



CONNECTING THE COMPLIANCE DOTS

**DISCOVER 3 WAYS
TO SAVE VALUABLE TIME AND MONEY
ON COMPLIANCE**

Connecting the Compliance Dots

Discover 3 Ways to Save Valuable Time & Money on Compliance



Executive Summary

No matter the business, whether manufacturing automobiles or creating a new prescription drug, ever-increasing regulatory requirements lurk in the background threatening to wreak havoc on innovation. But, as the pressure to comply grows, companies are still plagued with manual and disjointed processes that cost them dearly in time and money.

But there is a better, more efficient way to adhere to strict regulations while continuing a path of growth and innovation. The following white paper will provide an improved way to address compliance — one that will help businesses stay compliant, save time and money as well as provide a direct path to future success.

Introduction

Our world is constantly changing but the pace of change has increased exponentially. The way we adopt and adapt to new innovations far outpaces 10, 20 or 50 years ago (Eisenstaedt, 2018). Consider this,

- It took the airlines 68 years to reach 50 million customers
- It took the automobile industry 62 years to hit 50 million drivers
- Within 12 years, 50 million people were using mobile phones
- Within 3 years, 50 million people were using Facebook
- Within 19 days, 50 million people were playing Pokémon Go

Innovation is what drives growth and, ultimately, business success. However, if a business isn't staying ahead of the game, they're done for. Or, as one of the most influential theorists on management once said [Peter Drucker], 'innovate or die.'

'The best way to predict the future is to create it.' - Peter Drucker

But, how is it possible to innovate when a barrage of new regulations is being introduced all the time?

Compliance has been around for a very long time but gained considerable momentum in the 20th century – and, with each new regulation came an increase in complexity. In 2019 there were almost 72,000 pages listed in the Federal Register (Young, 2020).

And, there's no end in sight.

Organizations are spending more and more time on compliance and increases are only expected to continue.

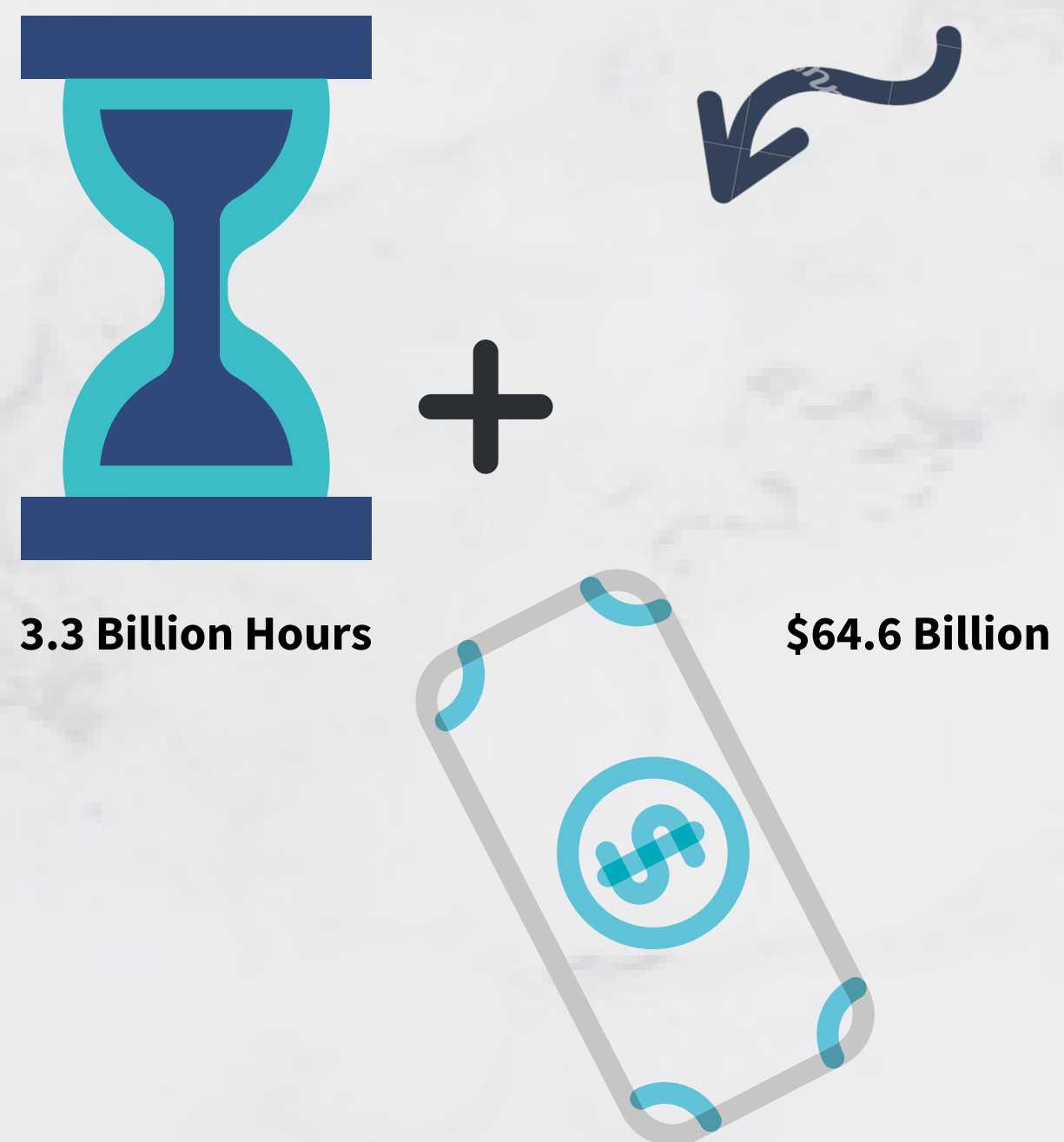
It's currently estimated that paperwork and compliance burdens alone total more than 3.3 billion hours and \$64.6 billion (Batkins, 2017).

So, what gives?

While there is a general movement towards digital transformation, many companies are still stuck between manual processes and automation — leaving them in a state of flux as time spent on compliance continues to increase each year.

These companies tend to be small and medium-sized businesses which are significant drivers of economic growth and innovation in the United States (US) — representing 99.7% of all US businesses and almost half of total private sector employment (O'Mahony & Ma, 2017). But, don't be fooled, the struggle is just as impactful for larger companies as well.

COMPLIANCE BURDENS



Regardless, many companies are still not changing their approach despite the increase in time required for compliance activities. When companies leverage labor-intensive processes across decentralized teams, it only drives an increase in cost.

Some of the biggest challenges for companies using manual processes are (Picot, 2019),

- Consolidating data from various departments
- Incorporating changes to existing regulations, and complying with new regulations
- Access to compliance data

The consequences of these challenges add up. Each new hour of paperwork means less productivity, fewer profits and diminished competitiveness.

The following white paper will discuss the three critical things every compliance program needs and how to incorporate them into training programs in order to save valuable time and money as well as improve overall compliance. As a result, companies will experience,

- **Consistency maintaining compliance** with real-time reporting and streamlined processes that work as part of the entire business ecosystem
- **Time and cost savings** by shifting from manual processes to automation
- **Better communication** among key business units and processes
- **Improved agility** when regulation changes occur

Tip 1: Powerful Integration is the Key to Significantly Reduce Risk

There are many moving parts when it comes to compliance — involving hundreds of people and multiple departments.

For highly regulated industries,

1. Business activities are usually dispersed among multiple regions, offices and factories. And, it's common that they require additional compliance training that goes above and beyond general training programs

MOST FREQUENTLY CITED VIOLATION

#1

**Failure to follow established
SOPs**

2. Ever changing regulations make it nearly impossible to manage at scale which leads to one of the most frequently cited violations—failure to follow established SOPs

3. There is very little way to know if compliance is being met until it's too late because data isn't accessible

Corporate training is a small piece of the compliance puzzle but a very important one. Yet, it's continually expected to live and perform in isolation. This results in,

Disconnected training activity. Different departments operate more like separate businesses, rather than as a unified whole

Lackluster communication. It feels like the right hand isn't talking to the left hand, creating chaos and errors

Duplicated efforts. Everyone is recreating the wheel — which slows forward progress

With that said, all the above creates a perfect storm of chaos and inefficiency. It's no wonder that companies complain of having trouble consolidating data and keeping up with changing regulations.

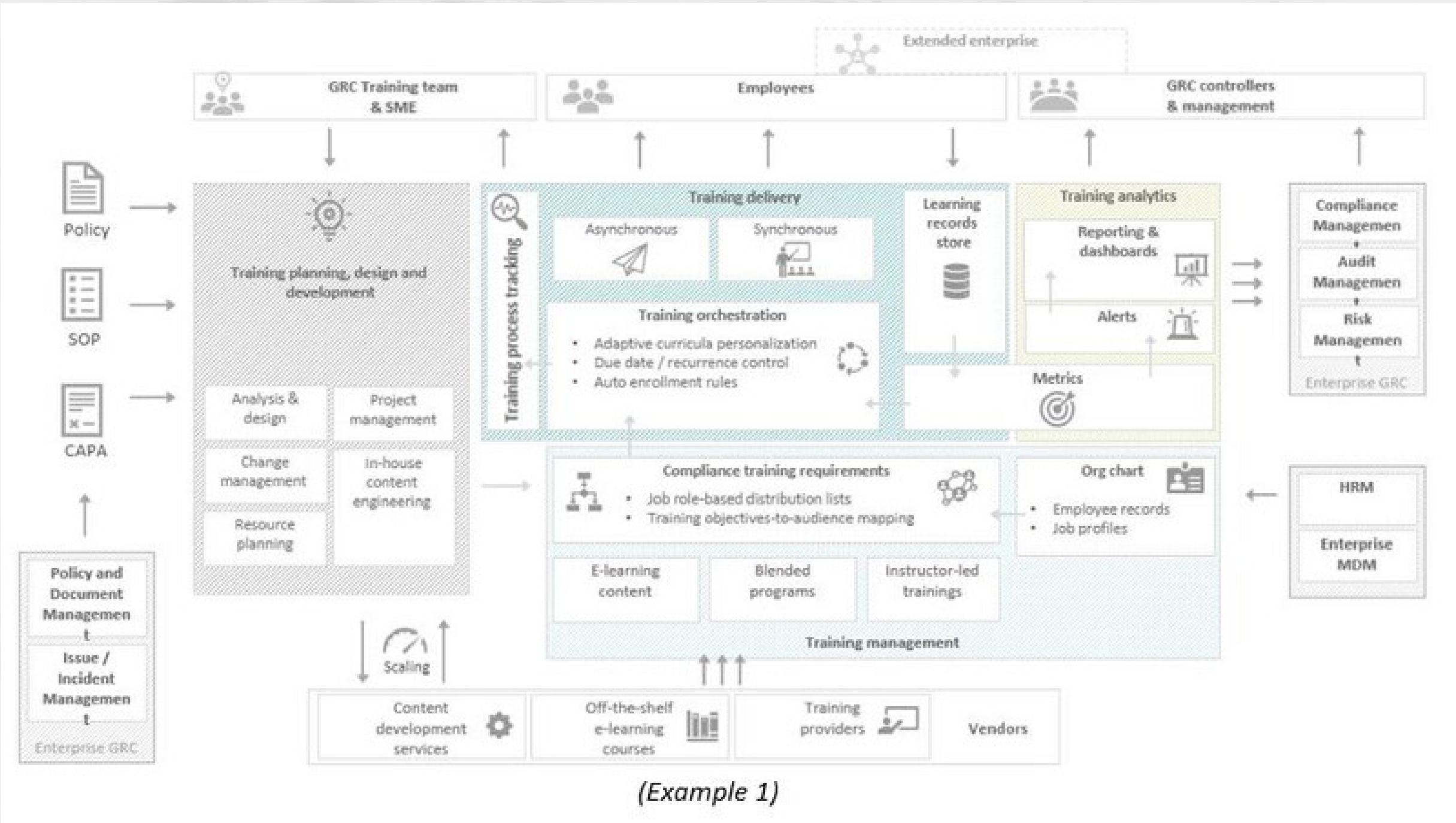
So, what's the answer? Integration.

In order to elevate a compliance program from ‘mediocre’ to ‘great,’ it must be integrated into the bigger picture and perform as part of the whole.

But true integration doesn’t mean the occasional meeting between business units or collaboration on a regulatory project. These are totally different things and too many companies are under the false impression they’re one and the same.

While collaboration is good, it still leaves gaping holes conducive for non-compliance. In order to have a bulletproof program there must be a cohesiveness, via integration, within the entire business ecosystem.

The illustration below is a perfect example of what an effective, integrated compliance solution should look like.



It’s simply not enough to throw training at employees and have them check the box that it was completed. There needs to be a behavior change and a clear systematic path of compliance from start to finish.

Integration is one of the puzzle pieces that solves some of the biggest compliance challenges of highly regulated industries. Notably, manual and disjointed processes.

People

Integration improves communication significantly. Instead of ‘the right hand not talking to the left hand,’ both hands are woven together in perfect harmony.

A ShareKnowledge client in the Oil & Gas industry is an example of how integration improved existing protocols.

As with other highly regulated companies, the client was dealing with hundreds of business units not being able to conduct training programs specific to their needs without interrupting central HR and compliance. On-boarding was significantly slowed; productivity did not fare well and their bottom-line took a major hit.

In a nutshell, communication was poor.

With so much disconnect, there was a lack of confidence around what one another was doing nor whether they were complying with regulations.

A newly re-engineered system gave the client the freedom to a) create content autonomously and b) control training management at a subsidiary, divisional and site level that didn’t interfere with controls and training established at higher levels in the organization.

This resulted in,

- Reduced duplication of effort across hundreds of business units by utilizing already existing content controls, permissions and workflows
- Accelerated documentation, distribution and adoption of internal knowledge throughout the company with an LCMS that is achieved natively within the LMS
- Increased training flexibility with independent content creation, control and training management at a business unit level

A fully integrated system removes the barriers to communication, which is essential for compliance.

Processes

Integrated risk management bridges the gap between disjointed processes and compliance efficiency.

One of the most difficult aspects of compliance for many companies is incorporating changes to existing regulations and complying with new ones.

When processes are manual and disjointed, companies are unable to respond with speed or at scale.

For example, standard operating procedures (SOP) are a staple when it comes to compliance and extremely important in order to follow Good Manufacturing Practice (GMP) requirements. Not following operations as called for by the appropriate SOPs is a major violation of GMP.

SOPs follow the concept of ‘say what you do and how you do it, and then actually do what you say’. This is a topic looked for by the FDA during facility inspections and failure to properly follow established SOPs is one of the most frequently violated GMP violations (Mead, 2016).

Using the example above, let’s look at some of the possible gaps in processes,

- Content is stored in various places throughout the organization causing version control issues
- Administrators are manually trying to update an SOP within the LMS where it could also be in multiple locations and learning pathways – creating inconsistencies
- Employees aren’t aware that there is new training and do not receive notifications to tell them otherwise
- Management doesn’t receive regular reports and thus cannot respond with agility if change is necessary

Each disconnection along the way adds up to time and money wasted.



The solution is integration.

There shouldn't be any reason for a business to complain about not being able to consolidate data from various departments when there is one central content management system integrated within the compliance landscape. This solves version control issues and provides one single source of truth from which to work from.

The second common complaint is having difficulty making changes to existing regulations and complying with new regulations.



Do you recall learning the song 'Dem Bones' as a child? The hip bones connected to the backbone, the backbone's connected to the neck bone, the neck bones connected to the head bone...'

A fully integrated system works much the same way — the CMS is connected to the training system, the training system is connected to the tracking system, the tracking system is connected to the...and so on and so forth.

A smart compliance system syncs learning to the SOP life cycle and can do this when processes are integrated.

Every bit of data related to compliance should be easily accessible as well.

As shown in example one, analytics is brought into the bigger compliance picture. Therefore, with reporting and dashboards, the enterprise GRC and/or other areas of the business can utilize the data in order to make calculated decisions.

Technology

Choosing the right technology for compliance strengthens its effectiveness and efficiency.

Integration occurs when separate people or things are brought together. So, for this to happen with compliance, technology must 'play nice' with all the other platforms throughout a business.

Because, the last thing needed is technology that performs in silos. Unfortunately, it happens a lot.

Since compliance information is often widely dispersed, administrators can spend a great deal of time on routine data-collection activities — compiling information from spreadsheets, shared drives and other systems. Such inefficient and disjointed processes rapidly become very costly, especially when specialized and highly compensated resources are manually compiling information.

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.

Non-integrated technologies make reporting one of the hardest parts of a compliance team's job —sometimes taking weeks to gather data and analyze it.

But there is a growing awareness that technology can be a compliance enabler.

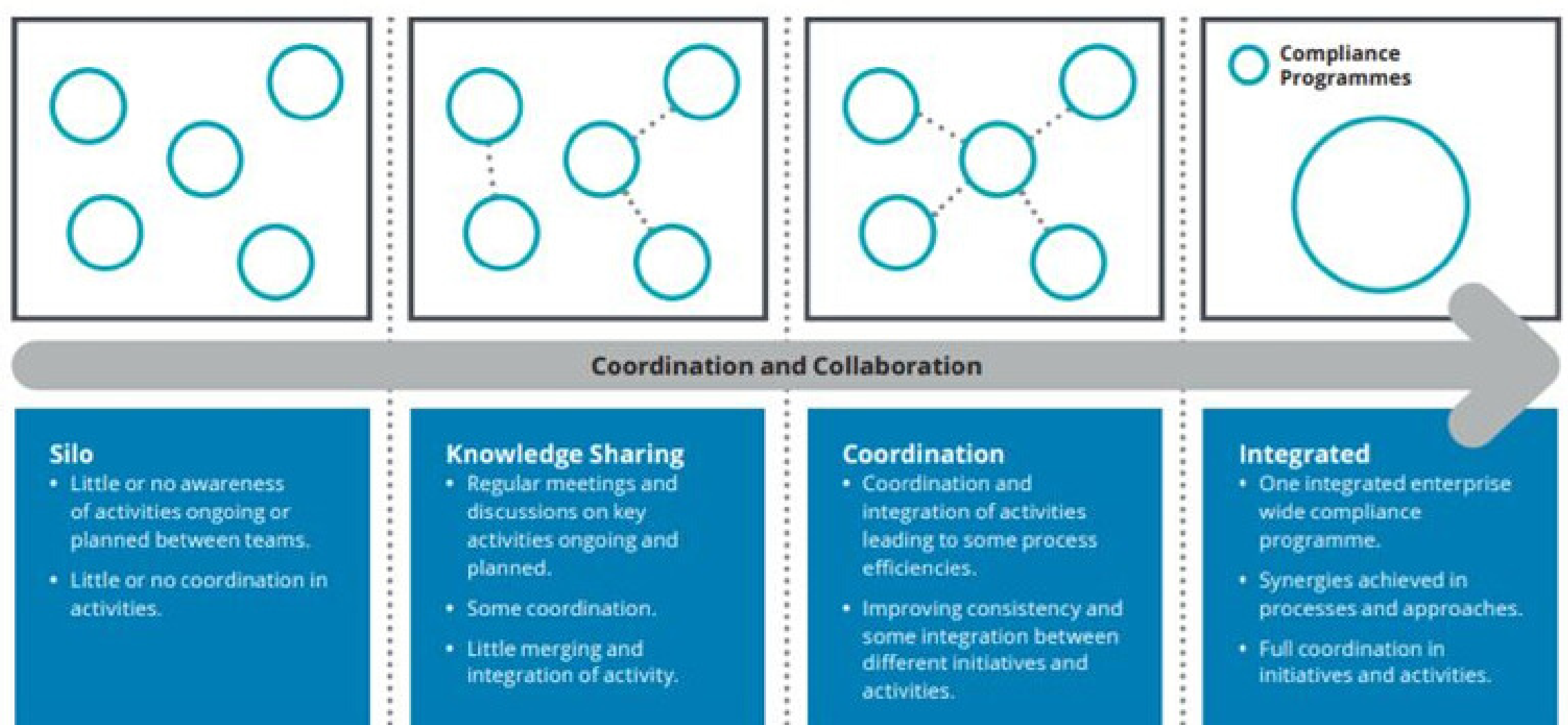
Using an integrated platform allows teams to link goals and objectives with data in order to get real insights about how one part of the program effects the other. This results in better program oversight which leads to fewer undetected incidents.

LAYERS OF INEFFICIENCY AND DUPLICATION

Historically, risk and regulation teams operated in silos, each carrying out their own approach and methods in response to increasingly complex laws and regulations – leading to inefficiency and duplication due to lack of coordination.

A few things to consider when choosing a compliance solution,

- Plan around technology or company issues that could increase costs and slow implementation
- Review software capabilities for opportunities to align with existing technology and processes
- Keep long-term requirements and your compliance roadmap in mind
- Drive and leverage support, engagement and buy-in from other functions (audit, risk, IT, HR, etc.)



<https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/risk/deloitte-uk-compliance-thought-leadership-16.pdf>

Tip 2: Set It and Forget It with Easy Automation

Automation is to compliance what a pen is to paper. They go together and are a power duo when it comes to successful compliance programs.

However, manual and disjointed processes continue to rise which can leave a business in a bad situation.

A bad situation that could potentially cost a business in upwards of \$14.82 million in non-compliance fees!

Based on a report by research firm The Ponemon Institute and security company GlobalScape, the annual cost of non-compliance for businesses now runs an average of \$14.8 million, a 45% increase since 2011. The range can be anywhere from \$2.2 million to \$39.2 million (Muresan, 2018).

Failure to comply has become more costly than ever for organizations, far exceeding the costs of compliance. So, it makes good business sense to ensure compliance with all relevant regulations.

What makes even better sense? Automation.

The benefits of automation are numerous.

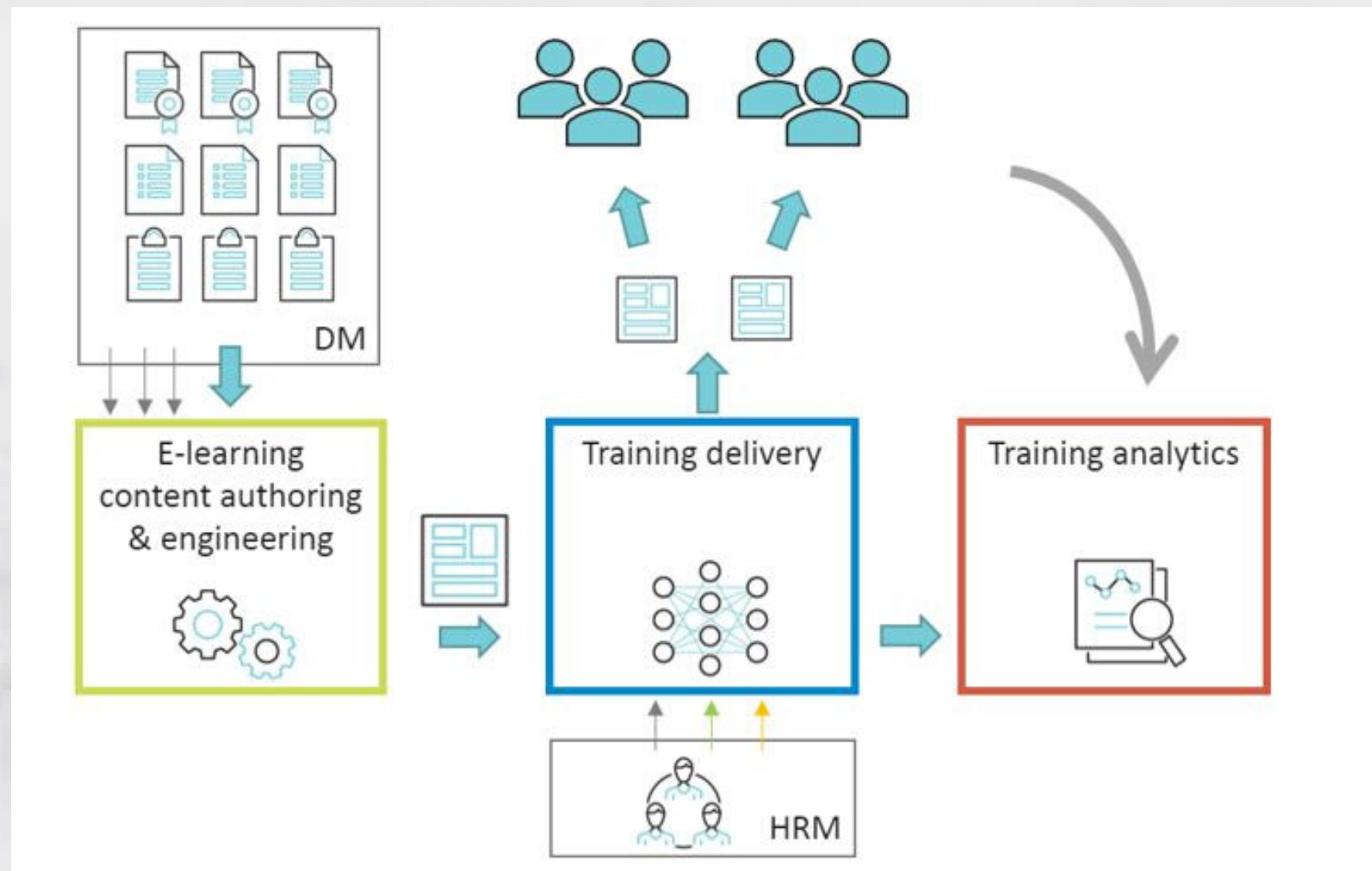
- It's more time and cost effective compared to manual controls
- It makes compliance policies uniform across computing platforms
- It minimizes the number of inadequate or inaccurate reporting mistakes
- It reduces the likelihood of encountering compliance fines or breaches

Smart automation is a term used frequently which essentially means that a system combines a deep understanding of workflow with robust granular data to allow highly efficient, accurate, and controlled decisions to be made.



So, when we think about how smart automation can be applied to corporate training, you'll see things like,

- Automated training creation, update and distribution
- Automation that is integrated into workflows
- Automation that is connected to corporate HR master data
- Automation tied into analytics and dashboards



People

Automation gives employees time back in their schedules to do more value-added work, e.g., focusing on innovation.

Incorporating changes to existing regulations is repetitive, mundane and time-consuming. In fact, according to the 2019 State of Compliance report (Picot, 2019), tasks that cause the most trouble are processes (81 percent) and tracking/assessment (68 percent).

If a compliance system can solve process issues with automation, it has essentially eradicated the #1 issue for workers when it comes to compliance.

This is a major feat and one that is incredibly impactful.

Highly regulated companies have many thousands of SOP's and work instructions. For instance, a manufacturing company might have 300 formalized e-learning courses but over 2,000 work instructions and SOP's that must also be addressed.

So, by implementing automated processes, delivery and acknowledgement of work instructions would be merged into the learning and compliance process and this would all take place in the same environment where content is created and approved.

This seamless method saves copious amounts of time for administration as well as tightening up compliance in order to reduce risk.

Processes

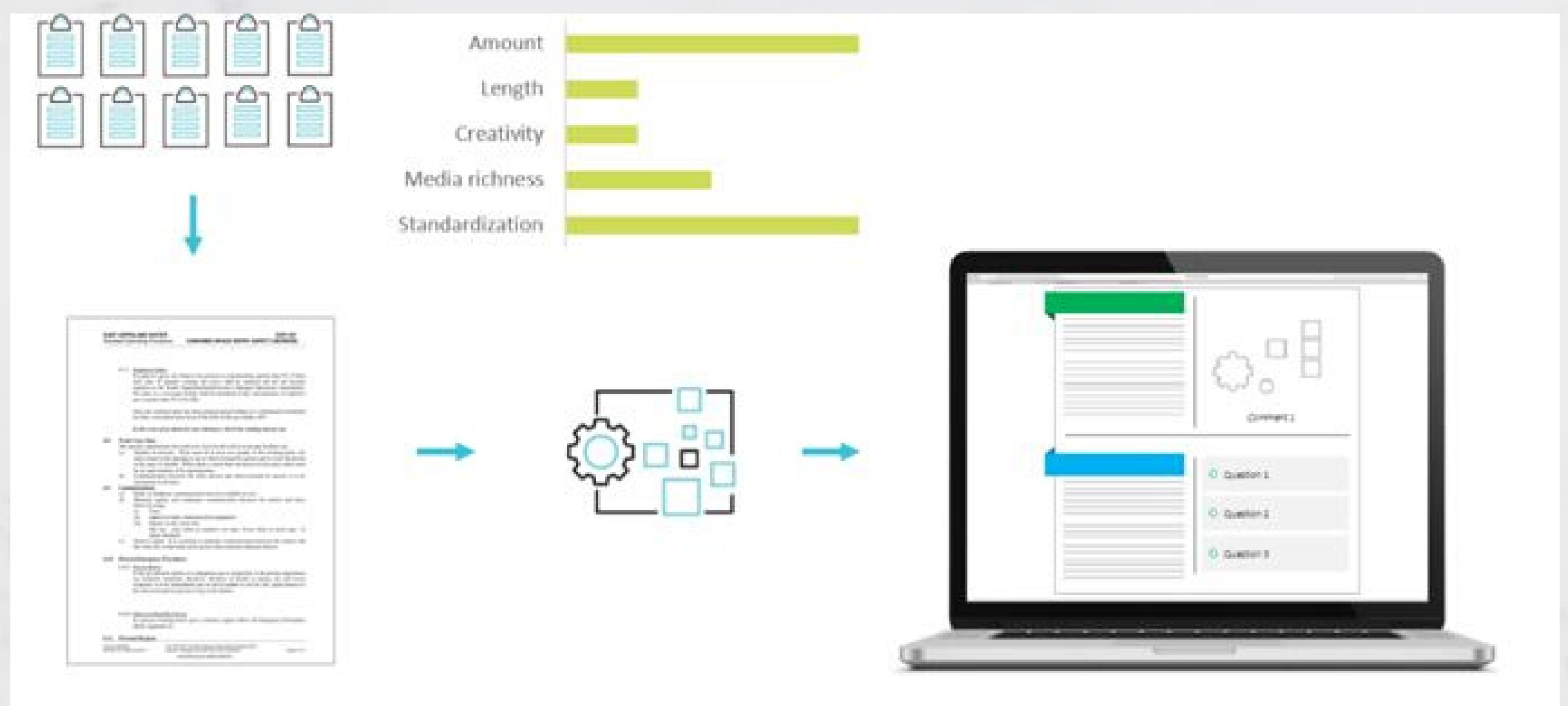
Automation smooths out the clunkiness associated with manual or disjointed processes (e.g., fragmented on-boarding processes, manually updating eLearning or inconsistent reporting).

Processes define and standardize work, preventing people from reinventing the wheel every time they begin working — and, of course, this equates to better efficiency.

When people interact with process, we can scale – which is exactly what is needed when regulations increase.

No more reinventing the wheel. Instead, with automated processes, growth is accelerated. One person, armed with great processes, could be as impactful as ten people in a less process-driven organization.

In the case of SOP's and work instructions, compliance is greatly enhanced with automation applied to assignments, notifications, version control, quizzing/testing, skills checklist and digital signature capabilities.



Onboarding is another example of how automation can quickly push new employees through the training pipeline in order to maintain productivity. With a growing skills gap looming over many industries, it's imperative to have these processes in place to keep up with the competition.

The ShareKnowledge client discussed previously successfully reengineered their processes to better incorporate automation. As a result, they were able to reduce training and onboarding costs by fifty percent.

As an organization grows, the scope of training requirements escalates. Automating assignments and onboarding tasks based on data in Active Directory, such as new hires, moves or promotions, is a necessity for example.

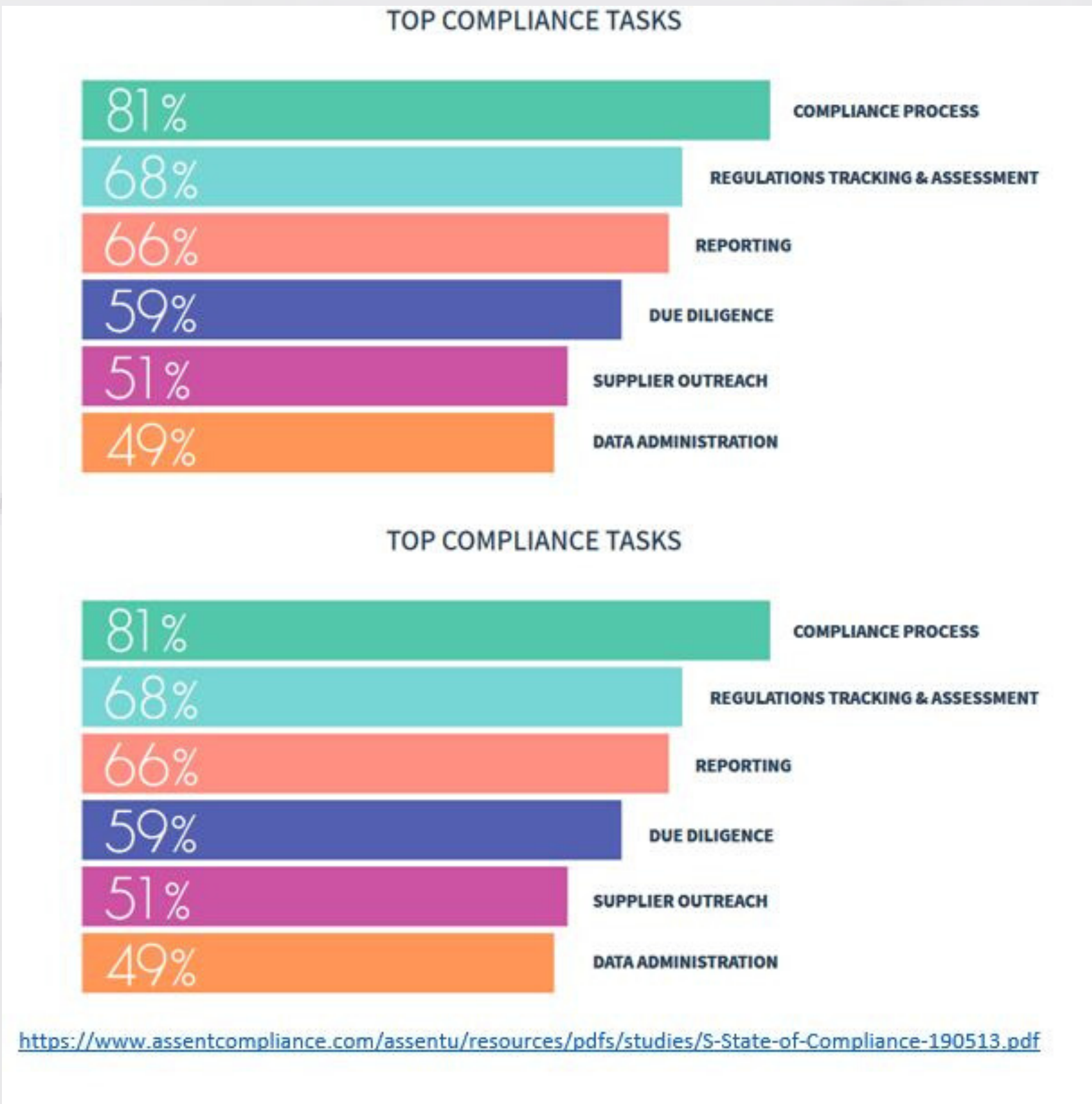
In addition, automating emails and reports to employees and their managers about upcoming certification expirations or new regulation deadlines...and having flexibility around those notifications are real-world challenges which can only be solved with a full-scale compliance solution.

Technology

But, many companies simply aren't leveraging technology in order to support compliance initiatives.

Technology is incredibly impactful for compliance — automating routine tasks so compliance professionals can focus on more complex issues like analyzing data. When organizations can focus on the 'why' rather than the 'what,' compliance efforts are freed up to spend time investigating data, understanding anomalies, and remediating issues, rather than merely collecting data.

91% of companies are spending more time on compliance efforts since 2015
81% of companies expect the time they spend on compliance to increase in the next three years



Tip 3: Time, Cost Savings Start with Real-Time Analytics

Analytics is the holy grail of compliance – improving business agility when regulations change.

If only it were that easy.

Again, one of the biggest problems cited by companies is having trouble accessing data. In fact, according to *The State of Compliance 2019*, 68% of employees cite tracking and assessment as the second most time-consuming task.

Identifying heaps of records in an international organization is like looking for a needle in a haystack. And, if executed manually it's an expensive and time-consuming process. Manually sifting through data also leaves the door open for misconduct or a policy violation to go undetected.

The fact is, companies don't know what they don't know. But in a digital age, most of the answers are there, buried in an ocean of data, waiting to be discovered. Once unearthed, that data must be deciphered if it's to unlock any true value.

That is where compliance analytics comes in — effectively enabling compliance, risk, and audit professionals to proactively detect and continuously monitor potential issues in real time.

Data analytics helps by,

- Identifying potential issues
- Prioritizing activity monitoring into higher risk areas
- Performing real-time monitoring
- Enhancing the efficiency of compliance testing
- Identifying where compliance issues may occur in the future

Compliance analytics helps companies to proactively identify issues, take corrective action, and self-report to regulators on a timely basis. And, advanced analytics, like artificial intelligence (AI) and machine learning technologies, are opening compliance functions up to new and exciting opportunities.

People

Analytics does the dirty work of processing data so people can quickly and efficiently make smart decisions surrounding compliance initiatives.

For a complete compliance picture, the analytics function must be accompanied by integration and automation. When that happens, compliance officers can take that information and use it in a variety of ways,

- **Descriptive analytics:** What happened in each situation?
- **Diagnostic analytics:** Why did it happen?
- **Predictive analytics:** What could happen?
- **Prescriptive analytics:** What is the best course of action for a given situation?
What can the business do to improve?

The quicker information is deciphered and analyzed, the quicker a business can adjust. Valuable time is being saved, employees are focused on tasks that move the business forward and compliance is proactively meeting regulations with ease.

Processes

Efficient analytic processes transform regulatory compliance.

Gathering and analyzing data is required and necessary to stay compliant. No matter what, it must be done but the 'how it's done' is variable. Meaning, the right processes and technology can alleviate the labor-intensive and costly methods traditionally used.

But, before new processes can be put in place, it's important to ask questions such as,

- Do we have a scalable technology to analyze different types of data sets?
- What activities are happening within the processes, and what are the roles and the responsibilities of the people involved?
- Is our organization using structured (i.e. ERP) and unstructured (i.e. mobile apps) data, and what are the capabilities of those existing systems?
- Can the technology process large volumes of numerical data related to organizational processes and transactions?
- What, if any, tasks are being completed manually?
- What potential pain points are we running into when using the system or throughout the process?
- Are any items or information being lost, or are there inconsistencies in information between multiple disparate systems?

It is then that process improvements can be made that will dramatically improve compliance.

The example below demonstrates how just one process improvement can make a big difference.

Oftentimes, workers in highly regulated industries are in the field or on a factory floor. But, it's imperative for companies to ensure they are trained and qualified in order to even step foot on a jobsite...or risk being non-compliant. If they don't have the data to provide this information, they can potentially put that worker at risk or jeopardize public or environmental safety.

In this scenario, it's crucial to have the ability to validate in the field the current standing of each employee against local regulations and/or to conduct skills checklist assessments. Similarly, employees and contractors in the field, in plants as well as in the office, need to be able to easily create and/or access documents supporting quality assurance standards, such as GAMP5 and ISO/TC Standards (ISO 9100, etc.).

Creating new processes that allow data to be captured in the field that pushes directly into the LMS significantly closes any inherent gaps in compliance.

Technology

Technology provides diverse amounts of data quickly, efficiently and presented in an easy to understand format.

Not only does it provide the current status of compliance training, but new technological capabilities can even predict what might happen in the future as well — creating increased efficiencies.

But how we get the data needed for analytics is by using the right tools and technology.

30%

internal audit departments
effectively leverage
advanced data analytics to
identify and assess risk

For instance, when thinking about company data, picture an iceberg. Above the water, you only see the tip of the mass. This represents structured data, which typically accounts for 20 percent of all enterprise data. Underneath the surface lies the bulk of the berg, and one of a company's most underutilized resources – unstructured data, usually amounting to 80 percent. Generally, organizations focus on mining structured data, as it is readily visible and accessible. On the other hand, unstructured data is a bit trickier.

Unstructured data is incredibly diverse, difficult to search/navigate and sometimes challenging to make sense of.

As technologies continue advancing in capability, many companies are looking to gather and dissect a combination of relevant structured and unstructured data, otherwise known as big data.

By converting structured data queries so that they can run against unstructured data sets, companies can unearth powerful and actionable insights conducive for compliance. It truly is a matter of survival of the fittest, regardless of industry. Even companies with 100-year-old histories are subject to fail if they're not properly equipped with the right technology.

Conclusion

According to the 2019 Global Innovation Index (Radu, 2019), the United States is one of the top three most innovative countries in the world.

And, America is aiming for the stars...literally. In July 2019, NASA announced they would land astronauts once again on the moon by the year 2024.

The only thing hindering NASA's efforts and the hundreds of thousands of other businesses around the country, and the world, is increasing regulations.

The new decade has just begun yet we've already experienced in a few short days the following (Young, 2020),

- On the regulatory front, the 2020 Federal Register took just five working days to exceed 1,000 pages.
- In just one week, 62 new final regulations were published in the Federal Register. That's the equivalent of a new regulation every two hours and 20 minutes.
- Federal agencies have issued 83 final regulations in 2020. At that pace, there likely will be 2,965 new final regulations.
- There were also 28 proposed regulations in the Federal Register last week, for a total of 41 on the year. At that pace, there will be 1,465 new proposed regulations in 2020.

So, for businesses to remain competitive and continue down a path of innovation, they must get under control the manual and disjointed processes that make compliance so difficult to keep up with.

Incorporating integration, automation and advanced analytics as outlined in this whitepaper will elevate compliance efforts, leaving more time and money to focus on new advances that will change the world.

Integration of compliance training into the entire business landscape effectively solves the problem of disjointed processes.

Automation makes compliance a smoother process and one that saves copious amounts of time previously done with manual processes.

Advanced analytics is the icing on the cake — putting businesses in a proactive state of compliance affairs.

If your current method of compliance isn't working how it should nor effectively as it could, then we would love to help you make that first step toward achieving your compliance goals.

ShareKnowledge LMS is an award-winning compliance training solution that has helped many companies in highly regulated industries get back on track and thrive under the constant pressure of changing regulations. Experts in compliance and highly knowledgeable in a wide variety of industries, we create customized solutions that are unlike any other on the market.

Contact us today for a free assessment.



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