Platina QMS
by Formpipe

eQMS for Continuous Quality Improvement

The constantly changing market within the life science industry calls for companies to constantly improve their performance and quality outcomes in order to stay competitive. Question is: Are you certain of the quality status of your organisation?

What is continuous improvement?

Continuous Quality Improvement (CQI) is an approach to improve and maintain quality that emphasises regular, internally driven assessments of the potential causes of quality defects, followed by actions aimed at either avoiding a reduction in quality or correcting the quality defect at an early stage.

The goal of continuous improvement goes beyond satisfaction of having reached a certain level of quality/efficiency. Rather, this approach should be a constant process to maintain and improve quality outcomes.

How does CQI affect your organisation?

There are several reasons for ensuring that your company continuously strives towards quality improvement, but the two main reasons are those of customer focus and reaching business objectives. In the life science industry this relates directly to GMP requirements and operational efficiency.

CQI and Quality Management System

In order to ensure continuous quality improvement there is a precondition of having access to good metrics, real-time visibility and regular surveillance of quality processes and results. This is the only way of getting an objective estimate of the fulfilment

Problems
- High competition
- Risk of decreased quality
- Time-consuming manual procedures.
- Difficult to produce statistics.
- No links between processes and documents.
- The risk of human error.

Solution
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Results
- Full searchability/visibility.
- Compliance.
- The right information at the right time to the right person.
- Improved process overview.
- Faster analysis and closure of CAPAs, Deviations, etc.
- Improved quality due to less human errors.
- Increased productivity due to streamlined processes.
- Real-time metrics visibility via pre-defined reports.
- Customer satisfaction.

of quality standards of the company. For this reason, your quality management system plays a big role in the organisation's continuous quality work. A QMS must be dynamic, and capable of providing useful metrics for analysis and trending.

To manage change management and continual improvement the QMS must govern and monitor the work of the organisation

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and the products being produced and delivered. It is imperative that employees are involved and have easy system access, as well as the ability to take active part in the QMS.

When using a userfriendly system that allows the employees to take an active part, the result will be a dynamic and 'active' QMS that can provide management with realtime status at any time. The metrics will be easy to extract as reports from the system, always showing the latest figures. This is the only way to ensure and stay in control of a continuous business and quality improvement.

Can you afford to waste time and money resulting from poor quality?

Studies performed by Aberdeen Group, state that, by being best in class when it comes to quality, it is possible to save up to 8% of the total revenue as compared to the laggards.
Are you certain of the quality status of your organisation?
To find this out you need to have proper reports and metrics that indicate the efficiency of your business processes and quality as well as possible bottlenecks and recurring non-conformities. This can be very difficult to obtain using a paper-based QMS. A paper-based system lacks important relationships, links and history to facilitate analysis when change is required. Maintaining a paper-based quality management system with unrelated systems to control different processes has therefore proved to be a costly and inefficient practice. As a result, companies are looking to deploy integrated electronic QMS's that can connect processes and enable real-time overview and analysis to be communicated to everyone involved. An eQMS simply turns traditional document handling into transparent, proactive and continuous quality management.

CQI with Platina QMS by Formpipe

Platina QMS connects and integrates quality processes into an electronic quality management system. It gives you control over the most critical quality measures for your enterprise. Platina QMS is not only used for quality control (reactive improvement) but also to facilitate preventive actions to eliminate inefficiency and poor quality resulting from repeated non-conformities (proactive improvement).

Users of Platina QMS are able to focus on the critical tasks while the system automates repetitive compliance and documentation activities. Automated workflows and support for electronic signatures eliminate the need to physically transfer documents while remaining compliant. Integrated with document workflows, Platina QMS delivers real-time process visibility directly in the system. The system standard functionality also includes built-in, pre-defined reports enabling easy trending and enterprise-wide visibility.

Example of pre-defined reports included:

Deviations
- Number of initiated deviations
- Number of major and significant deviations
- Number of recurring deviations
- Lead time from date discovered to date closed

Change Control
- Number of open CCs
- Number of initiated CCs
- Lead time from approval to date closed

CAPA
- Percentage of CAPA closed on time
- Lead time from date discovered to date closed

Benefits of CQI using Platina QMS:

Increased productivity
CQI with Platina QMS results in reduced human errors and less repeat work due to automated processes and document workflows. Less repeat work means increased productivity.

Improved customer satisfaction
Because CQI focuses on continuously improving the organisation's performance and Platina QMS is helping to identify problems and bottlenecks from within the system, it makes for improved quality and increased customer satisfaction.

Increased revenue
By removing errors, and increasing productivity and customer satisfaction, the company has the opportunity for increased sales.

About Formpipe

Formpipe is a leading developer of Enterprise Content Management solutions, enabling organizations to capture, process, store, archive and supply information in a systemized and controlled manner.

Flexible and scalable solutions help customers to lower costs, minimise risk exposure, reduce lead times and improve quality control.

Contact

Swedish Office – Nordic inquiries
+46 70 549 85 04

Swedish Office – European inquiries
+46 70 515 30 56
info.se@formpipe.com

UK Office
+44 78668 42978
info.uk@formpipe.com

US Office
+1 678-938-0957
info.us@formpipe.com

www.formpipe.com/lifescience

Formpipe.