

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.

CCL Template Data			Select CCL Template	Manage Columns 19/19					Export
Internal Part Number	Item Type	Type/Model	Technical Specs	Standard	Mark(s) of conformity evidence of acceptance	Life Cycle Status	Comments (PCN, FFF MPN etc)	Agency / Regulation	
-	External SMPSU	Mean Well (Sun power)	100-240Vac 50/60Hz 4A O/P: 24Vdc 9.2A 221W	IEC 60950-1: 2005UL/CSA 60950-1	TUV CB Certificate: JPTUV-027598 UL: E183223	EOL	PCN	UL	
-	External SMPSU	Mean Well (Sun power)	100-240Vac 50/60Hz 4A O/P: 24Vdc 9.2A 221W	IEC 60950-1: 2005UL/CSA 60950-1	TUV CB Certificate: JPTUV-027598 UL: E183223	EOL	Replacement part no MPN is GST220A24-R7B	TUV CB	
-	External SMPSU	Mean Well (Sun power)	100-240Vac 50/60Hz 4A O/P: 24Vdc 9.2A 221W	IEC 60950-1: 2005UL/CSA 60950-1	TUV CB Certificate: JPTUV-027598 UL: E183223	EOL	Replacement valid certificate with latest safety std 62368-1.	TUV	

Results

Expiration Status: E900 C1008 Sensor Kit

Expiration (2) Invalid(3) EOL (1)

CCL Dashboard CCL Template

CCL Template Data Select CCL Template

Production Manager
 Regulatory Team

Agency / Regulation	Certificate	Expiration	Applicable standards	Discrepancy (certificate)	Certificate Status	Safety Approval Certificate link	Discrepancy with latest std version	Non Compliance	
UL	DK-88914-MI-UL(E183223)	11/16/2020	N/A	IEC 62368-1:2014	Full Certificate Number updated.	Valid	UL	IEC 623681:2023	Low
TUV CB	JPTUV-027598	6/30/2009	N/A	UL 60950-1, EN 60950-1	Not a updated certificate with latest technical standards	Invalid	CB	IEC 623681:2023	High
TUV	JPTUV-132894-MI	12/15/2022	N/A	IEC 62368-1:2018	-	Valid	CB.Cert TUV	IEC 623681:2023	Medium

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, the pharmaceutical laboratory equipment company successfully transformed its compliance management processes, demonstrating the value of proactive compliance planning and risk-mitigation strategies.