How automation of quality management practices accelerated the growth of our client

QEDGE- SMART QUALITY MANAGEMENT SYSTEM

Client background

Holding the expertise of more than 3 decades our client is one of the leading global pharmaceutical formulation development, manufacturing and marketing company, headquartered in India. Besides very strong presence in domestic market it is also present in more than 70 countries worldwide like USA, Europe, Australia, Africa, Asia-Pacific and many more.

It's approved by many regulatory bodies across the world like USFDA (USA), MHRA (UK), TGA (Australia), CDSCO (India), EMEA (European Union) involved in a range of products including tablets, injectable, capsules and many more.

Business complexities

Pharmaceuticals, Healthcare and Life Science are few of the industries bound to comply with globally acclaimed quality standards to survive in this highly competitive business world and for that they need to follow rigorous internal audits to comply with the set standard operating procedures.

Initially our client was using Microsoft tools like word, spreadsheets to record, monitor and analyze quality data but that was not effective and failed to respond various complexities like:

- Costly, error prone, time consuming and not reliable
- Poor documentation control
- Lack of proper visibility of applied CAPA, investigations and deviations
- Very complex to streamline the fragmented data
- Unable to highlight pain areas
- Inflexible to produce customized graphical representations

Business solution

So our client decided to adopt QEdge- web based enterprise quality management software with cloud mobility and SAAS to aggressively respond to the above mentioned compliance related complexities. The company planning cell identified three criteria that had to be met:

- The ability to manage various quality processes with effective interlinking and overall control
- Provision for a central repository for effective tracking of all quality events by Quality assurance
- 21 CFR Part 11 compliance with electronic signature and date and time stamped audit trails

We worked very closely with our client during implementation process and conducted various training sessions to ensure the satisfactory response by the employee during transition from manual to electronic system.

Results for measuring ROI

As a result we developed a dynamic, configurable quality management software with a centralized platform to manage, report all its quality processes, track the status in real time and identify and analyze issues and trends as they arose. Among the many benefits here are few of the game changer benefits in the below:

Within few days of QEdge implementation for CRF, Deviations, Investigation, CAPA and risk assessment;

- Time spent on daily meetings for event discussions, investigation outcome and effectiveness checks were reduced to 20 minutes from initial 90 minutes due to increase in awareness of all functional users well in advance from the live tracking table and pending events dashboards

- Enhance overall productivity due to the workflow automation and email intimation hence no need to chase managers for approval and preview and the participants about the task arrival

- With effective tools like risk assessment, auto escalation of tasks to responsible profile, the control of QA over the process effectiveness have been increased to a significant level

- Ability to access real time data so QA could track the previous events with ease to apply CAPA

- Increase insights about every process with various ready to produce KPI and MRM reports

- Data interoperability with SAP enhance insights of different processes conducted in different departments

- Produce an accurate and clear picture in front of executives to formulate strategies accordingly

Do you think quality as an accelerator to your business?

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