The Zydus Hospira oncology accelerates forward with SAFE

Need

Zydus Hospira oncology were searching for a quintessential solution to facilitate and fulfil their EHS regulatory and compliances

Challenges

ASK-EHS provided them with a web-based EHS management platform that enabled them to effortlessly address several different statutory elements within their EHS domain

Benefit

Zydus Hospira oncology was able to digitalize a dogmatic paper and pen approach while ensuring, that automation ran and supported its EHS aspect, similar to its state of the art speciality pharmaceutical

Software based approach helps to achieve twin goals: compliance and EHS information management

Zydus Hospira Oncology private limited is a 50:50 joint venture between Cadila Healthcare and Hospira Inc. Cadila is a “billion dollar” company which was among the pharmaceutical pioneers in India. Hospira inc., is now part of global pharmaceutical behemoth – Pfizer; and was world's largest producer of pharma products in the injectables category.

Quintessential need for compliance

Zydus Hospira oncology manufacture and produce human pharmaceutical formulation dealing in specialty pharmaceuticals such as cytotoxic injectable products. These products are sold in the U.S, Australia as well as India.

Pharmaceutical manufacturing plants are specialized manufacturing environments. Based on the products, formulations or APIs manufactured, the safety net of compliance and regulatory framework, adapts and establishes the conformities for EHS ground rules. The other aspect in EHS compliance is conformity to specific country standards or norms and Good Manufacturing Practices (GMP). These are absolute requirements that allows the products to be sold in the markets of different countries with the regulatory authorities assured of their quality, safety and risks.

Zydus Hospira oncology used to follow a traditional pen and paper approach in their EHS domain. The management systems standards as stipulated by stakeholders global EHS management framework recommended: regulatory compliance, risk-assessment, communication, self-audit and senior leadership engagement, as part of the EHS management. These were among the few key elements which they wished would form the basis of a proactive feedback based EHS management system.

On SAFE path to compliance

Through our initial interactions, followed by subsequent ASK-EHS on-site demonstration, Zydus Hospira oncology could already identify and visualize a synergy – a large majority of their needs were being met to a greater degree by the SAFE software. This provided us with a firm footing to encompass and address the rest of their EHS objectives.

The amount of hand-holding in this process was minimal as Zydus Hospira oncology understood and appreciated the EHS domain expertise possessed by ASK-EHS.

Solution

SAFE SOFTWARE

- Task management
- Audit
- Register of regulation
- Site inspection
- Safety observation
- Manpower
- Change management
- Medical checkup
- Permit to work

“We were already aware of the superior quality standards of ASK-EHS…
..what convinced me was their approach to implement and accommodate our needs”

Mr. Alpesh Patel
Senior EHS personnel

For the implementation of SAFE, EHS management software, we initiated the pilot phase where the plant EHS team were trained on the knowledge and use of the software modules.

As part of the next phase in implementation, we trained and educated the technical team, the end-users within the EHS niche, on the use of SAFE and its different modules.

The total time spent on both these activities was limited to a total of 5 site visits. The training for technical team was wrapped up within 2 days. 200 users at Zydus Hospira oncology are currently being supported by a dedicated software support team along with expert HSE guidance to troubleshoot onsite issues.

Permit to work forms a critical part of the work environment and as a part of the SAFE software, 300 requests are raised each month.

Creating a comprehensive EHS management 'environment'

The core philosophy in this case is dictated by the principal of Plan, do, check, act; which is promulgated by the stakeholder in the setup. It is cushioned and supported by several other best practices such as objective setting, risk assessments, management of change, self audit and finally EHS program review.

SAFE software enabled Zydus Hospira oncology to engender all these elements within a web based dashboard. The different modules are individual tools in their own right. Providing incident reporting and management with a priority wise status reports. Register of regulations helps them to maintain and keep record of environmental compliances, like disposal of hazardous waste.

Safety observation empowers them to address and mitigate unsafe conditions found on the plant premises. Manpower module clearly defines and tabulates the duration of work undertaken by workers based on man-hours.

Audit is an essential part of pharmaceutical industry, not only due to its importance in the process of review. But also due to the fact that GMP or cGMP compliance for manufacturing demands – exact version of operating procedures in implementation and subsequent employee trained, in its accordance.

Medical checkup provided them with definitive information repository and management tool to store employee personal medical data, secure with a degree of confidence.

Permit to work module made commercial sense for Zydus Hospira oncology as they felt that the feasibility to purchase a tried and tested robust workflow would be cost effective.

Zydus Hospira finally implemented the modules in a controlled manner with collaborative thinking with ASK-EHS to help them understand and fine-tune the implementation process or simply put, to ease its users into a new system.

Improving pharmaceutical safety

With a detailed and dedicated web-based feature rich visual dashboard encompassing all the key facets of EHS domain – SAFE software has the ability to support the transitive relationships, different EHS processes share in the pharmaceutical manufacturing.

Pharmaceutical manufacturing plants also strive to achieve excellence via demonstrated actions and behavior. As is the case with any business, such concepts need to be communicated via numbers or defined parameters. Root cause analysis is one such prominent tool available for ascertaining and negating “issues”.

Gemba scorecard, Ishikawa diagram (Fishbone analysis) and why why analysis (based on Six Sigma principles) is a standard part of the SAFE software. This means that the numbers generated within the SAFE environment can be taken for further analyses without use of any other tool.

Zydus Hospira oncology in recent times, successfully completed their MHRA (U.K) inspection and already satisfy FDA (U.S) criteria.