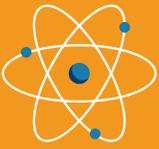


MetricStream

FDA CGMP Compliance: Key Guidelines for Life Sciences





Introduction

The life sciences industry faces immense challenges amid stringent regulatory scrutiny. The Food and Drug Administration (FDA), with its Current Good Manufacturing Practices (CGMP) guidelines, strictly controls every drug, device or biologics manufactured or sold in the U.S.

The FDA's CGMP guidelines ensure that drugs, devices, and biologics are consistently produced in a controlled environment with quality standards guiding their intended use. The FDA's latest guidance also clarifies the agency's current thinking on the creation and handling of data in accordance with CGMP requirements.

FDA has observed CGMP violations involving Standard Operating Procedures (SOP) that are out of date or inconsistent with regulatory expectations. These CGMP violations have led to numerous regulatory actions including warning letters, heavy penalties, and costly product recalls. Multi-billion dollar fraud settlements in the life sciences industry have been an eye-opener into the consequences of failing to adhere to FDA regulations. Civil and criminal actions taken against companies are warning to the industry about the serious consequences of non-compliance with the FDA.

Today life sciences companies are taking an integrated approach to quality and compliance management and adopting technology to automate key business processes. This helps them improve their operational efficiencies, lower the cost of compliance and create a transparent environment for proactively identifying, tracking and resolving quality and compliance issues.

That being said, let's explore some best practices that will help Life sciences companies in simplifying, strengthening and sustaining FDA CGMP compliance.



Proactive risk management

A proactive risk management approach ensures availability of high-quality drug or device by providing a proactive means to identify and control potential quality issues during development and manufacturing. Use of risk management improves the decision making whenever problems arise. Effective risk management can facilitate informed decisions, provide the FDA with greater assurance of a company's ability to deal with potential risks, and can beneficially impact the extent and level of direct regulatory oversight. Organizations can leverage technology to identify, assess, review, and mitigate both quality and compliance risks at each stage of the product lifecycle.



Efficient document control

Life sciences companies deal with thousands of documents including SOPs, batch records, regulatory filing, and quality reports. Streamlining document management and control processes for these documents is critical for both business and compliance purpose. Technology enables companies to adopt an electronic and automated approach to managing and controlling documents across the enterprise with a centralized repository and tools for collaboration. A robust document management system also helps a company ensure that the entire creation, review of documents such as, SOPs, work instructions, training records, and evidence documents, are seamless and that all the supporting evidence that needs to be submitted to the FDA is readily accessible.



Ongoing auditing

Life sciences companies need to conduct frequent internal audits to ensure that the established product and processes compliance and quality requirements are being followed. Every regulated organization desires to be in an

“audit ready” state so that whenever the organization gets inspected by the FDA they have all the documentation and processes available at their fingertips. By using technology, one can efficiently plan, schedule and conduct internal audits and allow audit findings to be reviewed and analyzed by a team. It also enables initiation of follow-up activities such as corrective/preventive actions when needed, and provides the ability to monitor the entire process.



Compliance training

As the FDA releases new guidance on the CGMP regulations, it is essential for the applicable business units within the organizations to get trained on the latest amendments to the regulation. An effective training management platform can train your employees on the applicability of the regulation and implications of non-compliance. Training courses can be assigned and training completion and the effectiveness of training can be tracked with the help of certain questionnaires.



Non conformance and deviation tracking

Tracking non-conformances and deviations and identifying the root cause related to non-conformances is integral to strengthen compliance with FDA's CGMP guidelines. Effective remedial actions, as well as evidential data need to be provided. Nonconformance and deviation review and approval cycles can be accelerated with automated workflow. Technology can also support recording and automatic rule-based routing of nonconformance issues for review, disposition, and closure.



Streamline corrective action

To prepare for FDA inspections, Life sciences organizations need to implement an effective CAPA (Corrective and Preventive Actions) system. CAPAs should be addressed in a timely manner

with clear committed dates and accountable owners. More often than not, cross-functional teams collaborate on development and implementation of corrective action plans. Technology can enable triggering CAPAs, performing root cause analysis, assigning follow-up actions while effectively tracking and routing cases from initiation to closure.



Real-time reporting and tracking

To strengthen compliance with FDA norms, Life sciences companies must continuously track quality issues and processes in real-time for data-driven decision-making. An integrated technology solution can provide complete visibility into the quality system with comprehensive aggregate reporting as well as individual issue status tracking. Graphical executive dashboards and flexible reports can provide statistics, analytics, and trending.

Conclusion

Non-compliance with FDA CGMP guidelines could impact life sciences company's revenue and tarnish its reputation. It could also affect partnerships with suppliers, and lower the company's competitive value.

On the contrary, effective FDA CGMP compliance could give the company a competitive advantage, and help them gain a reputation for reliability. The ideal way for an organization to achieve this is to commit to quality in all aspects of its business, invest in and promote a quality culture at all levels, implement a compliance program, have effective corrective actions, and reassess-sustainability. The key to success is to effectively leverage technology to support compliance and quality initiatives.

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