record inspection certifications and other safety documents as well as to document postings of employee safety materials.

Mobile devices speed up documentation processes by allowing managers to record safety procedures electronically in production areas and eliminate paper-based recordkeeping. It also facilitates training for specific equipment on the plant floor. Workers securely log into the LMS from their phone and complete the necessary training, thereby decreasing the chances of straying from compliance requirements.

Security

Security and highly regulated industries go together like peanut butter and jelly. While having a secure LMS doesn't necessarily simplify compliance, it's a critical requirement that must be considered.

Manufacturing companies may be privy to protected intellectual property or top-secret products that haven't been released to the general public. Or, it could be a situation that they have processes that give them a competitive edge and prefer to keep it private.

In these cases, a system that keeps secure logs of whom has accessed it as well as when and where can be valuable.

Conclusion

With the right LMS, the manufacturing industry won't have to 'just keep up' but will be able to stay 'one step ahead' of compliance among ever increasing regulations put upon them.

But, not every LMS will be able to meet the expectations and requirements of the industry.

With so many moving parts, it's important to vet any potential LMS vendor thoroughly before committing to a system that simply won't suffice for compliance.

In order to simplify compliance an LMS must,

- Have centralized content management
- Highly efficient version control and automation built into the LMS
- Complex reporting and dashboards that are easy to create and distribute
- Provide mobile training for a dispersed workforce

As a result, what used to be stressful (i.e. compliance) is now manageable so businesses can redirect energy into more important matters such as producing innovative products that will have a powerful impact on the way we live.

Instead of worrying about 'keeping up,' the manufacturing industry can now arm themselves with an LMS that will have them declaring 'We're ready for you Industry 4.0, bring on the productivity boom!'

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