

Quality Assurance – Key Performance Indicators (KPIs)

Overview

Compliance Implementation Services (CIS) was retained in 2009 by a mid-sized global pharmaceutical company to assess their current quality systems and develop Key Performance Indicators (KPIs) to determine the health of their quality manufacturing systems. A scorecard was developed to monitor the performance of the quality system in terms of achieving the set targets.

The client company's Global Quality Assurance (GQA) organization proactively retained CIS to provide ongoing compliance support for KPI/Metrics evaluation and remediation, as well as overall compliance support in the following areas:

- Regulatory Intelligence
- Vendor Management
- Internal Audits
- Stability Program

Scope

The assessment required an understanding of the client company's existing quality systems, as well as federal and international manufacturing regulations and guidances. The assessment involved several quality systems within the Global Supply Chain. CIS used the DMAIC methodology of Define, Measure, Analyze, Improve and Control to improve the Quality System.

Methodology

During the project, CIS performed the following key activities for KPI/Metric review:

1. On-site Assessment of the following:
 - Corrective Action Preventative Action (CAPA) System
 - Deviation/Investigation System
 - Change Control System
 - Complaint Program

Proven Expertise

CIS is a consulting firm specializing in compliance strategies for pharmaceutical companies. Our experts can quickly identify your exposure to compliance risks, help you develop a strategic plan and ensure its implementation and ongoing adherence to regulatory requirements.

Our Areas of Expertise:

- Supplier and Vendor Audits
- Inspection Readiness
- Key Performance Indicators (KPIs) Development
- Quality Systems Development and Enhancement
- Global Quality Process Harmonization
- Root Cause Analysis and CAPA Effectiveness
- Document Control System Development & Enhancement

- Training Program
- Internal Audit Program
- Documentation Management System
- Stability Program
- Supplier Control Program

2. Conducted a thorough Data System Review of every existing electronic system that is capturing data.
3. Based on Data Review, developed a Score Card for the Quality System highlighting statistical targets as well as industry standard targets based on historic performance.
4. Developed a Global Dashboard to provide an overall score indicating compliance risk level for their total quality system.

5. CIS led weekly Global Supply Chain Status Meeting discussions with leadership team to ensure clear communication regarding project progress as well as remediation of issues.
6. CIS developed monthly Senior Executive Leadership presentations for the executive board regarding KPI/Metrics progress.
7. Implemented Quality System remediation plans for high-risk areas discovered within the quality system.

Deliverables

CIS provided the observations made as a result of the assessment activities during a review with the client company's key stakeholders in the project. After the review, CIS provided the complete set-up of the dashboards for each quality system and the global dashboard, which included all calculations and targets. CIS also provided an action plan outlining best practices to address and resolve all high risk areas in a timely, compliant fashion. CIS is currently in the process of implementing the client-approved action plan.

CIS' Compliance Experts understand US and EU Regulations and can help you implement and meet cGMP requirements.

Benefits

The client has benefited from the assessment conducted by CIS in the following ways:

1. The client company has external, independent confirmation outlining areas for improvement to minimize business and compliance risks that may exist within the current quality system.
2. The client company has recommendations and action plans to remediate identified compliance gaps or risk areas in the quality systems.
3. The global client company has received recommendations for improvements based on both U.S. and international standards.
4. The client company is now in line with the two principals outlined in ICH-Q9 (Quality Risk Management) which state that the risk to quality should be based on scientific knowledge.
5. The client company now has developed and can monitor effective control systems for process performance and product quality as stated in ICH-Q10 (Pharmaceutical Quality System).



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