Tenneo
Learning Platforms

Role of LMS in Improving Compliance & Employee Performance for Pharma Organizations

One of the industries that are heavily regulated by external authorities is the Pharma Industry. And very rightly so, because the pharma industry revolves around drug manufacturing and healthcare. This makes it highly necessary that they are regulated by the government and external authorities to ensure public health and welfare.

Compliance isn't just about being audit-ready or checking off guidelines & regulations. It's about setting up a process of ethical workflows and governance to ensure performance standards are met and exceeded. It's about ingraining values in your workforce to do the right thing at the right time in the right way.

Chapter
01

Need for Compliance in Pharmaceutical Industry

There are various bodies that regulate clinical trials on drugs manufactured to assess their fitment and effectiveness. The United States Food and Drug Administration (FDA), the American Medical Association (AMA), the Indian Medical Association (IMA), the Central Drugs Standard Control Organization (CDSCO) are a few regulatory bodies that are responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs.

The manufacturing aspect of the pharma industry involves drug research, manufacturing and clinical trials. The training required for manufacturing drugs is highly regulated as well, with compliance training forming the major and the most crucial aspect of pharma training.

The personnel working in drug manufacturing must undergo stringent training and retraining to adhere to the guidelines for maintaining quality and safety of the drugs regulated by the authorities. For instance, a pharmaceutical organization must define the tasks and the environment in which a lab technician would work. This job description must align with the regulations and guidelines prescribed by the regulatory bodies. There are Standard Operating Procedures (SOPs) defined for each task and the environment for researching and manufacturing drugs and conducting clinical trials. Here, being compliant with the regulations becomes of utmost importance to avoid hefty penalties and damages.

Moreover, maintaining a record of SOP training is necessary for audits. There are certain guidelines on how the training report must be generated to maintain compliance. One such guideline is 21 CFR Part 11. It is the FDA's regulation for electronic documentation and electronic signatures. It outlines the administration of electronic records in a quality management system and gives guidance for industry best practices. 21 CFR Part 11 is a guideline for the training of people who are involved in the process of manufacturing drugs. There is a certain mechanism defined in 21CFR Part 11 for maintaining records of the trainings conducted.

Chapter
02 Two Important Aspects of Compliance Training – Process and Evidence

- **Process**

It is important to identify the employee compliance training needs mapped to the Standard Operating Procedures (SOPs). Once the SOPs are set, you must structure the training in sync with the regulation guidelines specific to your industry. You can also leverage the LMS to assess the compliance level of your workforce and automate recurring compliance courses based on the training tenure.

- **Evidence**

Training evidence is necessary for compliance audits. These audits generally monitor three things -

Right people getting the right training at the right time.

Compliance training acknowledgement from the workforce.

Accomplishment of the compliance training goals.

LMS helps you address these requisites with reports and certifications, digitally signed accords, and evaluation mechanism to map the training results against the training goals.

Chapter
03

How v8 makes Compliance Training Effective & Efficient

v8 helps pharmaceutical organizations maintain compliance and train employees to be compliant as per the guidelines and regulations. It also helps in maintaining training records as per the mechanisms defined in 21 CFR Part 11. The Compliance Management Module of v8 assists you throughout the compliance process, right from identifying training and compliance needs to maintaining a training record for compliance audits.

Compliance Management

You can create compliance masters using LMS v8 to streamline your user management process. The relevant users will be able to take the training required to meet compliance regulations. Additionally, you can set rules for each compliance requirement including the training courses, length of training, assessment and certifications in accordance with the regulations and compliance guidelines.

Configuration

Each compliance can be subject to validity and once that is expired, the user must apply for the authorization again. You can also create compliances that have prerequisites based on user attributes (vintage, department, etc.) or other dynamic attributes. v8 also enables you to map compliance training with specific job roles and have it assigned to a user or a training group.

Reports & Dashboards

You can monitor employee compliance levels using compliance reports & dashboards across the organization. Moreover, you can also track compliance exceptions and identify users who are yet to complete training or are non-compliant with certain guidelines.

Audit Logging

v8 offers a built-in digital signature mechanism for learner activities (course completions and announcements. With its effective audit logging mechanism, v8 helps you generate reports that can be used in statutory audits. These reports can be generated as per the guidelines mentioned in 21 CFR Part 11.

Compliance Connectors

The compliance connectors provide a path for seamless integration within the LMS and the HRIS for mapping employees & their job descriptions against their training & compliance needs. You can also integrate with the Document Management System for pulling in Standard Operating Procedures (SOPs).

Read and Sign

This feature ensures that learners are made aware of their expected participation in the training programs, and they acknowledge that they have received the training. This also serves as evidence for regulatory bodies that want to monitor the training participation and completion rate.

Chapter
04

Tenneo LMS to Comply with 21 CFR Part 11

Controls for closed systems	Designed to be a closed system and uses login credentials to authenticate each user.
Validation of system	Through audit trails and tracking user and data changes. Documentation for inspection also provided.
FDA copies/Quality documentation	All quality-related relevant data documents are readily available.
Protection and recoverability	For protection and recoverability, we have backup planning and execution techniques.
Limiting system access to authorized individuals	Access to the data is given only to authorized users with individual login credentials.
Audit trails	All quality relevant data have an audit trail. The audit trails track user specific changes exact to the second.
Authority checks	Tenneo LMS has an elaborate role-based authority concept which meets the requirements of 21 CFR Part 11.
Device checks	The system has validated input and output interfaces. The webservice based interfaces accept and provide data securely in JSON format.
Training	All experts that are involved in the creation (coding) of Tenneo LMS are trained in computer system validation and 21 CFR Part 11 compliance.
Duplicate User IDs	The uniqueness of each combined identification code and password prevents duplicate ID creation.
Procedures for identification codes	Administrator periodically maintains active accounts and disables inactive accounts.
Passwords	Admin can enable password expiry dates. Passwords can't be recalled if a person leaves or is transferred.
Electronic Signatures	Tenneo LMS supports digital signatures as a part of certificates that are issued on training completion.
Secure SAAS	Tenneo is working with Amazon as the hosting partner. The AWS certification for ISO 27001:2013 enables us to safeguard information.
Approval workflows	Workflows for content approval, user registration approval, certificate printing approval etc. make our system very robust.

Chapter
05

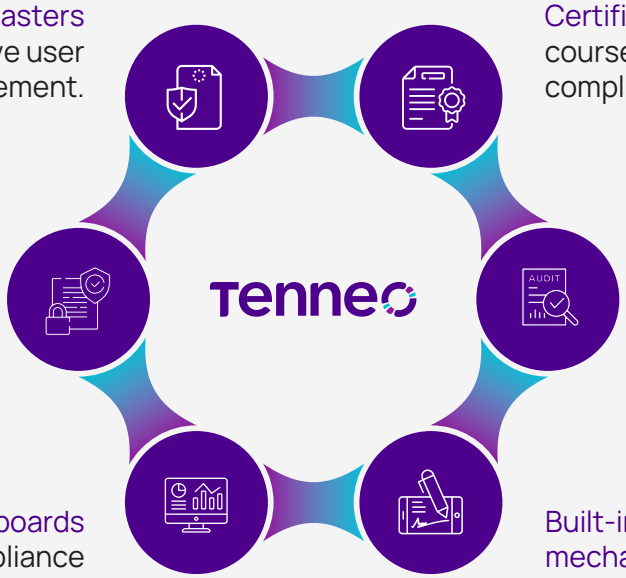
Compliance Management Module

Tenneo LMS provides a comprehensive compliance management module that treats compliance training separately from other trainings.

Compliance Masters for effective user management.

Certifications courses on completion of compliance training programs.

Role-specific compliance training for particular user groups.



Effective audit loggin for better reports used during the statutory audits.

Dashboards for monitoring compliance progress & exceptions.

Built-in digital signature mechanism for course completions & announcements.

Chapter
06

Comply with Confidence with Tenneo LMS

Tenneo LMS enables pharmaceutical organizations to adhere to SOPs and track the training and compliance progress of each user as per the guidelines defined for compliance requirements. Organizations can train their employees to perform better and be more efficient while being compliant to avoid any penalties or reputation damage.

Simplify the Complexity of Compliance

Breakdown the complex training structures into accessible programs for your workforce without any additional cost.

Reduce Damage Risks

Mitigate risks and avoid any potential legal issues. Remember, compliance training is never expensive, non-compliance is!

Track, Monitor, Retrain

Get early visibility into non-compliance through progress analysis and compliance exceptions. Automate retraining as and when required.

Increase Completion Rates

Bid adieu to boring training workflows by leveraging gamification, video-learning and micro-learning and witness the soaring course completion rates.

Chapter
07

Role of Medical Representatives in Improving Business Outcomes

The Medical representatives are the face of your pharma products. They play a critical role in the pharmaceutical industry as they are responsible for promoting and selling a company's products to healthcare professionals and contributing to the overall business outcome.

Right from the product knowledge and sales techniques to compliance and customer relationships, they have to undergo stringent training processes to ensure success. While compliance training ensures process adherence, it is important to further train MRs to enhance their sales performance and negotiation skills.

Chapter
08

Need for Training MRs to Improve Sales & Performance

The OTC drugs do not require a doctor's prescription. Another major difference between the two is advertising. While OTC drugs can be advertised under certain regulations, pharmaceutical industries are not allowed to market and advertise the scheduled drugs. This makes the Medical Representatives (MRs) their frontline sales as well as marketing channels. MRs are the face of your products and must have efficient training to be able to aptly represent your organization out there in the market.

The pharmaceutical industry majorly consists of two types of drugs – Scheduled drugs and Over the Counter (OTC) drugs. Scheduled drugs are highly regulated and cannot be sold by anyone except pharmacists subject to doctor's prescription.

Chapter
09

Enhancing Sales & Performance of MRs with Tenneo LMS

Tenneo LMS v8 is an ideal training partner for your MRs. v8 makes compliance training effective and efficient while enabling MRs to gain all the product knowledge they need to improve their sales figures. It helps them constantly upgrade their knowledge and represent your company products and empowers them to learn as and when needed.

01

Sales Enablement

Proper product training helps MRs to pitch their product correctly to the healthcare professionals. v8 provides on-demand learning to MRs where they can search for any required material instantly. The video library feature makes learning easy and engaging. v8 can prove to be a great sale enablement tool that allows MRs to quickly find content that they know will address their audiences' queries and improve the sales probability.

02

CRM Integration

v8 offers 100+ connectors, including CRM connectors for seamless integration. These connectors integrate the LMS with your HRIS, document management systems and other applications. MRs can easily maintain and track records of all healthcare professionals, plan and monitor visits to doctors, and understand what information must be given to them to improve sales.

03

AI-driven Learning

v8 provides a mechanism for gathering intelligence when MRs want to instantly search for any learning material. The AI-based intuitive search mechanism helps MRs find instant answers by searching for a particular video or content in any other format and showcase it to the doctors for quick redressal of their queries. v8 provisions for Natural Language Processing & deep search to make the learning process simple and effective.

04

Skills Metrics

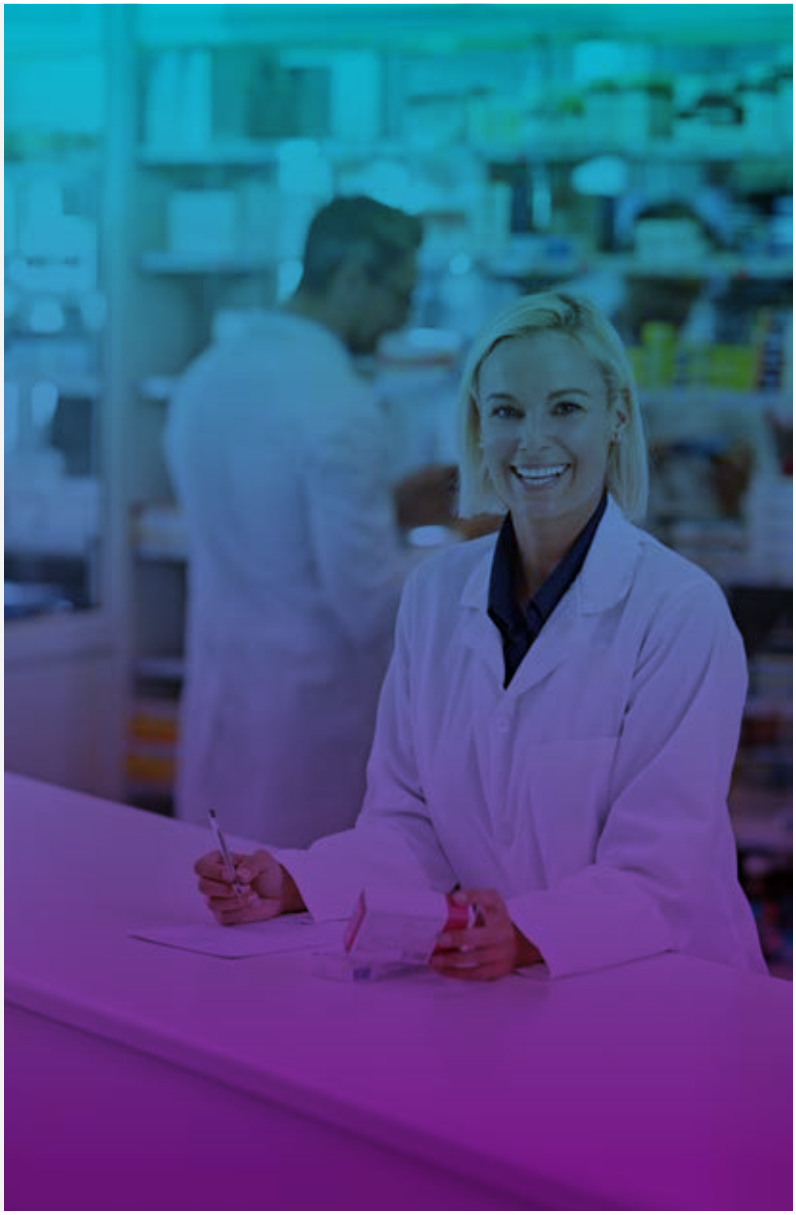
v8 enables you to define certain skills thresholds and map the abilities of MRs. Pharmaceutical organizations can leverage the skills metrics to monitor the soft skills as well as the product and technical knowledge of MRs and basis on the insights obtained, they can guide them towards certain training and retraining programs to upskill themselves. The skills and competencies framework can also help in making informed decisions about transferring highly skilled MRs to better markets.

Chapter
10

Final Word

Tenneo LMS v8 can be an invaluable tool for enhancing the sales and performance of medical representatives in the pharmaceutical industry.

By providing on-demand learning, integrating with CRM systems, incorporating AI-driven learning, and monitoring skills metrics, v8 can help MRs gain the knowledge and skills to improve sales. Moreover, pharmaceutical organizations can train their employees to perform better and be more efficient while being compliant to avoid any penalties or reputation damage.



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