COMPLIANCEWIRE®

ComplianceWire® 2023: Compliance Learning Benchmarking Study

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Safety. Science. Transformation.™

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Executive summary

In this report, ComplianceWire® from UL Solutions presents its analysis of current trends in training science. The study identifies the top priorities of life science companies in 2023 and suggests that the top priority lies in measuring training effectiveness. Businesses are clearly focusing on quantifying the value they get from their valuable training time, and some of them are not pleased with what they find. Some key highlights include:

- In-person audits are back, but the COVID-19 pandemic better enabled us to handle them remotely, and we have some new technology resources to support them.
- Failure to document and follow standard operating procedures (SOPs) is still a top finding. While required by regulation, companies are realizing that we are not using optimal training methods, and we discuss some strategies here.
- Utilizing our Compliance to Performance Maturity Model, we analyze the state of the industry and progress toward an Industry 4.0 ideal.
- We show trends in learning technology usage that reflect a decline in the hype around virtual reality technology but present an interesting case where it is useful for life science companies.
- We allow you to benchmark your learning program and topics against both your peer companies and common audit findings to improve your learning program.

These topics and the associated data are presented in more detail in the report that follows. We at UL Solutions ComplianceWire® sincerely hope you find the information useful. If we can work together in our mission to increase the safety and effectiveness of the global pharmaceutical and medical device supply chain, please reach out. We are here to help.

Introduction

We use what we call the “Compliance to Performance Maturity Model” to guide customers’ efforts to fully qualify their people to perform their jobs and have a demonstrable, positive effect on worker performance. Here is an illustration of our model.

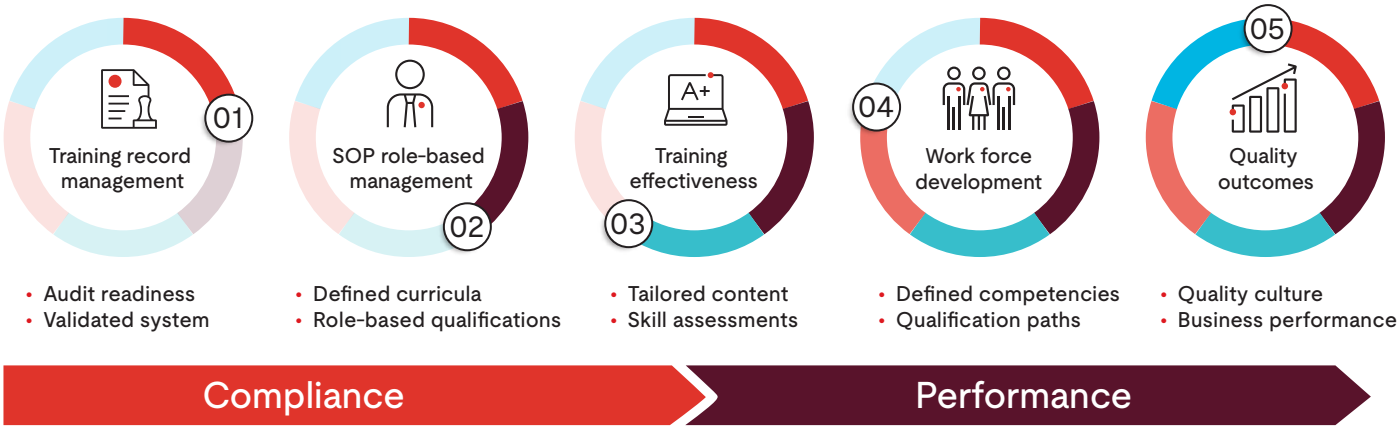


Figure 1: ComplianceWire®’s Compliance to Performance Maturity Model

In our view, companies progress on their compliance-to-performance journey in stages. In the early stages, companies focus on converting their training records from paper to an electronic format, and on preparing for audits. This is considered the bare minimum for life science companies that use an electronic system.

As companies enter subsequent stages, they begin using their electronic systems to automate role-based training, conduct the right mix of learning assessments and to proactively manage their work force. This enables the availability of qualified people to meet work force demand.

At the later stages, companies assess training expenditures in view of business outcomes, such as improved productivity, reduced scrap rates and reduced incidence of quality issues. Companies at this stage in the maturity model enjoy a reduced risk of regulatory compliance failures and product quality failures that can harm patients. This provides an implicit dividend for their brands and bottom lines.

About our study

Every year, UL Solutions conducts a study of ComplianceWire®'s roughly 600 customers, most of whom operate in the pharmaceutical and medical device sectors. The study's goal is to share recent trends with our customers and the life science industry as a whole, particularly from a regulatory and usage perspective. The study pulls together survey and usage data from the ComplianceWire® platform. While many of the top 100 life science companies are represented, our sample includes companies of all sizes and ComplianceWire® users who represent a broad mix of internal stakeholders within those companies. Respondents include people from human resources, quality, quality systems and information technology (IT), manufacturing operations, product design and clinical researchers. Survey responses are completely anonymous.

We combine our survey data with anonymized macro-level data from the ComplianceWire® platform itself to show how these subjective responses correlate with actual data collected on the platform. Interestingly, our sample also includes learners from the United States Food and Drug Administration (FDA)[1], China's National Medical Products Administration (NMPA), the Gujarat Food and Drugs Control Administration (FDCA) in India, and the Saudi Food and Drug Authority (SFDA).

Our survey is global. ComplianceWire® is among the most widely used learning and qualification management systems in the pharmaceutical and medical device industry worldwide. With a 20+ year history as one of the first cloud-based, fully validated and vital components of manufacturers' quality management systems, ComplianceWire® has more than 3 million active users in more than 130 countries. If you consider the number of people in the pharmaceutical industry who have ever used ComplianceWire® through one employer or another over the course of their careers, one could argue that ComplianceWire® is among the few enterprise-level IT systems that most of the people in life sciences have used at some point in their careers.

We continuously improve ComplianceWire® like any quality system. We have issued 53 major upgrades for ComplianceWire® for an average of 2.52 upgrades annually while remaining in a validated state continuously for 21 years.

ComplianceWire®'s content libraries are also in constant evolution. Our off-the-shelf content — a good portion of which we co-developed with the FDA — has more than 100 modules that have been used over the years to train more than 48,000 federal, state, local and tribal inspectors. Not only are these modules used by the FDA, but the FDA has also supported its mission of protecting public health by making these training materials available to industry. Through our CRADA with the FDA, more than 6 million course completions have been recorded for our FDA-specific libraries. We continually update the content for regulatory currency, instructional technology

About ComplianceWire®

ComplianceWire® is among the premier cloud-based learning and compliance management systems on the market. We help companies meet both their learning needs and the special regulations that apply to the life science industry.

We developed ComplianceWire® specifically for the life science industry; it supports compliance with current Good Manufacturing and Clinical Practices (GxPs and federal regulations around electronic signatures (U.S.-based 21 CFR, Part 11, and EU-based Annex 11).

We have issued

53 major ComplianceWire® upgrades

for an average of

2.52 upgrades annually

while remaining in a validated state continuously for 21 years

While ComplianceWire® serves other markets, the life sciences are part of the system's DNA, and there are many specific features that make life simpler for GxP learners and training administrators. Over its 20-year history, ComplianceWire® has successfully delivered more than 620 million training events.

More than **620 million** training events **delivered**

refreshes and other changes. As an example, in our most recent review period, we updated nearly 40% of our courses. By looking at our most frequently used courses, pharma and medical device companies can benchmark their own training programs against a large cross section of the industry.

A quick look at the data

This is the second survey we have conducted since the start of the COVID-19 era. Therefore, we modified the format somewhat from previous years to include some COVID-19-related questions. While parts of the survey are retrospective, we also asked customers to look forward and tell us their expectations for the coming year. We use this data as part of our continuous improvement process internally.

We hope you find the data informative and that it helps you improve your programs. We conducted the survey in April and May of 2022 but did not publish the data in the interest of capturing multiple points in time. This year, we can present the data from 2022 and 2023 side by side, which allows us to see patterns of change over time. We collected this year's data in March–April of 2023.

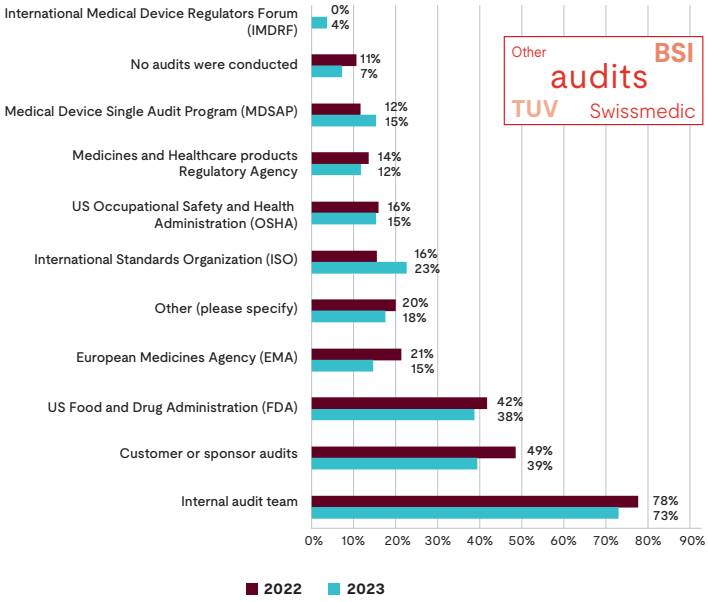


Figure 2: Answers to the question, "Which party or regulatory organization conducted an audit (or investigation) within your organization since June of 2022?"

Trends in auditing

Each year, we ask, "Who is auditing our customers?" Looking across the differing audit teams, we can see the relative frequency of various audit types across the industry.

In **Figure 2**, we see the percentage of respondents who identified their auditors and a few frequent choices from the "other" category as a mini-word cloud. We see small differences in audit activity by both the FDA and EMA, with a larger decrease in customer or sponsor audits. While there were still areas of the globe on lockdown for COVID-19 during the period requested in the survey, the data reflects that the important monitoring that the agencies perform — and that the industry performs on its own — is normalizing. That is, in 2022, there was a return to in-person audits post-COVID-19, and the slight decline suggests that the frequency of audits is settling in at a more normal level. There were also some declines in ISO and MDSAP-based audits. Some audit cycles are multi-year, meaning that an audit might occur every two years, for example, so we will continue to watch these trends.

As you can see in **Figure 3**, there was a marked increase in on-site audits in 2023 compared to 2022, and a corresponding decrease in remote audits. If you add up the decrease in the "both" category and the change in "remote," the sum matches the increase in on-site or in-person audits almost perfectly.

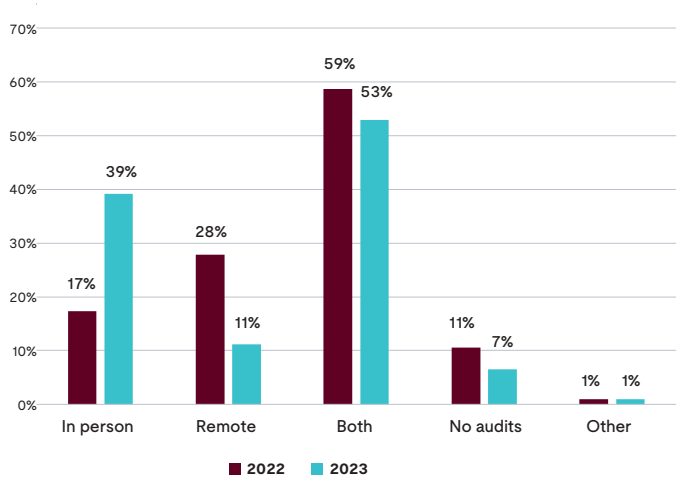
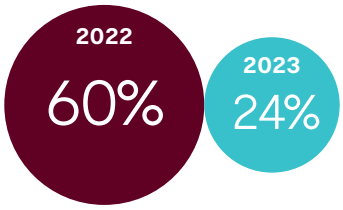


Figure 3: Answer to the question, "Were your audits in person or remote?"

Another question was, “What is the percentage of remote audits in which you are participating?” The percentage dropped precipitously from 60% in 2022 to 24% in 2023, so while audit activity was the same or slightly down year-to-year, in-person audits are clearly on the rise. In our opinion, this is healthy for the industry, particularly if you view audits as a chance to review your processes, get feedback and move forward on a continuous improvement path.

Remote audits lose ground to in-person

What is the percentage of remote audits in which you are participating?



While in-person audits are back, the COVID-19 pandemic made companies more comfortable supporting remote audits. Unfortunately, there is a lack of purpose-built tools and resources for supporting them. Our survey respondents reported supporting audits and virtual audits with papers (15%), shared drives (61%) or a blend of tools that weren’t designed for the task (24%). To deliver a secure, intuitive system to support this frequent activity, ComplianceWire® has partnered with AuditPass[2] to offer customers a software-based tool to address this inefficiency and allow organizations to collect specific audit data to analyze and review their audit process.

What are auditors finding when they arrive?

We also asked respondents, “What are the auditors finding?” Since our survey is completely anonymous, respondents shared the types of findings that auditors highlighted; the major categories are presented below.

As shown in **Figure 4**, companies are not following their own SOPs in many instances; that finding increased over 2022. There were also a fair number of training findings, although the trend did not seem to change year to year. Apparently, companies face challenges maintaining their procedure documentation as well. There was also a slight increase in documentation problems year over year. This maps well to publications and presentations the FDA has presented in various forums.[3] On the positive side, companies appear to be putting more energy into quality problem investigation.

At ComplianceWire®, we have partnered with DeepHow, an artificial intelligence (AI)-enabled video SOP authoring company.[4] With DeepHow technology, we can capture expert performance using only a smartphone and create not only a more effective training module, but engage DeepHow’s generative AI engine to write the first draft of your SOP for you. The AI yields more effective content and speeds up the process of documenting your SOPs to address regulatory requirements.

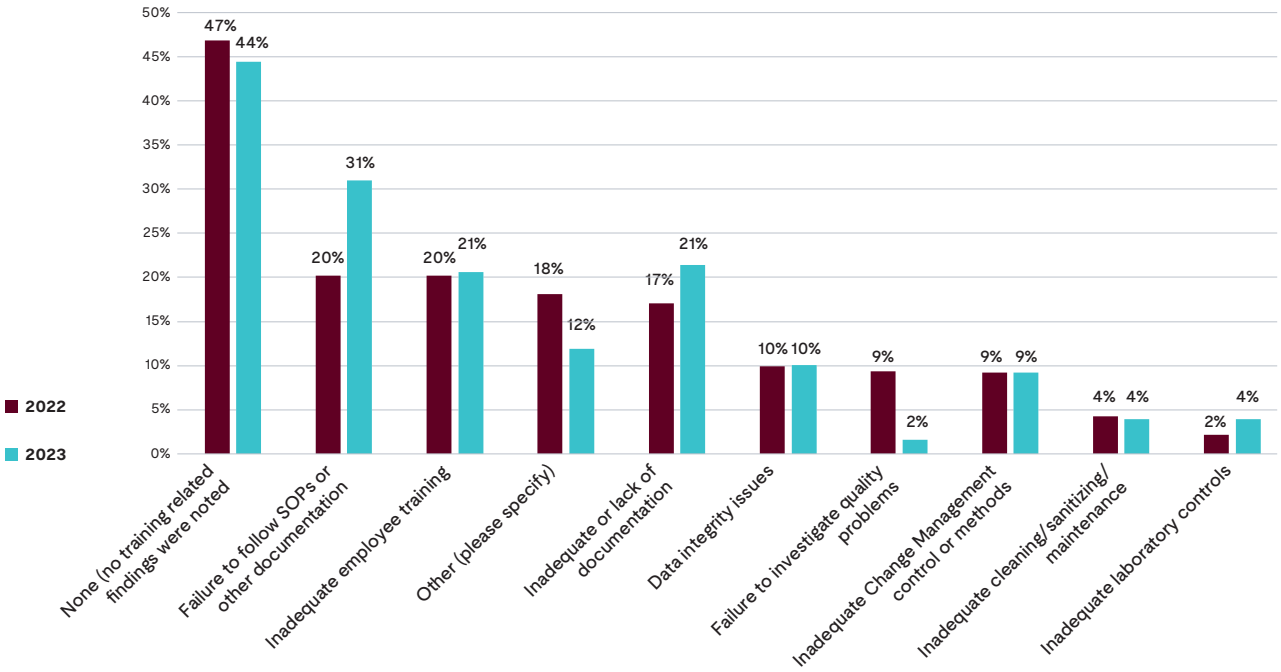
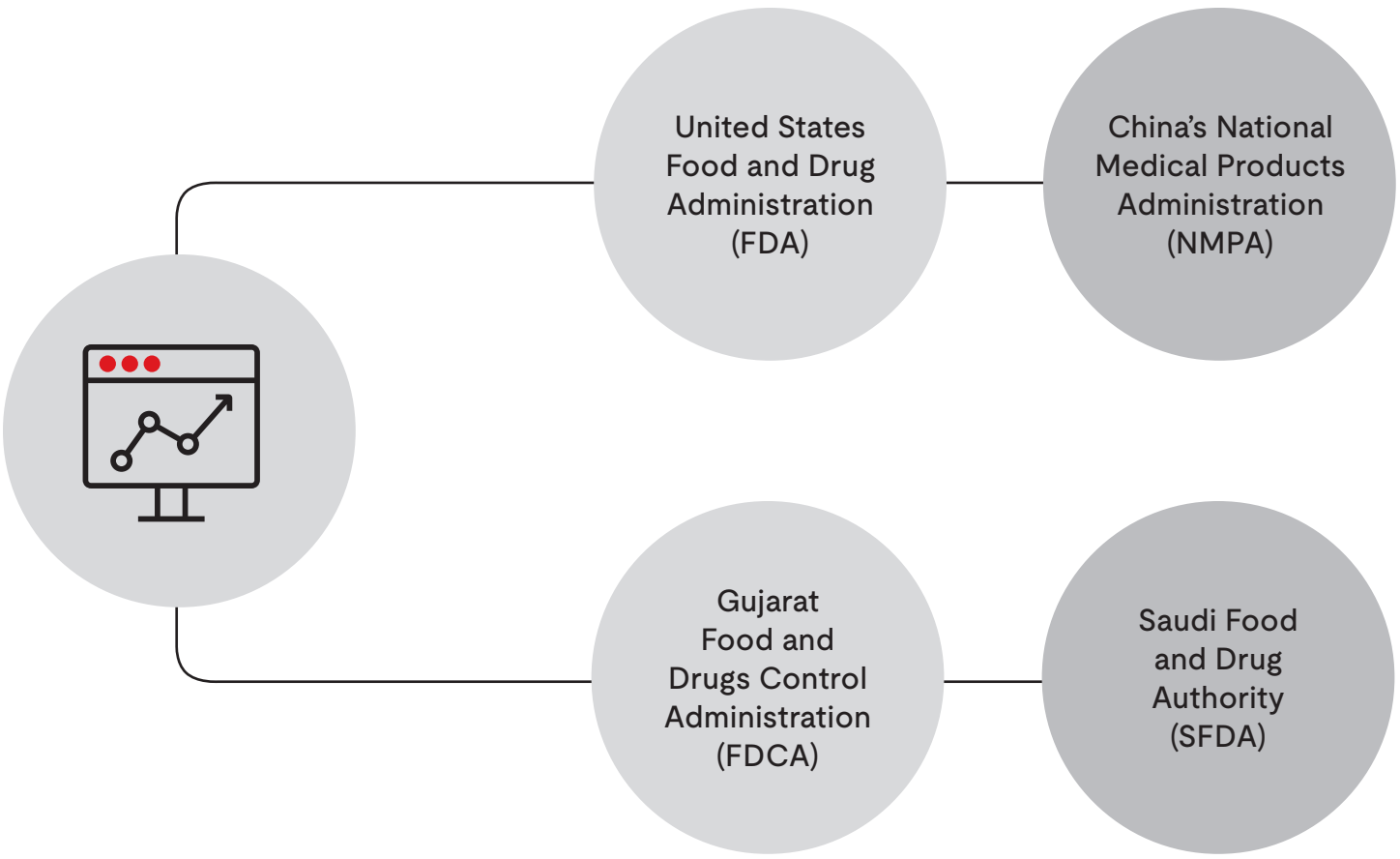


Figure 4: Response to “Please indicate any audit findings from the last year.”

Optimal performance requires training that includes not only knowledge components, but performance components as well.

Our sample includes learners from:



Upcoming priorities

We asked our industry customers to look forward and tell us about their upcoming priorities for the coming year. We use this information to help us understand market needs so we can offer services that respond to customers' needs. The data are presented below.

Answer choices	2022	2023
Measuring training effectiveness (quizzes, on-the-job monitoring) to ensure that employees are retaining and applying knowledge/skills on the job	57%	59%
Collecting training data to support the organization's quality or compliance metrics	51%	54%
Implementing a training strategy that develops a learner's competence within their role	49%	49%
Improving SOP effectiveness and policy management	39%	49%
Creating online courses internally	35%	30%
Adding risk-based approaches to your training programs	21%	28%
Consolidating learning management systems	21%	25%
Showing the impact of training on business performance (yield, quality, scrap rates, etc.)	21%	20%
Buying off-the-shelf online training to supplement or replace internally developed content	12%	8%
Other (please specify)	11%	10%

Table 1: Answer to the question, "What are your top priorities for the coming year?"

Table 1 shows that within the life science learning space, learning effectiveness is the No. 1 concern, as it was in 2022. The biggest year-over-year change was an increased desire to improve the effectiveness of SOPs. Our response to this identified need was to develop some services to help meet the need and address the pattern we see in the data.

The FDA cites the failure to follow SOPs as one of the most frequent findings. This is corroborated by our survey respondents, who called it out as a frequent finding in their own companies as well. Add to that our respondents' concern about training effectiveness and the very specific increase in survey respondents listing improving SOPs as an explicit goal. Clearly, SOPs are a struggle in the industry. ComplianceWire® offers specific services to address these needs for customers at each level of the Compliance to Performance Maturity Model.

We designed a service to help customers develop their initial role-based competencies. Manufacturing complex products like pharmaceuticals and medical devices can be challenging. We have experts on staff who have worked in these environments many times and can help structure the training program correctly the first time. If your learning program is mature and you have already established a well-functioning program, we have another service that can help you risk-map your training programs to reduce training time, improve onboarding speed and optimize learning effectiveness while reducing risk to patients.

Self-ratings of quality training programs

The survey also included a self-assessment of performance. Respondents had the opportunity to evaluate their organizations on various dimensions, including record management, implementation of role-based training, training effectiveness, proactive work force management and relationship to business outcomes. These dimensions correspond to the five levels of the compliance-to-performance journey in our maturity model. A sixth question we asked respondents was to assess where they fit in the overall quality culture of the organization.

#1

What was the No. 1 Concern in the Life Science learning space?

Learning effectiveness, ensuring that employees are retaining and applying knowledge on the job

Management of training records (compliance)

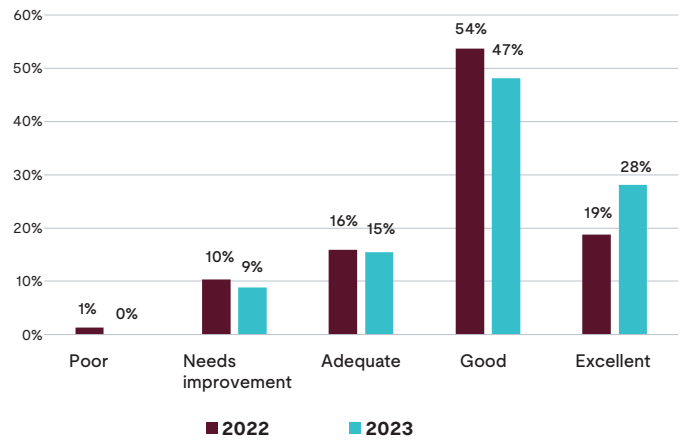


Figure 5: Self-ratings of respondents' record-keeping performance.

Implementation of role-based training

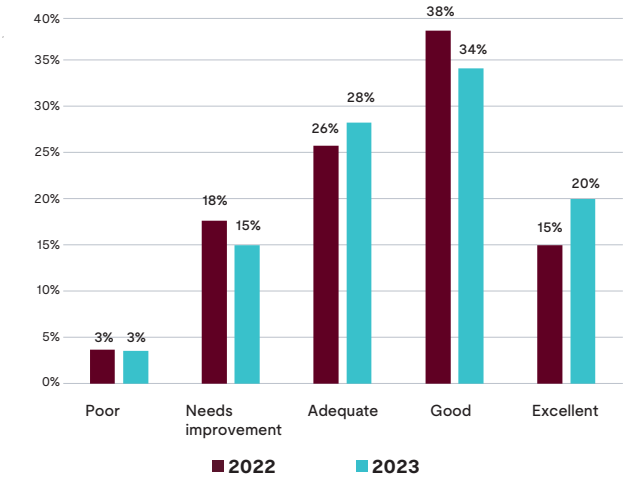


Figure 6: Self-ratings of respondents' implementation of role-based training.

Level 1 – Training record management

At Level 1, we asked how well respondents felt their companies were performing at maintaining training records in accordance with regulatory requirements. Given the global nature of our audience and the range in company sizes (from less than 250 to more than 10,000), we can still expect to be surveying companies that are transitioning to electronic systems from paper. At a certain number of employees, however, managing paper records becomes untenable and companies move to electronic systems.

When we look at self-assessments from the group of respondents in **Figure 5**, you can see they are generally positive about their ability to manage their training records. This is to be expected because in the life sciences, this is essentially the minimum requirement to be in business. In fact, you can even be surprised that any self-assessments show "poor" or "needs improvement" ratings. It is also a conservative interpretation of the data to count the "adequate" ratings positively. Specifically, if record keeping is adequate, is that good enough? Given the choice, would we want our families to use a medicine or medical device that is merely adequate? Allowing for "adequate" to be viewed positively could be looking at the data more favorably than it actually is. We will be returning to this point for later metrics.

Level 2 – Implementation of role-based training

Moving up to Level 2, we see that some respondents are less positive about their performance. Why is this important? To implement role-based training, job roles must be defined and training requirements must be articulated abstractly so that the system automation can help maintain compliance. ComplianceWire® assigns training to roles, allowing administrators to "set it and forget it." Once properly configured in the system, you realize considerable savings in administrator effort required to manage a training program — as long as you have the training program properly defined. This is a key area where our consultants can help customers define their roles and curricula.

When we examine **Figure 6**, we see an uptick in the percentage of respondents who feel that their implementation of role-based training is poor or in need of improvement. We see minor changes from year to year, but nothing dramatic. It is not surprising that these numbers are still positive. The ComplianceWire® team of internal learning and professional services experts has been promoting the benefits of role-based training for years, and we help our customers automate their training programs.

Role-based training is also key for system integrations. Specifically, when your human resource management system (HRMS) and your document management system (DMS)

are connected to a ComplianceWire® instance with role-based training properly configured, you can accelerate your training process, reduce administrative overhead, maintain compliance and reduce risk. The process is illustrated in Figure 7.

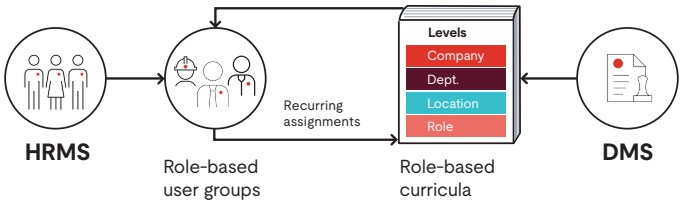


Figure 7: Automating compliance and performance with role-based training and systems integration

With a fully integrated and properly configured role-based training system, any time a new person joins the team or changes roles, or when a document or other training item is introduced or revised, the system's intelligence automatically delivers the proper assignments and enables tracking them to completion and, therefore, compliance. Based on the self-assessment responses above, approximately 20% of organizations still need improvement in this area.

Level 3 – Training effectiveness

Level 3 is where your training program really gains momentum. Is what you're doing making a difference, or are you just "checking the box" so you can get through the training portion of your audit? Do you have quality problems that are attributable to human error?

There are reams of paper written about effective learning; we won't bother to repeat all that here. We believe that an effective training program is one where the methods and measurements lead to the production and retention of desired behaviors in the work force. The training methods should be appropriate to the desired output behaviors and reinforced as needed to optimize human performance and support the behavior at the point of use. If you would like someone to perform a laboratory method quickly and accurately, the training should include not only knowledge components, but performance support components as well.

ComplianceWire® provides all the tools you need to empower you to meet your needs. Off-the-shelf computer-based training (CBT) modules like the ones we co-develop with the FDA include repetition and knowledge assessments for improved retention. Our CBTs are based on a "mastery model," meaning that you cannot earn a completion unless you can demonstrate that you have mastered and retained the material. UL Solutions' UL Create™ content authoring platform allows local SMEs to collaboratively author professional-looking CBT content quickly and easily, with learning assessments included. We also provide ways to supplement "read and understand" training in ComplianceWire® with quizzes and stand-alone exams.

Additionally, ComplianceWire® has a powerful and very flexible Forms tool for on-the-job training (OJT) for use by qualified trainers to verify that their students have mastered the procedural skills needed to be qualified for their jobs. There is a business performance aspect to training effectiveness (see Level 5), but for now, let's consider respondents' self-ratings for training effectiveness below.

Training effectiveness

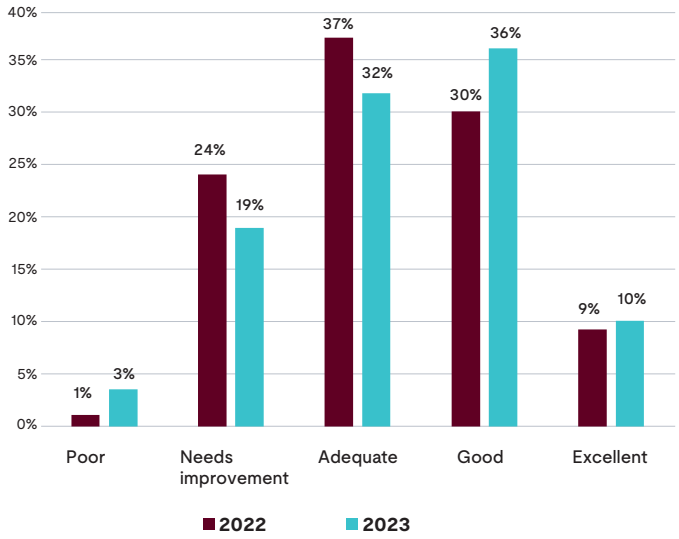


Figure 8: Self-ratings of respondents' training effectiveness

From Figure 8, we can see that fewer respondents think that their training programs are good or excellent at showing training effectiveness. At the same time, the number of "adequate," needs improvement" and "poor" ratings are creeping up as compared to Figures 5 and 6. This suggests that while we are keeping records and trying to automate training functions to maintain compliance, we as an industry are not as certain that we are doing more than that. Are we collectively delivering the right value to the organization for the time and effort spent on training?

Level 4 – Proactive work force development

When managing a supply chain, businesses track inventory levels, forecast demand, and order supplies and ingredients or components that are later turned into finished products such as pharmaceuticals and medical devices. Per regulations, a qualified worker can play a key role in any batch or lot of product. In ComplianceWire®, we have constructed ready-to-use reports that allow businesses to assess their inventory of qualified workers. If they forecast a surge in demand, they can plan for that by constructing training programs that upskill their teams to have a more flexible work force.

People, however, are unlike ingredients or components; they have dreams and aspirations. It is extremely useful to provide those human capital assets with developmental experiences. In fact, that is the basis for the switch in terminology from human "resources" to human "capital."[5] If your people are assets and you invest in them, you can grow their value to the organization and to your people personally in their careers.

UL Solutions has addressed this requirement through **suggested curricula** in ComplianceWire®. That is, you can set up developmental curricula for your team. You can easily include or exclude the reporting for those developmental assignments in the reports you create for batch records or audit purposes. You can see the self-rating responses for proactive work force management in **Figure 9** below.

The data in **Figure 9** show a less rosy picture of proactive work force management. As we move up the levels of the Compliance to Performance Maturity Model, the number of programs that our respondents felt were poor or in need of improvement creeps steadily upward. Also notable is the steady downward shift in the "good" or "excellent" categories. At Level 1 (see **Figure 5**), more than 70% of self-ratings were in the "good" or "excellent" categories. At Level 4, we are down to about 35%.

Proactive work force management

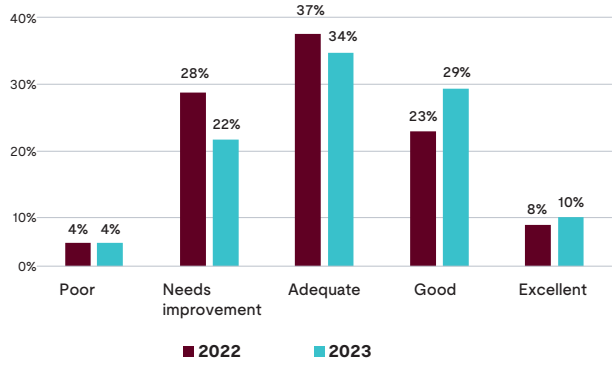


Figure 9: Self-ratings of respondents on the proactive work force management dimension

Level 5 – Clear relationship between training activity and business outcomes

Learning mavens will recognize a strong correlation between Level 5 of our Compliance to Performance Maturity Model and Level 4 of the widely used Kirkpatrick learning assessment model.[6] Specifically, we suggest having metrics and processes in place to show a direct correlation between training activity and business outcomes. Again, it is a given that we need qualified personnel making our medicines and medical devices, but do improvements in training processes lead to productivity improvements, waste reduction, better product quality or reduced risk to patient safety? It's challenging to put those types of data together.

There is a lot of discussion in the industry[7] about Pharma 4.0, or Industry 4.0, where we have all the manufacturing, supply chain, sales and safety data together in one repository to enable correlation of all these metrics. However, reality often lags behind aspiration. We have worked extensively with customers on these types of projects, including generating data repositories, connecting ComplianceWire® to other systems via our extensive API set and consulting with them on what metrics to use and how to visualize the data in common analytics tools like Tableau or Power BI. We would be happy to share those lessons learned with customers who are moving up the maturity model levels and want to achieve that final stage. **Figure 10** below shows the data.

While the changes from 2022 to 2023 in this category are relatively minor, respondents are again shifting more toward the left side of the chart, indicating less confidence that training is really affecting business outcomes. If the respondents to this survey don't see it, how much harder will it be to convince their management when negotiating budgets? This stage is critical to ensuring that the training function is properly resourced and managed.

Clear relation between training activities and business outcomes

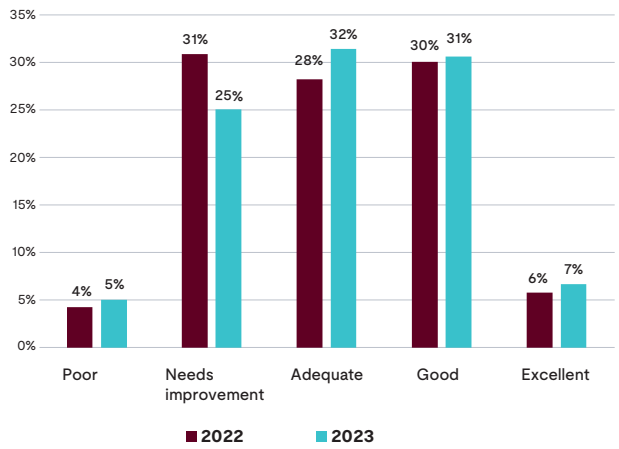


Figure 10: Self-ratings of respondents on the relationship between training activity and business outcomes

Beyond Level 5 – Are you part of the quality culture?

When we move beyond Level 5, the survey asks if the respondents' training programs are part of a robust quality culture. To this point, we have taken the relatively conservative interpretation of the "adequate" rating as being adequate. If someone were to assess their quality culture as "adequate," is it truly a quality culture?

We aren't so sure. Consistent with the broader UL Solutions corporate mission, our ultimate goal is to contribute to a pharmaceutical and medical device supply chain that is safer for consumers and patients. Helping to improve systems to Level 5 and beyond is why we're in business. **Figure 11** shows that there are some shifts year to year in the "good" and "excellent" categories — still about 52–53% above the "adequate" level. Collectively as an industry, we can do better. We would expect no different from an industry full of quality professionals focused on continuous improvement.

Training is part of a robust quality culture

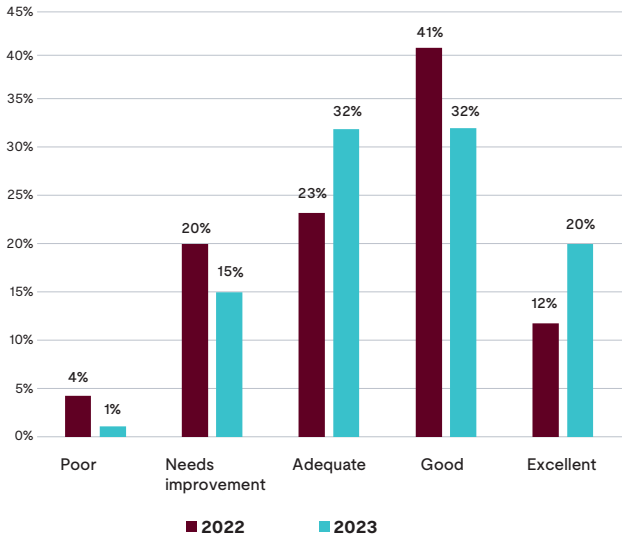


Figure 11: Self-ratings of respondents' view of whether training is part of a robust quality culture in their organization

Updates on learning technology usage

Our survey enabled us to characterize the use of different types of learning technologies. While many technologies like virtual reality (VR) and augmented reality (AR) show promise, finding the right use cases for life science manufacturing is challenging. A careful review of **Table 2** shows some decline in both use and plans to use this type of technology, and more people reported they had no interest in VR/AR. However, there are examples where VR has delivered cost-effective training.

At a recent (May 2022) industry gathering, Sanofi shared how they use VR to prepare people for working in aseptic environments.[8] The key finding was that VR was effective, cost-effective and could address all the specific aseptic training needs of one of the world's largest pharma companies with a total of 13 VR headsets. While VR technology may be viewed as something video gamers would get the most use out of, 13 VR headsets is not a substantial purchase, nor is it a big risk for such a large corporation.

Other notable findings include a decrease in traditional CBT usage and online meeting technologies like Webex and Zoom. In our minds, that is a good thing — not because we don't like CBTs (we do), but because after the isolation of the COVID-19 pandemic, it is gratifying to see that people are getting together again for some good old-fashioned, high-bandwidth, face-to-face interactions.

13 **Sanofi needed only 13 headsets to effectively train its worldwide work force on aseptic environments using virtual reality**

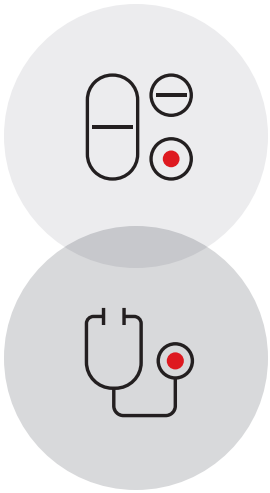
	Using now		Planning to use		Would like to, but no current plans		Not currently using		No interest	
	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023
Virtual reality	14%	6%	7%	3%	11%	12%	37%	37%	32%	42%
Augmented reality	4%	3%	7%	2%	16%	11%	34%	34%	39%	49%
Text message training	4%	5%	3%	0%	5%	5%	34%	38%	53%	53%
Virtual classrooms (Zoom, Webex, Adobe Connect, etc.)	80%	71%	7%	10%	7%	10%	5%	6%	0%	3%
UL Solutions e-learning courses	81%	61%	9%	10%	3%	8%	4%	15%	3%	6%
e-Learning courses developed in house	71%	59%	11%	13%	9%	8%	7%	17%	2%	3%
e-Learning courses from other third parties	52%	56%	9%	7%	16%	11%	19%	18%	4%	8%
Video SOPs	19%	13%	15%	9%	18%	24%	29%	37%	18%	17%
Non-SOP videos	51%	44%	10%	9%	14%	14%	11%	21%	15%	11%
Mobile learning	18%	18%	15%	5%	18%	17%	32%	39%	17%	21%
Micro-learning	17%	15%	14%	14%	17%	14%	33%	36%	18%	21%
Virtual twin simulations, e.g., simulation of a manufacturing floor	4%	1%	3%	8%	24%	17%	36%	42%	33%	32%
Game-based learning	9%	5%	11%	8%	22%	24%	32%	38%	27%	26%

Table 2: Industry usage of specific learning technologies, current and planned use in 2022 and 2023

Top pharmaceutical and medical device GxP courses

There is virtually no reason to focus your team on maintaining training in GxP basics when you can provide a proven resource off the shelf. To understand what other companies are doing and how they use this valuable content, we provide the data about the most frequently used courses in your GxP peer group, whether it be pharma, device or clinical. First, are you using the same resources your peers use to improve your training program? Second, are you proactively training your team to avoid common violation areas to improve your audit results?

Highlighted in bold type in **Table 3** is the considerable overlap in what pharma and medical device companies use for good manufacturing practice (GMP) content. However, in our FDA libraries, we have many pharma-specific courses as well as those that are specialized for medical device environments. You can obtain full lists from our website.[9]



	Pharmaceutical GMP courses	Medical device GMP courses
1	**Introduction to cGMPs**	**Introduction to cGMPs**
2	Principles of Good Documentation	**Handling an FDA Inspection**
3	**Handling an FDA Inspection**	**Orientation to GMP Compliance**
4	GxPs	Introduction to the Quality System (QS) Regulation
5	**Orientation to GMP Compliance**	Good Documentation Practices for Medical Device Manufactures
6	cGMP Refresher: Pharmaceutical Quality System and Quality Culture	**Change Control**
7	**Change Control**	**GMP Principles of SOPs**
8	**GMP Principles of SOPs**	**FDA Training and Qualification Requirements**
9	**FDA Training and Qualification Requirements**	An Introduction to ISO 13485 — The Quality Management System for Medical Devices
10	**Principles of Aseptic Processing**	**Principles of Aseptic Processing**

Table 3: Top 10 pharmaceuticals and medical device GMP courses in 2022; courses common to both lists are bolded

Top 10 courses – clinical

Many of our customers are innovative drug or device companies that run clinical trials, manage contract research organizations (CROs) or are themselves CROs. These companies must comply with clinical trial regulations. ComplianceWire® delivers to physicians, nurses and patients, for example, instruction on how to use technology involved in a given clinical trial; clinical protocols for review, signature and informed consent; etc. The top 10 courses from our clinical library are listed here.

Not surprisingly, the courses focus not only on the primary obligations of sponsors and investigators, but also on patient privacy, safety and informed consent.

Top 10 clinical courses

1. GCP/ICH Obligations of Investigators Conducting Clinical Trials
2. GxPs
3. GCP/ICH Obligations of Sponsors, Monitors and Investigators
4. HIPAA — The Impact on Clinical Research
5. GCP/ICH Obligations of Sponsors and Monitors
6. Overview of the Clinical Research Process
7. Ethics as the Foundation to Clinical Research
8. Drug Safety and Adverse Event Reporting
9. Good Clinical Practices (GCPs) for New Product Investigations
10. Protection of Human Subjects in Clinical Trials

Table 4: Top 10 courses from our clinical library

Inspections and enforcement

Many of our customers — particularly those outside the U.S. — need to understand what to expect when the FDA or another regulatory agency visits to perform an inspection or audit. Regulatory agencies themselves benefit from companies being ready for inspections, as well-prepared can provide inspectors with what they need to do their jobs effectively. Our customers rely on our FDA Inspections and Enforcement library to help them maintain a state of continuous audit readiness and see to it that their teams know what is expected of them. Here are our top 10 titles from the FDA Inspections and Enforcement Library.

The top 10 list in **Table 5** corresponds well to the inspection data we presented in **Figure 2**, showing a robust audit activity on the part of both the FDA and the European Union (EU). Companies use these courses to ensure that their teams remain continuously audit-ready and know what to do when regulatory agencies come to call.

Course title
1. Handling an FDA Inspection
2. FDA Training and Qualification Requirements
3. Part 11: Electronic Records; Electronic Signatures
4. Good Laboratory Practices (GLPs)
5. Basics of Inspections: Beginning an Inspection
6. Basics of Inspections: Issues and Observations
7. EU Directives and Inspection Readiness
8. Failure Investigations for Medical Device Manufacturers
9. Interviewing Techniques
10. Part 11: Electronic Records and Signatures — Application

Table 5: Top 10 courses from the FDA Inspections and Enforcement library

Being proactive regarding citations

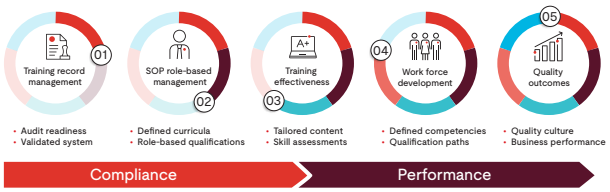
We researched the most common audit citations, using as sources data from our FDA collaborations and research we conducted using the FDA's publicly available citations. That is, which violations did the auditing agencies cite most frequently? With that knowledge, we determined which courses contained information that would help life science customers avoid the most common citations. A key aspect of a healthy quality culture is being proactive. Accordingly, as part of your quality program, you could include the courses that help your organization proactively address potential quality issues through awareness and knowledge of common violations ahead of time. A small sample follows. Interested parties can contact us at our website[10] to request the full list.

21 CFR 820.30(g) -Design validation - risk analysis not performed/inadequate			
DEV40	Design Control Regulations for Medical Device Manufacturers	**PHDV103**	Approach to Computerized Systems Validation and Compliance
DEV42	Quality Systems Inspection Technique (QSIT)	**PHDV63**	Understanding GMPs for Facilities and Equipment
DEV43	Introduction to the Quality System (QS) Regulation	**PHDV77**	Key Concepts of Process Validation
DEV50	A Guide to ISO 13485 - The Quality Management System for Medical Devices	**PHDV78**	Application of cGMPs to Analytical Laboratories
FDA29	Risk Management 1: Key Concepts and Definitions	**PHDV79**	A Step-by-Step Approach to Process Validation
PHA50	Resolving Out Of Specification Test Results	**PHDV87**	Environmental Control and Monitoring
PHA51	Writing Validation Protocols	**PHDV88**	Implementing an Equipment Qualification Program
PHA55	Documenting Validation Activities	**QSR03**	QS Regulation 3: Design Controls
PHDV102	Requirements for Computerized Systems Validation and Compliance		
21 CFR (820.100(a)) - Lack of adequate procedures			
DATA01	Introduction to Data Integrity	**MDR03**	CE Certification for Medical Devices
DATA02	Auditing of Computer System Validation to Ensure Data Integrity	**PHA47**	Understanding the Principles and Practices of Process Controls
DATA03	Data Integrity: The Role of Quality Assurance for Data Integrity	**PHA48**	Writing and Reviewing SOPs
DATA04	Data Integrity for Quality Control Laboratories	**PHA64**	GMP Principles of SOPs
DEV40	Design Control Regulations for Medical Device Manufacturers	**PHA67**	FDA Training and Qualification Requirements
DEV42	Quality Systems Inspection Technique (QSIT)	**PHDV101**	Management Responsibility for Quality: What FDA Expects
DEV45	Failure Investigations for Medical Device Manufacturers	**PHDV75**	Essentials of an Effective Calibration Program
DEV46	Complaint Management for Medical Device Manufacturers	**QSR04**	QS Regulation 4: Document and Purchasing Controls
GCP29	Recruitment and Retention of Study Patients	**QSR09**	QS Regulation 9: Records
ICHreg04	Validation of Analytical Laboratory Procedures		
21 CFR 820.198(a) - Lack of adequate complaint procedures			
DEV46	Complaint Management for Medical Device Manufacturers		
21 CFR 820.50(a) - Evaluation of supplies, contractors, etc requirements			
Aseptic01	Basics of Cleanroom Operations	**PHA38**	Introduction to cGMPs
FDA27	Interviewing Techniques	**PHA55**	Documenting Validation Activities
FDA28	Field Examinations	**PHA67**	FDA Training and Qualification Requirements
GCP01	GCP/ICH Obligations of Sponsors, Monitors, and Investigators	**QSR04**	QS Regulation 4: Document and Purchasing Controls
GCP29	Recruitment and Retention of Study Patients		
21 CFR 820.70 (e)- Contamination control, lack of or inadequate procedures			

Table 6: Sample of UL Solutions FDA libraries, mapped to common violations, medical device

Summary

We thank our wonderful and valued customers who took the time to share with us their views on the state of learning within the industry. Our annual benchmarking survey, the pulse that we have on a broad cross section of the global pharmaceutical and medical device industry, and the wide adoption of our ComplianceWire® learning management system allow us to provide useful insight into learning trends. If our experts, technology and content can be of service to you on your journey from compliance to performance, please contact us at UL.com/ComplianceWire.



Endnotes

[1] UL Solutions has a unique Cooperative Research and Development Agreement (CRADA) with the FDA. Under this agreement, the FDA acts as subject matter expert (SME) for UL Solutions regulatory courses, which the FDA then uses to train their own inspectors. UL Solutions can then offer those courses to industry, making it a truly unique offering in the life science industry. Several other governments have similar arrangements with UL Solutions.

[2] See https://auditpass.site/ for more on AuditPass.

[3] Pitts, Simone (2022). FDA Inspectional Trends and Insights on the Remote Assessment Process. Paper presented at the UL Solutions ComplianceWire® Knowledge Summit, June 2022, Princeton, NJ.

[4] See https://www.deephow.com/ for more on DeepHow.

[5] Llopis, G. (2018, Jan. 8). HR Departments Must Urgently Become Human Capital Department. Forbes. https://www.forbes.com/sites/glennllopis/2018/01/08/hr-departments-must-urgently-become-human-capitaldepartments/?sh=2144b35d21a6

[6] Kirpatrick Partners (2023). What is the Kirkpatrick Model? Retrieved from https://kirkpatrickpartners.com/the-kirkpatrick-model/ May 19, 2023.

[7] Harachand, S. (2023, April 5). Pharma 4.0: Taking CDMO Factories by Storm. Contract Pharma. https://www.contractpharma.com/issues/2023-04-03/view_features/pharma-4-0-taking-cdmo-factories-by-storm/

[8] Giandomenico, E. (2022). Aseptic Best Practice Training Using Virtual Reality. Presented at the 2022 Association for GxP Excellence (AGXPE) Conference and Expo, San Antonio, TX, May 1–4, 2022

[9] See UL.com/compliancewire for a full list of courses.

[10] The ComplianceWire® website is UL.com/compliancewire

UL.com/Solutions