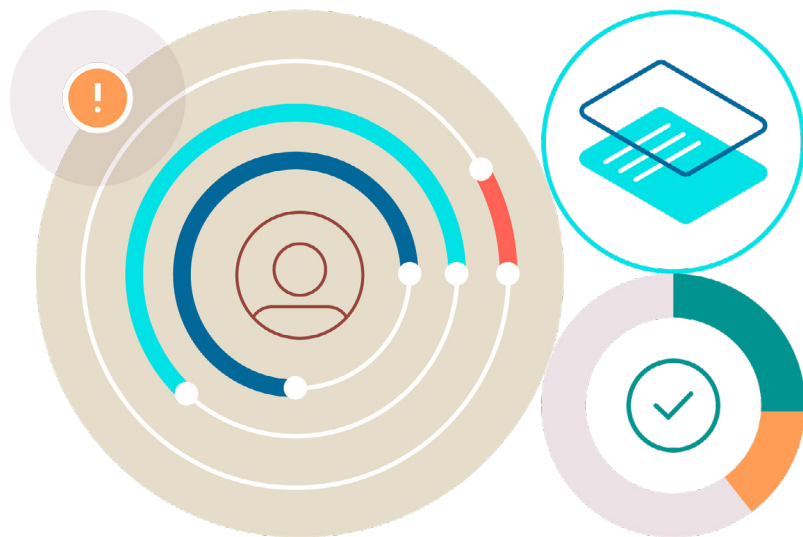**CASE STUDY**

Sai Life Sciences Automates Training Program with UL Solutions

Company overview
Company: Sai Life Sciences Limited
Industry: Contract research development manufacturing organization
Number of sites: Seven

Pharmaceutical and life science company Sai Life Sciences Limited, headquartered in India, was looking for a learning management system (LMS) for its training program. More than 2,000 employees involved in the entire life cycle of pharmaceutical products required training across all areas of the business. Manually tracking and maintaining training logs had become too cumbersome. Sai wanted to move away from paper training to an electronic system, so they began a search for an appropriate LMS.

The challenge

In the pharmaceutical industry, training plays a major role in helping personnel improve their scientific and technical knowledge and skills through training mechanisms for drug discovery, development and manufacturing under current Good Manufacturing Practices (cGMP).
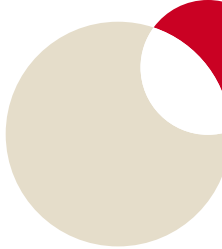
Sai's vision included a paperless work environment, so the company needed to implement an electronic LMS for training. Sai leadership decided on the following requirements for its preferred solution:

- Effective and centralized training management across all sites
- Electronic review, retention and retrieval of good practice (GxP) training data
- Advanced e-Learning content
- Effective traceability and review of each action performed
- Quicker implementation of an electronic system

"Because we are in a knowledge-based industry, we foster the skills and competency of our people through best-in-class L&D practices. We have mapped the learning needs of about 120 roles across all our sites and review them periodically. Training is organized in different categories like quality, technical, safety, soft skills and other need-based training. ComplianceWire® is well-configured per our procedural requirements, through which we ensure effective governance of training activities across all sites and set highest compliance standards."

Dr. Damodharan M, senior vice president and head — global quality and regulatory affairs

Solutions

UL.com/ComplianceWire

How UL Solutions helped

Using a set of selection parameters that included compliance with 21 CFR Part 11 and EU Annex 11 validation requirements, stringent technological and support specifications and access to a wide range of training content, the Sai team unanimously chose ComplianceWire® Learning and Qualification Management System, a web-based training and learning management system available through ULTRUS™ software from UL Solutions, as the best system for the company.

After selection, Sai's top priority was to simplify implementation across all sites and users simultaneously. To audit and qualify ComplianceWire®, Sai's leader for global quality and regulatory conducted a physical audit to verify 21 CFR Part 11 Compliance Requirements at UL Solutions' facility in Princeton, New Jersey. Next, they completed a thorough mapping of Sai's training procedure and features of the ComplianceWire application.

A test environment was then configured and enabled for approximately 1,800 users, who were assigned a trial learning module on data integrity. About 93% of users completed the assignment within four days, demonstrating how successful the LMS can be. Sai's technical administrators also evaluated and approved the operational qualifications for the LMS. Finally, the production environment was configured, and access rights distributed to administrations, who also received multiple training sessions.

In all, the LMS was fully implemented in less than 45 days, providing Sai with a qualified and 21 CFR Part 11 compliant application for all its employees, and a single point of contact and control for all queries, feedback and improvement actions.
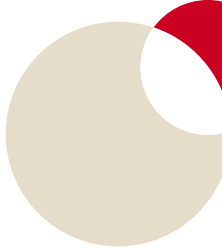
First impression	
• Application is easy to navigate • User-friendly application • Effective compliance monitoring	• Trial assignment completion by 93% of users • Built confidence for Sai Management to adopt more new electronic systems
LMS administrators	
• A team of 50+ personnel across all sites manage LMS with different access privileges	• 30+ personnel closely monitor LMS and compliance activities
GxP integrations with ComplianceWire	
Integrations within one year of LMS • LMS – HRMS integration • LMS – Single Sign-on integration	• LMS – CourseCreate integration • LMS – Percipio integration

"ComplianceWire® is robust, scalable and configurable per our organization-specific needs and can integrate with GxP software. Centralized governance of training activities across all sites has become more effective and systematic. Automated user creation, schedulable compliance reports, system-generated reminder notifications, SCORM-based audio-visual training content development in CourseCreate are some of the key features of this application. Support extended by the UL Solutions team, both pre- and post- implementation of LMS is commendable!"

Vinoth Kumar GP,
Corporate training manager and
LMS organization administrator

100-seat training hall to conduct instructor-led training sessions

"Training management and compliance monitoring across all roles and departments of our manufacturing facility has progressed significantly using ComplianceWire. It is easy to retrieve training data during audits from this application."

Vinil Sai A,
Site training coordinator

Results

In addition to the internal benefits for the company, Sai has received a number of industry recognitions since its move to ComplianceWire. These include:

- ATD Excellence in Practice Award 2021 – Learning Technology (LMS implementation and integrations to LMS)
- ATD Excellence in Practice Award 2021 – Change Management
- (Quicker adaption of an electronic system, organization-wide)
- Prestigious Golden Peacock National Quality Award (2020)
- Learning Leader of the Year — 2020 (Dr.M.Damodharan), from Inventicon, Asia

"Most common feedback from new employees during their induction training is that ComplianceWire is an easy-to-navigate and user-friendly application."

Nitin Rajendra Todkar, Department training coordinator

Increased compliance score

Organization-level compliance score >99.5% for the year 2019 >99.75% for the year 2020
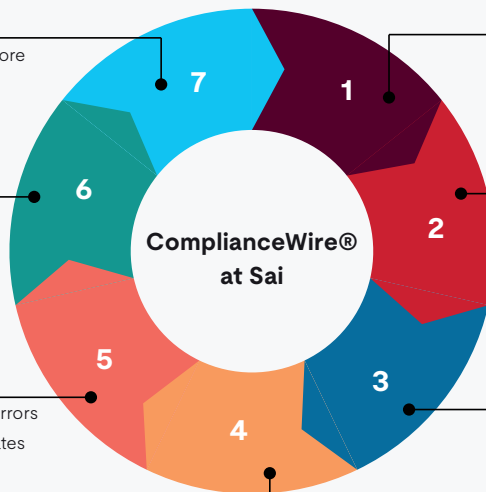
Upskilling the training team

Training coordinators became system administrators. A dedicated team of 80+ competent personnel are qualified to operate LMS

Change-driven performance outcomes

- Reduction in number of human errors
- Increased timely QMS closure rates

80% to 100% qualification score

For effective learning, qualification score is set to 100% for all applicable training assignments

ComplianceWire® at Sai

Manual systems to e-learning system

- Fully validated and 21 CFR Part 11 compliant application
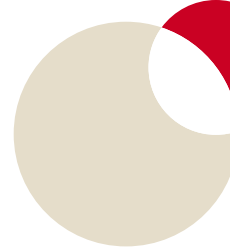- Governs around 250,000 assignments/year

Training categories

- 12 different sub-categories got added
- Quality (10 sub-types)
- Safety (four sub-types)
- HR/soft skills (five sub-types)
- Technical (three sub-types)
- Miscellaneous (five sub-types)

"Read and understand mode of content" to advanced audio-visual content

Learning content management system

- SCORM-based in-house audio visual, technical videos and automated training content and external content libraries (3000+ training items that includes controlled documents and SCORM courses).

UL Solutions

UL.com/ComplianceWire

ComplianceWire Learning and Qualification Management System is designed from its inception to serve life sciences companies, and address stringent and evolving regulatory requirements in order to support compliance. Life sciences companies around the world need a reliable qualification-based LMS designed specifically to meet the unique enterprise needs of the life sciences industry. Throughout the product life cycle from research through sales, ComplianceWire supports personnel training and qualification in conformance with local, national and international regulations. Sai's experience shows that finding and implementing a comprehensive and compliant LMS can be easy and rewarding.

"ComplianceWire is a secure, cloud-hosted application that meets the compliance requirements of an electronic system as per 21 CFR Part 11 regulations. Functionalities of ComplianceWire and associated GxP integrations are validated and qualified as per internal procedures also."

Narasimham Attanti,
Computer system validation expert

State-of-the-art manufacturing block

"With the CourseCreate tool, creation of training modules incorporating audio-visual files and chapter-wise evaluation for effective learning is ensured. It also supports one-click publishing of developed courses to ComplianceWire for assignments. It is easy to track and manage version updates of training items."

Priti A. Paranjpe, e-Learning content developer

UL Solutions

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ComplianceWire and ULTRUS software

ComplianceWire Learning and Qualification Management System is part of ULTRUS software, which brings together digital products from UL Solutions to help customers manage regulatory, supply chain and sustainability challenges.

Learn more about ComplianceWire for digital life sciences training and e-learning.

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