BROUGHTON SOFTWARE

CREATING A CULTURE OF QUALITY FOR DATA INTEGRITY IN A BUSINESS

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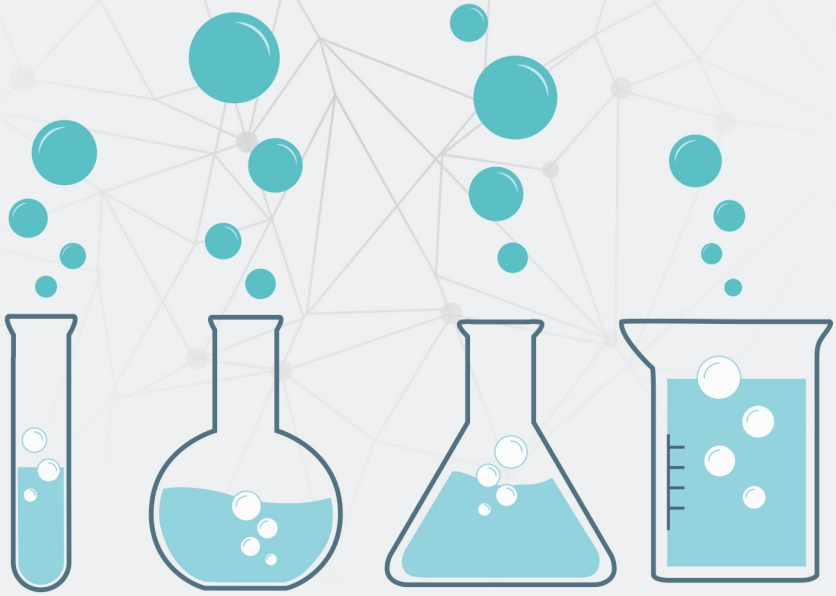


Creating A Culture Of Quality For Data Integrity In A Business

Creating a Culture of Quality is not simple or easy, a reality confirmed by regulatory agencies such as the Medicines and Healthcare Products Regulatory Agency (MHRA), who recently released guidance on data integrity expectations for the pharmaceutical industry. The agency now expects industry to be proactive in its efforts at data integrity, rather than react to inquiries or defend their processes if audited. The MHRA expects businesses to design and operate systems that produce medicinal products with consistency and accountability.

To satisfy the changes to regulatory requirements, pharmaceutical companies must continuously improve to create a Culture of Quality. Data integrity is a fundamental component in a quality pharmaceutical system, ensuring that medicines are safe and effective. A Laboratory Information Management System (LIMS) is a vital partner in ensuring data integrity, helping to create a culture that values quality.

A Culture of Quality

Culture is the backbone of the organisation, a safe haven for staff to return to time and again. It is a playbook of carefully designed strategies, procedures, and systems. People feel safe with a strong structure built on core values. When people operate in a safe environment, the stability works its way into their DNA, allowing them to achieve their highest aspirations and the company's goals.

Leaders must carefully plan what they wish the organisation and its people to achieve. Culture development takes effort and time. It is not a short-term process, brief training sessions, or skill transfer. Culture is constructed and infused into the heart of the organisation. The people and the procedures harmonise, creating a culture that is greater than the sum of its parts.

Best Company Cultures

Employees value a culture that contributes to the greater good. They also want a low-stress workplace, since they spend much of their lives at work. Business Insider recently explored the nature of culture in a report titled, "The 25 Most Enjoyable Companies To Work For." Authors used employee reviews on Glassdoor, a job hunting and company review site. Using employee ratings from 2014 on a scale of 1 to 5 (one-lowest, five-highest), analysts derived the 25 companies with the best culture.

A Business Systems Analyst at Genentech (#14), a biotechnology company, reviewed his company's culture, stating, "Extremely talented and motivated people collaborating in a unique 'mission driven' culture."

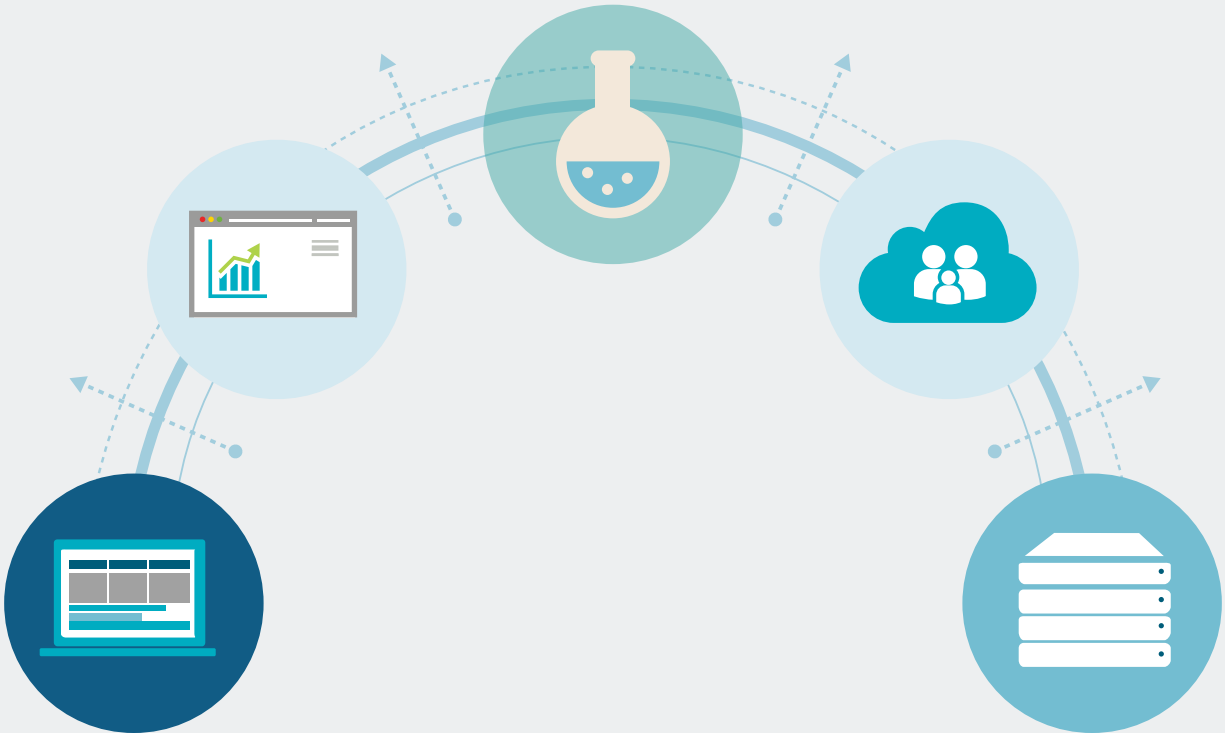
"Culture and good values define who we are as a company. There is an ongoing commitment to improve the customer journey and ensure our product strategy is well defined," said a Senior Systems Manager at Citrix (#19), a software company.

The people working at these companies have absorbed the values delivered from their leaders. They have shown up at work, day after day, and learned that they are valuable. Employees have learned that their product or service is important to their customers. They work hard to reinforce the trust placed in them. They also have fun with their colleagues and support each other's endeavours. Leaders, staff, and customers blend into a culture that is noticeably successful.

Data Integrity

Data integrity is critical to the culture of quality. When trusted data is analysed with confidence, quality professionals can make informed decisions on product quality. Processes controlled with poorly written operating procedures and inadequate training programmes will not code a culture of quality into the organisation's genetics. Neither will neglect of people's personalities, thinking patterns, and decision-making capabilities. Ensuring data integrity within your organization is a strategic decision to ingrain into day-to-day positive habits.

Companies can often have data integrity issues, which are hazardous to the company's long-term prospects and have a demoralising effect on the company culture. Manufacturers in India have been on the hot seat for some time due to data integrity problems. The data is intended to ensure that products meet pre-established specifications, such as purity, potency, stability, and sterility. In the absence of trustworthy data, these products cannot be trusted. As a result, the US Food and Drug Administration (FDA) has subjected many of these companies to import alerts, preventing entry of their products into the US.



Best Practices for Data Integrity

To ensure data integrity, companies should know the guidelines from regulatory bodies such as the MHRA. The guidelines can help companies to deploy their systems with confidence. **The new MHRA data integrity requirements** are intended for GMP quality control laboratories and apply to both paper records and electronic data.

Computer systems merit special mention from the MHRA and companies should know the requirements in order to deploy strategies into their systems and culture. Data includes metadata and all data should be audited, along with confirmation that the audit has taken place. If reviews and audits find errors or omissions, procedures should be in place to clarify and correct them using ALCOA principles: A - attributable to the person generating the data, L – legible and permanent, C – contemporaneous, O – original, A – accurate.

The Drug Information Association (DIA), an association of life science professionals, has also published guidelines on data integrity. Its report titled, “Computerised Systems in Clinical Research: Current Data Quality and Data Integrity Concepts,” develops standards and benchmarks for computerised systems in the pharmaceutical industry.

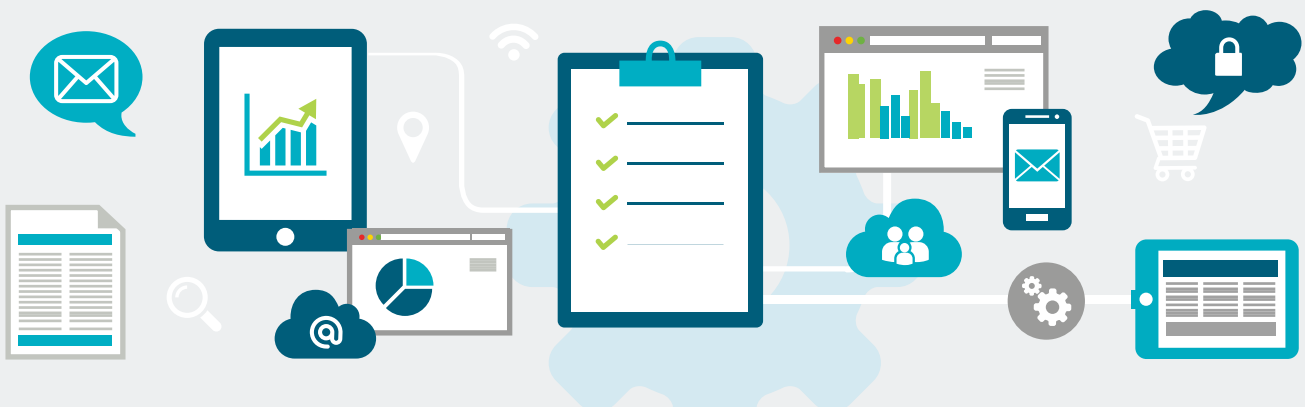
Culture Creation

In an evolving sector such as the pharmaceutical industry, companies attempting to create culture and foster data integrity often face barriers. Building culture from the ground up can be a formidable task that organisations master in varying degrees. Companies often need help building quality systems and integrating personnel into a cohesive whole. Regulatory guidance can provide some help in building quality. Another avenue is to seek expertise and products that make the process easier.

At a recent ISPE-FDA-CGMP conference, George Millili, Ph.D., Senior Principal and Technical Advisor at Genentech (A Business Insider Top 25 company for Culture), presented remarks titled, "Proactive Scale-up and Technology Transfer Practices." He stated that the pharmaceutical sector is facing data integrity challenges and is seeking ways to get products to market faster. The industry needs key technical and quality elements that include an understanding of the rigour required to develop quality systems.

Laboratory Information Management Systems

Leaders can utilise LIMS to plan and execute strategies that respect the rigour involved. User-friendly LIMS helps staff to feel a sense of competence and even excitement about a tool that helps them perform quality work. When the organisation is full of confident people using a robust but manageable tool, the company codes quality into its core.



LIMS address some of the most common data integrity issues such as raw data access and audit trails. Additionally, LIMS software can facilitate communication between different companies as the pharmaceutical industry is moving in the direction of partnerships, mergers, and acquisitions, wherein communication is the key to progress.

According to Markets and Markets, a research group, companies are increasingly utilising LIMS software. Its report titled, "Laboratory Information Management Systems/ LIMS Market - Forecast to 2019," states that quality control laboratories, manufacturers, and other pharmaceutical entities are increasingly using LIMS due to a few major factors.

Chief of these is the pressure to comply with regulations. Another factor driving growth is the need to replace older or customised systems with a commercial off-the-shelf (COTS) software solution. Biobanks or biorepositories are increasing in number, spurring a need for LIMS. Additionally, electronic record keeping is growing and more companies are now aware of the benefits of LIMS.

Addressing Data Integrity Issues

In short, data integrity aims to prevent unintentional changes to information, eliminating the potential for significant data integrity errors occurring in the pharmaceutical manufacturing process. Common issues are found in QC chemistry laboratories and QC microbiological laboratories.

Common Data Integrity Issues Found in QC Chemistry Laboratories

Audit Trails – For electronic data acquisition systems, audit trails are not available or are not enabled, therefore, there is no record of data modifications or deletions. Some companies have software that contains audit trail capabilities but they do not turn the audit trail on, and are cited for not enabling it.

Unique User Logins – Software that ensures data integrity and preserves the company's culture of quality has unique user logins. This feature gives each person a username and password, so that the software can track the person's work. Each user should have a unique username and password for both the analytical software and the operating system. This is essential for tracing work performed to a unique individual, and is critical for Good Manufacturing Practice (GMP) compliance and data integrity. Companies are often cited for having multiple users share the same username and password or, worse yet, having all users logging in as the administrator with privileges that may include the ability to modify or delete data.

User Privilege Levels – Each data acquisition system should have defined user levels based on the role the user will have in the system. Examples of common user roles include analyst, supervisor, manager, and administrator. Privileges assigned to each level should be clearly defined and be appropriate for the requirements specific to each user type. Examples of privileges include the ability to create test methods, modify high performance liquid chromatography (HPLC) integration parameters, modify data, validate data, and approve data.

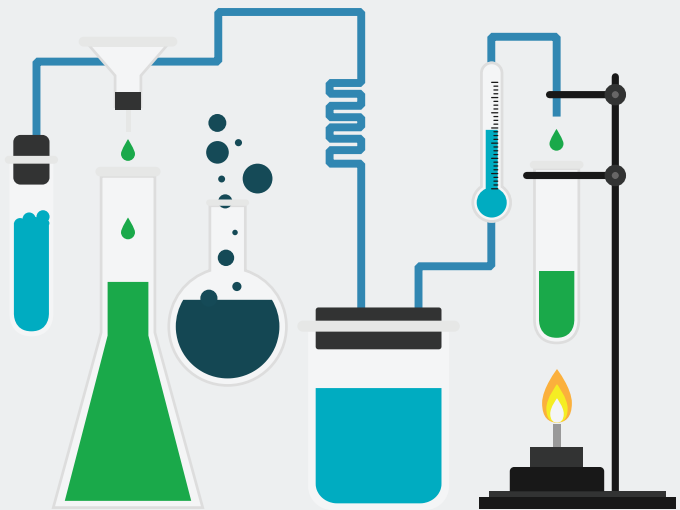
Unofficial "Test" Injections – Some firms have been cited for injecting samples prior to beginning an official sequence. This practice results in essentially generating data for products, but not reporting the data.

Control Over Processing Methods – Use of high performance liquid chromatography (HPLC) processing methods (including integration parameters) that are not defined or controlled. This includes the practice of manual integrations without justification or approval, and processing injections in the same sequence with different processing methods and integration parameters. Another important example of this practice includes processing standards that are used for quantification of samples with different processing methods (integration parameters) without justification provided.

Control Over Electronic Systems – Failure to establish adequate controls over computer systems to prevent unauthorized access or changes to electronic data. This can include failure to have mechanisms to prevent unauthorized user access to the system, and ability to rename, move, delete, or not save file results. Mechanisms should be in place to ensure that files cannot be accessed outside the analytical software (e.g. via the operating system) and edited, moved, renamed, or deleted.

Common Data Integrity Issues Found in QC Microbiological Laboratories

QC microbiological laboratories have relied heavily on manual testing and recording operations, which opens the door to significant issues with data integrity. The issues observed often relate to the falsification of data. For example, recording fewer contaminants from a sample to ensure that the result meets the specification is a simple data integrity problem.

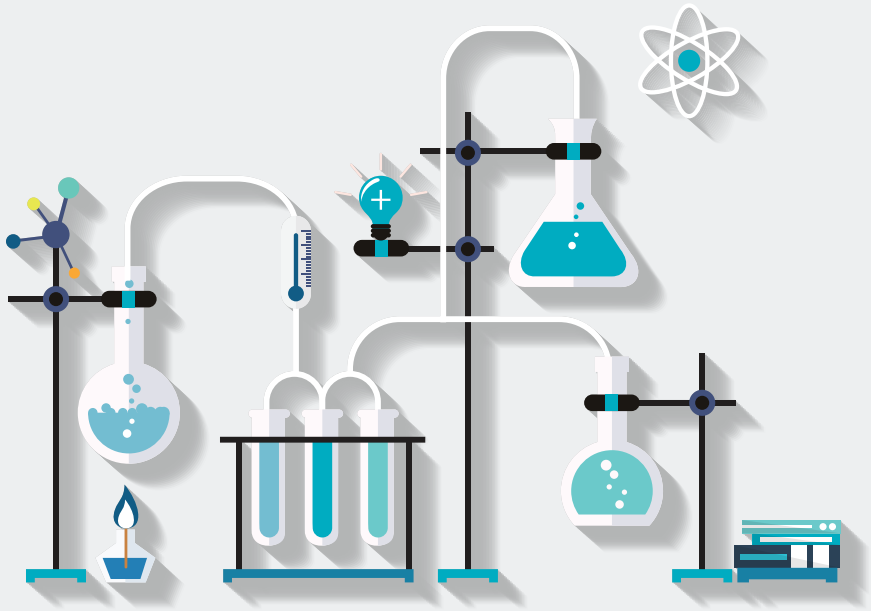


A challenge for any GMP manufacturer is to ensure their QC Laboratories are not guilty of falsification of data. Reviewing data trends can provide useful indicators – unlikely scenarios such as purified water systems with no microbial excursions or clean rooms with no environmental monitoring excursions are simple triggers that should prompt further investigation. If it looks too good to be true, it may well be!

Microbiological samples are often read and then rapidly discarded, so it is sometimes difficult to obtain evidence of falsification. Microbiological data patterns can often identify data integrity and falsification with a simple review of the data. For example, media growth promotion results can yield interesting patterns. There have been instances where only even numbers of colonies were recovered (apparently to make the averaging of the duplicate samples easier). When looking at growth promotion testing, it is often worth checking that the specification limit calculations have been performed and applied correctly. These are often found to be incorrect, resulting in missed out of specification (OOS) results.

The LIMS Solution

LIMS provides solutions to common data integrity issues. Overall, the crucial component to any data integrity review is to ensure that data is recorded exactly as intended and upon later retrieval, ensure that the data is the same as it was when it was originally recorded. A highly configurable and simple to deploy LIMS can address the most common data integrity issues found in quality control laboratories.



LIMS can also help QC laboratories track their reference standards and reagents including their expiration dates. Equipment maintenance is also a priority as poorly calibrated equipment can skew test results and degrade batch quality. A focus on stability studies is critical as studies can last three to five years and missed time-points can create major issues for the pharmaceutical supply chain. A well-designed LIMS can help manage stability studies and integrate with QC testing for complete control over sample and data lifecycles. Environmental Monitoring data should also be considered. LIMS can also facilitate the management of batch and non-batch related environmental monitoring in sterile manufacturing facilities and control the large volume of associated microbial data.

Plan to Continuously Improve and Uphold Standards

A plan to continuously improve and uphold regulatory standards over time creates a Culture of Quality. Creating such an environment is to have respect for planning and to commit to adhering to these standards over time. A LIMS can help a company to improve its culture of quality. With a LIMS, mistakes can be avoided and security can be ensured. LIMS software also enables communication with other companies, allowing a blending and harmonizing with other company cultures.

The global pharmaceutical community becomes more connected, making a concerted effort to achieve cohesive production of much needed medicines and their safe supply to end-users. More and more companies are taking advantage of deploying LIMS within their QC functions to secure their data and meet regulatory requirements. Having the tools in place at the right time, along with strategic decision-making and planning can create a business that stands out as having a Culture of Quality, a culture that values quality.

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