

ULTRUS™

CASE STUDY

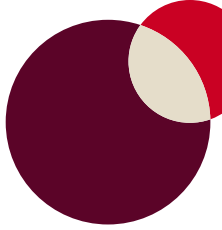
Competency-Based Training for Performance Improvement

Lupin Limited
India



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Overview:

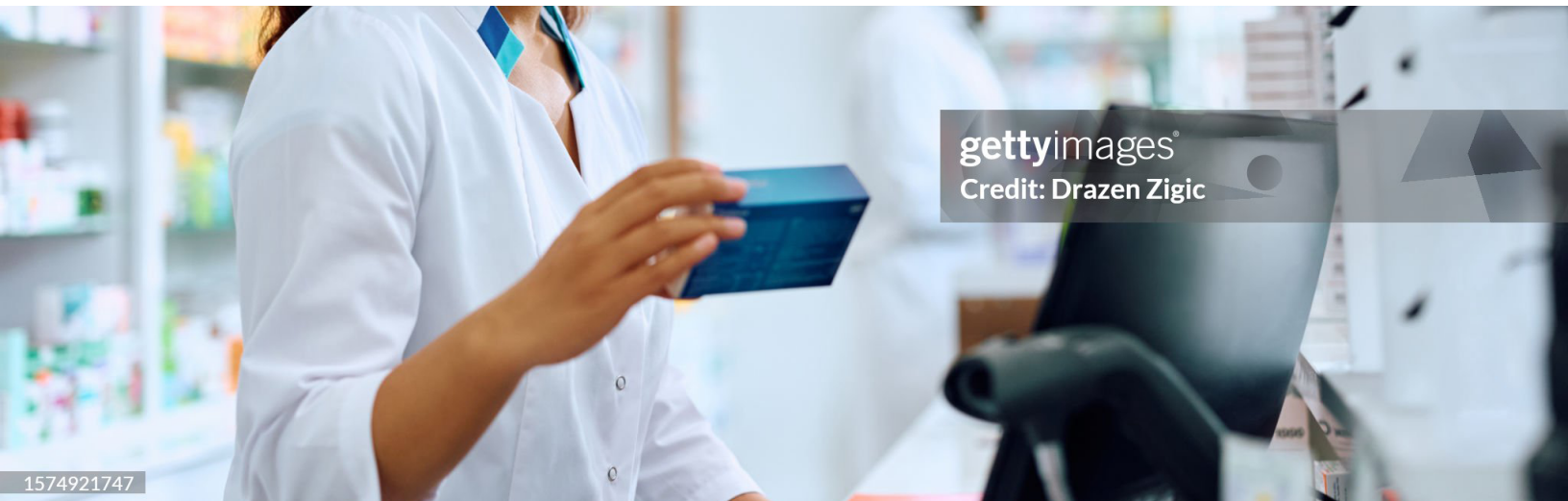
When Lupin Limited identified a desire to upgrade their training programs to achieve higher performance, they knew that they had to be willing to embrace change. Moving from a standard operating procedure (SOP)-based system to one focused on competencies would require a paradigm one that involved a different approach to organizing, delivering and evaluating employee training. But the payoff in terms of regulatory compliance, training effectiveness and productivity were worth the companywide effort.

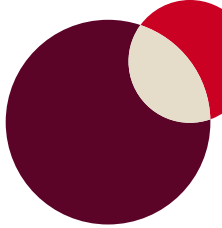
“Lupin entered into the era of competency-based training through the UL Solutions framework of training. The design was completely from UL Solutions and that coupled with Lupin’s execution finesse, made the project a grand success.”

Company overview:

- Company – Lupin Limited
- Industry – Pharmaceutical, active pharmaceutical ingredients (API) and finished dosage forms
- Number of sites – 12 Indian manufacturing sites, three global sites
- Functional areas impacted – API, oral solid dosage, injectable, dermatological, ophthalmic, packaging, quality control (QC) laboratories

*Nilanjana Basu
Head, Technical Training*





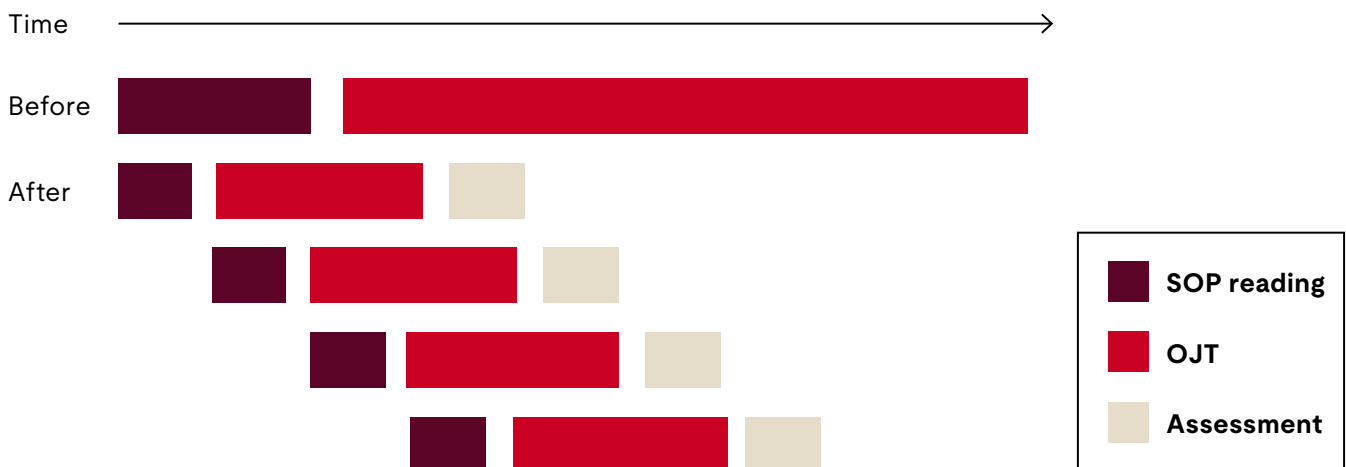
The challenge:

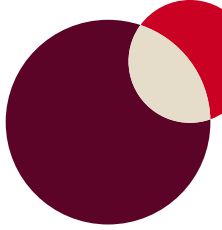
Facing an evolving regulatory environment and increased focus on performance expectations, Lupin recognized the positive impact that training on technical competencies could have on their organization. This was particularly true for their colleagues in operations and quality control laboratories. Their expectation was that the existing SOP-driven training process could be transformed into a more comprehensive system that would address the following challenges:

- Lack of documented, technical-based competence
- New joiners required to read large number of SOPs before beginning hands-on training with little connection between SOP content and actual job tasks
- Human performance-related deviations and invalid out of specification due to insufficient training resulting in resource-intensive investigations and lot release delays

The training process (figure 1) for new joiners began with company induction that included site orientation as well as training on the company’s quality policy and basic current Good Manufacturing Practice (cGMP) and Good Documentation Practice (GDP). Upon completion, colleagues would transfer to their assigned department where their next few weeks were spent on the overwhelming task of reading SOPs, typically more than 100 that were on their assigned curriculum. Next, they were assigned to a trainer who demonstrated various on-the-job (OJT) tasks or methods for which they would be responsible. There were no requirements for colleagues to practice tasks or be technically evaluated for competence.

Figure 1 – Before and after processes





The UL Solutions response:

Lupin partnered with the ComplianceWire® learning team, part of ULTRUS™ software from UL Solutions, to design, pilot and implement an improved training approach that would meet emerging regulatory expectations as well as fuel productivity improvements. Lupin found it critical that the new process be compatible with the existing learning management system and be able to be rolled out companywide across 12 sites and varying functions.

Approach:

Lupin selected ComplianceWire to work with their corporate quality team to develop a competency-based program that integrated current regulatory expectations and industry best practices. Using a risk management approach, Lupin chose to redesign their process with input from two functional areas that were common across the company, namely oral solid dosage form manufacturing and quality control (QC) laboratories. Two initial plant sites were identified for pilot projects. Using a facilitative approach, ComplianceWire led the teams through the process highlighted below (figure 3).

Each functional area identified the individual roles of colleagues in the unit as well as the competencies that colleagues need in those roles. Eight to 15 technical competencies were common for each role. For example, a colleague functioning as a compression operator would require the following competencies: department-level procedures, cleaning and sanitization, in-process testing, compressing machine operation and setup, ancillary equipment, etc.

Existing SOPs and training elements were mapped to each competency and an overall training plan/curriculum was developed for the role. The teams were consistently able to identify SOPs that were assigned to roles that were not needed, thereby reducing the required number of readings by 20% to 40%. Additionally, many SOPs were identified as redundant or able to be consolidated, which led to an SOP simplification project.

Assessment checklists were developed for each competency with GMP impact to evaluate observable trainee technical competence and document competence. The teams brainstormed metrics that could be used to demonstrate effectiveness of the training program, and ComplianceWire provided recommendations for ongoing governance and performance measurement.

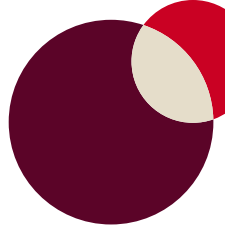
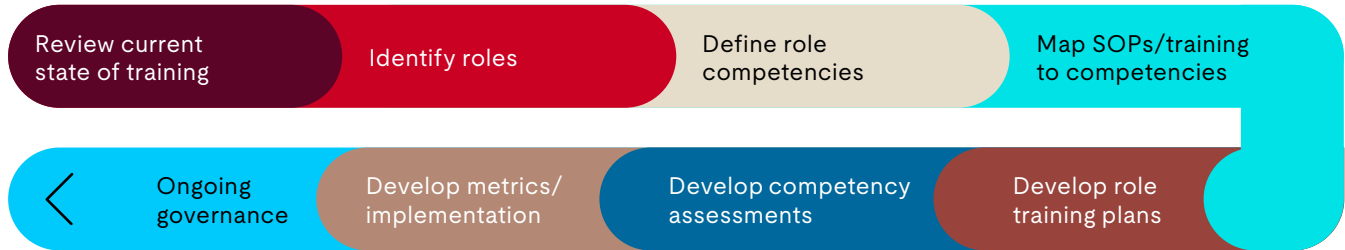


Figure 2 – Development process



The new training plans broke down the trainee’s activities into small modules that covered a single competency and one to 10 SOPs. After reading those few SOPs, the trainee would then work with a trainer on the floor or in the laboratory to learn the task following a “demonstration, practice and mastery” approach. When the trainer and trainee determined that the colleague was ready, the trainer would administer the competency assessment. Upon successful completion, the trainee became certified to work independently on that activity.

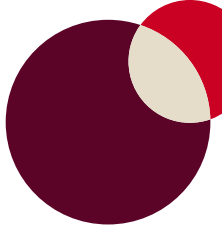
The modular approach was flexible so that each department could order the training modules to meet their operational needs and schedules. Multiple modules could be in progress at one time. The result was that an employee could be certified and become productive on some unit tasks while continuing to train on the balance. Of course, all assessments were documented, providing evidence that the employee was qualified to carry out the GMP activities, a critical regulatory requirement.

New training process:

“ComplianceWire’s learning team helped in designing the entire process and implementing in the phase-wise manner. After the pilot, we rolled out the entire approach through the QC and production. ComplianceWire has guided us step by step through the entire process.”

*Digambar Nigade
Vice president, Corporate Quality*





Pilot programs at two sites for OSD and QC laboratories were successful. ComplianceWire facilitated the process at two additional sites for active pharmaceutical ingredients and injectables. Lupin has successfully completed implementation in all sites for QC laboratories and is pursuing a rollout of the remaining manufacturing sites companywide in 2020. As with all new programs, there was initial resistance at some sites to implement the new process. However, to date, 1,000 employees have been trained using the new process and as sites share their experiences and successes, more sites are eager to embrace the program. Among the improvements achieved are:

Compliance

- Consistent and competency-based
- Objective performance evaluation
- Documented competence

Employee productivity

- Flexible, just-in-time training
- Improved quality of learning
- Reduced employee time to productivity

Error reduction

- Fewer training-related deviations
- Decrease in invalid OOS/ laboratory incidents
- Less time spent on deviations and corrective and preventive action

Employee confidence

- Training promotes compliance
- Objective feedback to trainees
- Employees become qualified

“The biggest impact is that the new joinee is able to be delivered at the shop floor once he has been trained on a particular competency. The main learning from this project was the fact that we are now able to train the person in a particular activity and get him/her functioning on the shop floor using a just-in-time training approach.”

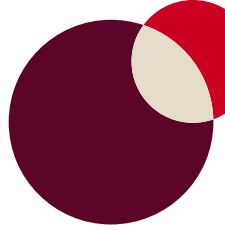
Vijay Mahajan
General manager, Manufacturing

“The new joiners are more competitive and skilled. The new joiners are better equipped to handle the machines and instruments as compared to the old process new joinees. This process has achieved minimization of error, improvement of quality of work and has resulted in quick onset of new joinee at the task post training.”

Nilanchal Mahanty
Department training coordinator

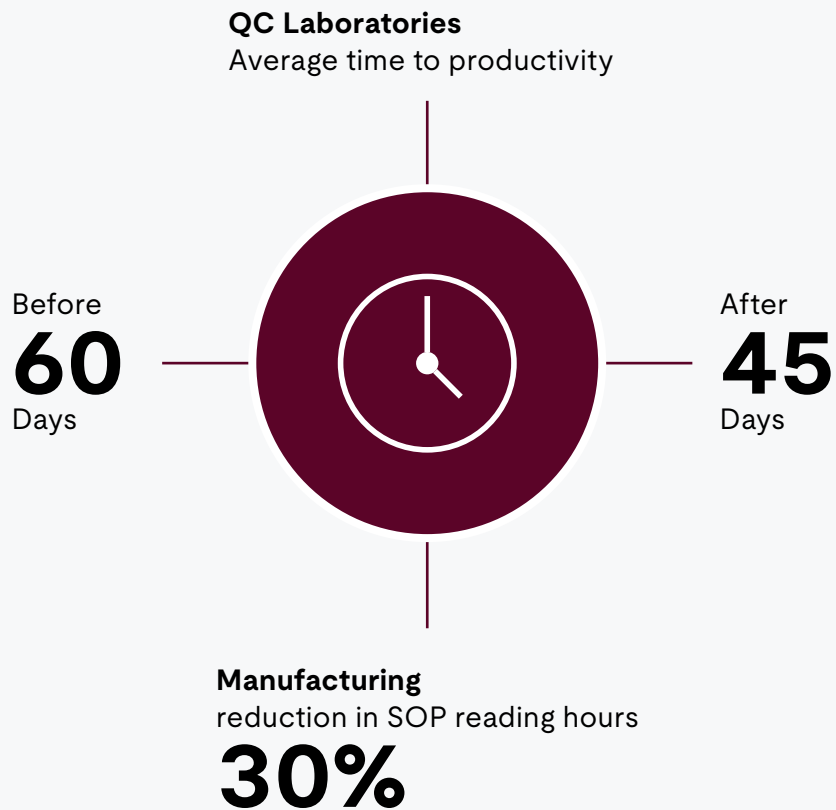
“This approach will definitely help in facing regulatory inspection by making the new joinee more confident and skillful in answering the auditor’s questions.”

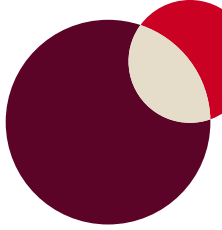
Bhaskar Pandhare
Production trainer



Most importantly, the quality of learning increased and they achieved documented proof of analyst qualifications. In operations, in addition to the reduction in required SOP readings, Lupin identified potential for further SOP simplification and has subsequently taken on a major SOP simplification project.

Productivity improvements





Conclusion

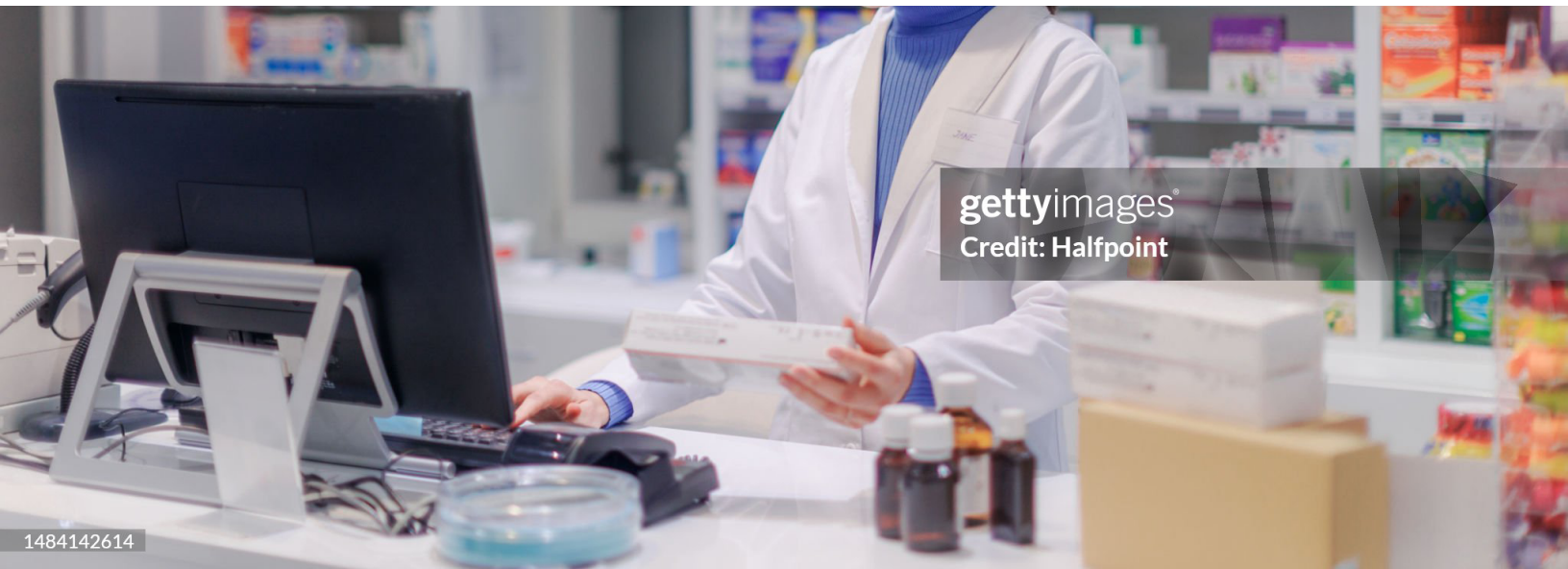
Implementing a role and competency-based training program allowed Lupin to dramatically improve the quality of learning imparted to employees in a more consistent and compliant manner. Employees now receive training in smaller, more in-depth modules and can prove their competence on the job. Each functional area has gained flexibility in scheduling training activities to meet their needs and implement just-in-time training. As a result of the improved process, Lupin was able to achieve not only significant productivity and quality improvements but also an increase in employee satisfaction.

“The technical expertise of the ComplianceWire team was of global standards. Because they were practitioners of the methodology during their professional tenure, the approach was very practical, and queries got resolved very quickly.”

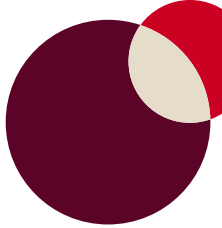
*Saurabh Agrawal
Manager, Technical Training*

Training statistics

- 600 QC analysts
- 400 Manufacturing shop floor operators
- Seven functional



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