

PROQUIS

Quality in Life Science Industry

Life Science companies are constantly striving to get new products out in the market whilst meeting the stringent compliance requirements. Intense competition in the industry calls for better measures to meet these demands. As a responsibility to the society, life science companies need to address a broad range of regulatory issues in addition to governance, risk and compliance. However, regulatory compliance forms the core of any life science company and it ensures a competitive supply chain, higher customer confidence and most important of all a profitable business.

In the process to achieve these end objectives, many organizations focus their energies on a high product quality which can only be achieved by having a high quality of processes behind it. Life science companies are constantly being challenged to meet the rising standards of quality and comply with rigorous standards. Moreover, in the current environment, it is critical that companies focus on high product quality to save operational costs. So what exactly are these challenges facing the life science industry?

Home grown or self built quality management systems

Many companies develop their own quality management systems or use spreadsheets and word documents for regulatory compliance. However, many times these home grown solutions fail to provide comprehensive quality management and address broad regulatory issues.

Stringent government regulations and approval process

With complex procedures and data to be handled, life science companies are bound to have a strict quality control in each department. Especially when dealing with regulatory authorities such as FDA, the organizations have to be aware of their laws and ensure each step in the approval process is followed as desired. In absence of any information, a company might have to bear huge financial losses.

Demanding Customers

With increased awareness and marketing, a variety of changes have been observed in the life science industry. The competition is getting intense and the consumer is demanding. To a high degree this is a result of more information available on internet and companies spending a lot of money on consumer awareness campaigns as an obligation to the regulatory authorities.

Disconnected Processes

Disconnected quality processes can cause delays and poor results. For example, a change control process that's not connected to CAPA, training, supplier control and customer complaints can cause a delay in implementing the proposed changes. This will not only delay the process change but will also affect the quality of information flow within the organization.
High Cost of Validation

As per 21 CFR Part 11, life science companies have to get their computer systems validated to comply with regulatory requirements. Even if the companies automate the documentation, they have to achieve the daunting task of getting a computer system validated.

Poor data accessibility

It can be challenging to retrieve documents when you are dealing with a high volume of complex data at a time. Without a systematic storage of information it can take hours to

search for a single document and collate data. This makes it difficult for the company to benefit from its previous investment in development and testing.

What's the solution to overcome these challenges?

Life Science Organizations have to take an integrated approach to compliance management and quality to lower the costs of regulatory compliance and improve the key business processes. Many companies are taking the route of automating business processes to maximize the operational efficiency and reduce the time to market for new drugs and healthcare solutions. Electronic control of documents, audits, customer care and CAPA through a software solution has many benefits, just to list a few:

- Proactively identify, track and resolve compliance issues across the entire organization with comprehensive and tighter control over all areas of compliance - document, issues and non conformances, customer complaints and audits
- Lower the risk of non compliance by utilizing the systems built upon industry best practices that allow an effective compliance with ISO 9000, FDA 21 CFR Part 11, Part 820, ISO 14971:2007 and ISO 13485:2003
- Increase visibility of key business processes and bring about transparency and clear communication across organization and quality management team
- Lower the production costs by fast approval and collaboration with your partners and customers
- Gain competitive advantage in a crowded market by simplifying the certification and audit process
- Be fast to market by simplifying the regulatory approval process with a better technology and low margin of error
- Make informed decisions and track issues real time with reporting tools

Conclusion

Many organizations find themselves managing quality separately, even when there is a high degree of overlap between the processes and actions. This may result in deployment of multiple systems to address each issue. Tackling compliance related issues this way can result in poor management and confusion. Use of a single system to meet all the challenges related to regulatory compliance in life science industry can ease the life of quality supervisors in achieving the stringent quality goals set by regulatory authorities. By automating the documentation for CAPA, audits, customer and supplier data, the organizations can be sure of easy data accessibility, informed decision making, low production costs and secured key processes.

About Proquis

Proquis is a provider of compliance management solutions to highly regulated industries like medical device, healthcare, nuclear, defense and aerospace, where there are many stakeholders, including both local/national governments and governmental regulators, each being highly influential in the business operational delivery, strategy and planning.

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