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Main Benefits of Using your LMS for Regulatory Compliance Training

01

Proactive Approach to Compliance

Multinational and global companies deal with different regulations and various regulators around the world. Training records are nearly always reviewed during an inspection or audit by regulatory authorities to check that employees have received the appropriate training and their competencies or certifications are current and valid. Using a Learning Management System (LMS) ensures your organization is always ready for a compliance audit.



2 out of 3

organizations say that demonstrating compliance is very important or critical to them

AND



1 out of 2

organizations are relying on their LMS to demonstrate compliance

HOWEVER



Only 1 out of 3

are ready for a compliance audit (for low performing organizations)



Only 2 out of 3

are ready for a compliance audit (for high performing organizations)

Source: Brandon Hall Group, 2014

02

Effective Tracking of SOPs

In highly regulated environments where personnel are required to work according to written procedures, documented instructions or standard operating procedures (SOPs), there needs to be a set of guidelines that defines the tasks to be done. There should also be clear definition as to what has to be documented to demonstrate that the activity was actually performed. If any deviations to the procedure are made, they have to be documented at the time of the deviation, not later.

Training plays an important part when implementing a new or updated SOP since the training is what teaches employees on the new procedures. This is where the LMS plays a vital role — being able to schedule and track the training of individuals on the SOP's. Organizations must be able to keep accurate records of individuals and their training plans.

03

Electronic Training Records

There is no regulatory requirement that dictates whether organizations must use paper or electronic media to document their personnel training records, but there are many benefits in using electronic training records:

- Training plan generated in LMS can be stored easily and it is accessible to all appropriate personnel
- Training class: individual signs on to a training class and it is recorded in the LMS database
- Training completion is automatically recorded in the LMS database
- Data is always up-to-date
- Training records can easily be viewed online or printed as a report
- Data integrity: before each operation, an electronic signature is required before operation can happen
- Training records are updated with courses taken; course revisions trigger training to maintain compliance
- Audits: changes made to sensitive data include info on who, what and when changes occurred.

Companies typically find that using electronic record keeping and electronic signatures provides many cost and time saving benefits as well as better risk management.

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Software Validation

Compliance with GxP predicate rules (e.g. 21 CFR 210 or 21 CFR 820) in combination with electronic records as per 21 CFR Part 11 or EU GMP Annex 11 for computerized systems, is mandatory in regulated environments. Compliance with these regulations requires much more than just producing electronic versions of paper records.

Regulatory bodies like the FDA request that your LMS is validated for intended use. Failure to validate the LMS can lead to a Warning Letter. For organizations that are not directly governed by the FDA, 21 CFR Part 11 is still an approved standard for electronic signatures, auditing, and record keeping. A good LMS vendor provides consulting services for your LMS to be validated in client environments worldwide for intended use along 21 CFR Part 11, 21 CFR Part 211, and 21 CFR Part 820, as well as EU GMP Annex 11 and EU GMP Part 1 requirements.

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Integration

A good LMS offers additional compliance-related functionality by helping an organization:

- Create better audit trails and reports that may help reduce auditing costs
- Respond more quickly and effectively to opportunities and challenges
- Avoid potentially expensive legal and other liabilities

But in configuring an LMS for compliance-related work, some organizations may discover that an LMS alone may be insufficient for their needs and may therefore prefer to simultaneously employ different complementary systems and then integrate these systems with the LMS to form a comprehensive online compliance scheme.



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