

Case Study: Critical Component Manager

Introduction

The **iLensys Regulatory Master** serves as a **critical component manager**, overseeing essential elements for product safety and diligently addressing the risk of regulatory non-compliance. Through its proactive approach, the **Regulatory Master** promptly notifies clients of any deviations, empowering them to prepare a proactive mitigation plan. This case study explores how the implementation of the **iLensys CCL Manager System** revolutionized compliance management for a prominent pharmaceutical laboratory equipment company.

Issue

An Analytical Electrical & Electronic equipment company faced recurring non-conformity issues due to the lack of a systematic approach to **maintaining Critical Component List (CCL)** items for compliance purposes. This resulted in frequent non-conformities during quality audits, necessitating a comprehensive solution to address the root cause of the problem.

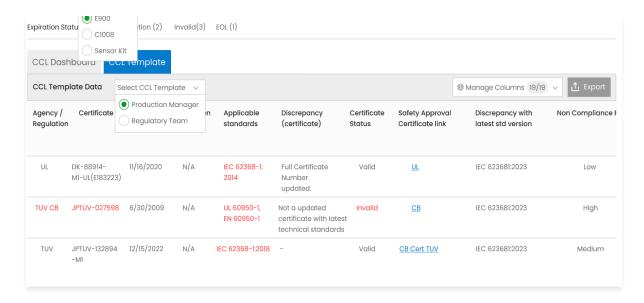
Solutions

In response to the compliance challenges faced by the pharmaceutical company, the iLensys CCL Manager System was implemented to monitor the lifecycle, validity of certificates, and deviations from standards for CCL items proactively. Key solutions implemented included:

- Utilization of the iLensys CCL Manager System to oversee critical component items effectively.
- Automated notifications to clients upon detection of any critical component issues
 within specified parameters, along with providing recommended alternative
 solutions.



Results

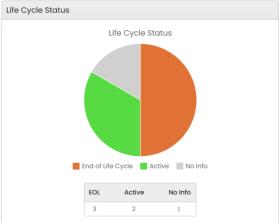


The adoption of the iLensys CCL Manager System **led to significant improvements in compliance management** for the pharmaceutical company, including:

- A remarkable 70% reduction in non-conformities observed during audits.
- Enhanced management of CCL items from a compliance perspective, resulting in improved audit performance.

Benefits







The implementation of the iLensys CCL Manager System offered the following benefits to the pharmaceutical equipment company:

- Ensured continuous compliance by entrusting iLensys with the monitoring and notification responsibilities.
- **Minimized product downtime** associated with End-of-Life or High lead time issues related to CCL items.
- Achieved a substantial 70% decrease in non-conformities during audits, highlighting the effectiveness of managing CCL items proactively.

By leveraging the iLensys CCL Manager System, an Analytical Electrical & Electronic equipment company successfully transformed its compliance management processes, demonstrating the value of proactive compliance planning and risk-mitigation strategies.