2021 LIFE SCIENCES QUALITY TRENDS

After a busy year adapting to the impacts of the COVID-19 pandemic, a reenergized focus on quality management has come to the forefront for many life sciences companies. Medical device manufacturers had to maintain quality and compliance with ramped up production to meet high demand, pharmaceutical companies tested medicines for efficacy against the virus, and biotech firms pushed resources toward vaccine development. This has propelled trends in 2021, such as building a culture of quality, a renewed emphasis on risk-based thinking, digitizing and integrating data and utilizing analytics, and improving vendor management. These trends have emerged to help keep life sciences companies moving forward with efficiency to ensure lifesaving medicines and therapies can consistently and effectively reach customers and patients.

TREND #1:

Building a Culture of Quality

It is imperative to ensure that quality is seen not just as a task executed by an organization's quality department, but instead as a cross-functional competitive advantage for a business. Across an organization, all employees should understand the importance of quality. In order to build a culture of quality, employees should be consistently involved in quality management.

Progress can first be benchmarked **using a gap analysis** to discern the current state of understanding of quality initiatives, and further improved through process training, cGMP training, and employee feedback to create direct involvement in the quality improvement process. Employees' ownership of quality in their work can help improve quality across the organization and build an overarching culture of quality. And, to build credibility for a culture of quality, managers and executive leadership should explicitly display commitment to quality to set an example for the organization. In developing a culture of quality through a **peer-driven approach**, the benefits result in higher quality products and documentation, employee satisfaction, audit success, and a reduction in time and money spent on remediating mistakes.

TREND #2:

Digitizing and Integrating Data

Digitization and data integration can leverage technology to advance the quality management process with expanded use of eQMS (electronic Quality Management Systems), while still remaining compliant. This can be achieved by:

Digitized data creates flexibility for life sciences companies by allowing quick identification of trends and issues.

01 focusing on creating better access to data in structured documents

02 using automated workflows for rapid changes and accessibility

03 reducing the steps from collecting data to entering it digitally

04 monitoring data integrity

Paper-based quality management systems are becoming more and more difficult to use for life sciences companies, with poor accessibility and high risk associated with maintaining a large bulk of files. Paper systems **must be managed manually** and are inefficient, which makes it difficult to operate with accuracy. eQMS helps a life sciences company keep track of the details **using software for automated workflows and electronic signatures,** while increasing productivity and compliance. In recent years, medtech companies in particular have been implementing electronic QMS to utilize the cloud capabilities **to better control processes.** Especially over the course of the COVID-19 pandemic and shift to remote work, this has enabled organizations to operate more efficiently and lessened the impact of changes to supply chains, keeping products more readily available. The automation that an eQMS enables has been key for many life sciences companies throughout the pandemic, and the benefits can last through 2021 and beyond.

TREND #3:

Improving Vendor Management

As more and more operations within pharmaceuticals, biotech, and medical device firms are outsourced, greater responsibility falls on internal quality departments to scrutinize the quality of their vendors. This has been made more difficult in a pandemic era, but remote audits can provide support.

With many life sciences companies supported through third-party vendors, auditing the vendor's methodologies is important. For software, **validation documentation or black box testing** can help establish whether it reaches expectations and quality needs. Certain key items of the vendor should be audited in order to ensure a good organizational fit. In pharmaceuticals, vendors should be selected based on the ability to provide quality in the needed quantity throughout the partnership, as well as whether they have a strong reputation and **are agency regulated or ISO compliant.** Other considerations, especially for biotech companies, include whether the vendor will require subcontractors, the project management structure, and whether flexibility is an option to ensure that timelines can be met. Contracts can also help establish quality requirements and **clear tools to measure quality.** It is also key to develop an oversight plan to help clearly establish guidelines for vendor management.

In the past, completely on-site audits were important in vendor selection, but the pandemic created an opportunity to execute audits remotely, bringing some positive implications. Keeping businesses on track, documentation reviews, interviews, and even site tours conducted virtually have **provided flexibility and lower safety risks,** and minimized environmental impact with less travel to conduct on-site audits. Managing vendors also requires requalification every few years, which can also be adjusted to be completed virtually moving forward.

As virtual Vendor Management becomes more prevalent, it does not diminish the burden on the quality unit, as the same attention and rigor will be needed, if not more. It remains important to properly resource and equip the internal quality department to perform this key activity.

Prior to the pandemic, the Medical Device Coordination Group (MDCG) required onsite audits but later approved cases for remote auditing to keep medical device supply moving.

TREND #4:

Utilizing Quality Analytics

Enhanced utilization of quality analytics can be used to address unforeseen issues quickly, or even prevent them from ever happening. It is important to ensure that data is reliable and validated so that it can be used to make rapid decisions.

Recently, **Target RWE acquired NoviSci,** a software analytics services company for healthcare and biotech data, and Amgen has invested in NoviSci. These acquisitions indicate how important the growth of analytics services is becoming, especially with the high importance of accuracy in life sciences in 2021 and beyond.

In some cases, data scientists can have trouble analyzing raw QMS data without an additional third-party solution. Raw data may not provide enough insights to make accurate decisions in real time, and without context, the data is not actionable. However, **Artificial Intelligence and Machine Learning can provide more clarity** by considering a large number of variables more quickly and thoroughly than a human could. With a rise in the use of these technologies, the **FDA recently provided an action plan for AI and ML** to better regulate advanced medical software, based on their 2019 framework feedback. These guidance efforts will also work closely with the Medical Device Cybersecurity Program. Overall, **analytics can be used across life sciences companies** to better ensure quality, lower costs, and increase yields.

TREND #5:

A Renewed Emphasis on Risk-Based Thinking

Considering lessons learned from the COViD-19 pandemic, it is no longer acceptable to be reactionary. The imperative for speed to market requires companies to be preventative, calling for a risk-based approach to quality. In recent ISO standards, risk is clarified as being “the unknown”, even when the unknown could be something positive. This means that risk-based thinking could even help a business uncover opportunities for growth, making risk-based thinking a strength.

A risk-based approach redirects focus from cost to quality, which helps a company maintain best practices by preventing problems before they become costly and damaging. Additionally, shifting toward a risk-based approach may have benefits in reducing the **extent of direct regulatory oversight** since an organization’s resources are being prioritized for proactive risk prevention.

Organizations that are ISO 9001 compliant are well set up for a risk-based approach, but proactive strategic planning should be adopted by all life sciences organizations. Tools for developing a risk-based approach include fault tree analysis to understand process connections, risk ranking to prioritize audit preparations, and improvement monitoring (preferably with an eQMS). Artificial Intelligence and Machine Learning can also help with scenario planning for risk mitigation efforts in order to achieve optimal outcomes. However, the **WHO has provided guidance that more informal risk management** can be acceptable in cases where appropriate. Recent guidance from the FDA also suggests renewed focus on a risked based approach. Overall, as organizations pull in insights on quality-related events and training, risk management should become top priority for its employees.

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