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BUILDING A TOMORROW-READY LAB

WHITEPAPER

SURVIVAL OF THE FITTEST

Charles Darwin famously said on survival – "It is not the strongest of the species that survives, nor the most intelligent; it is the one most adaptable to change." Resilience has become an essential message in today's post-covid, next-normal world.

In business, resilience is beginning to play a key role in organizations' strategies. Historically, companies that have adapted to changing market demands have fared much better than those that did not. After Covid-19 surfaced in 2020, many businesses recognized the need to be prepared for unforeseen adversities. Thus, businesses need to have a conversation about their resilience, and that conversation needs to begin right now.

Today, everything is changing - work from home, operations, data storage & retrieval, quality management, supply chains, and perhaps, life itself. In the face of this change, one word that has become the core element of the conversation is 'digitalization'.

Industry experts at Gartner agree, “Businesses that can shift technology capacity and investments to digital platforms will mitigate the impact of the outbreak and keep their companies running smoothly now, and over the long term.” Rightly so, companies that had established digital systems before the pandemic hit were much better prepared for it. With so many changes to the way of work, digital systems proved to be a boon for uninterrupted operations, communications, data management, audits, trainings, etc.

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Digital transformation is a key factor of resilience. It is an important component for businesses to be Tomorrow-Ready. The life sciences industry has accelerated its path to digital transformation, which had been well underway post-2020. Digitalization goal posts which were probably 5 years away are now much closer than expected.

Tomorrow-Ready means to be prepared for the uncertain future, as well as catching up to the industry's path towards the 4th revolution, i.e. Industry 4.0. For the life sciences industry, it means to continue operations in the current circumstances and in the same breath, build strength in data and systems, maintain product quality, and stay consistently in compliance with the regulatory requirements. These are the 3 key themes of resilience, which we will discuss in this paper.

Let us talk about resilience in the QC lab. In the quality control lab, challenges such as complex procedures, multiple data systems and instruments, understanding of compliance & adhering to regulations, more inclination towards compliance than focus on efficiency, etc. are common. These challenges can sometimes also act as bottlenecks. Thorough detailing of targeted benefits from digitalization will help build a more efficient, cost-effective, and quality-conscious lab.

According to a survey conducted by the FDA Group, skilled professionals are in short supply. Digitization of processes can reduce this dependency by 30-40%. Rather than relying on users to drive the process, a system can be implemented.

Labs today use many tools such as LIMS, lab notebook, SDMS, LES, ERP, CDS network systems, and others. Each of these systems addresses a different aspect through digitalization. But, when you look at it, 20-30% of the features of these systems overlap. As a result, the user community is hindered from finding a single system that will address the challenges. The result is a lot of disparate data systems.

The systems listed above do address the immediate needs. Short-term benefits such as 30-40% increase in productivity, up to 50% reduction in overall quality control costs, 65% reduction in deviations. These are excellent numbers, but when we take resilience into account, companies must broaden their horizons.

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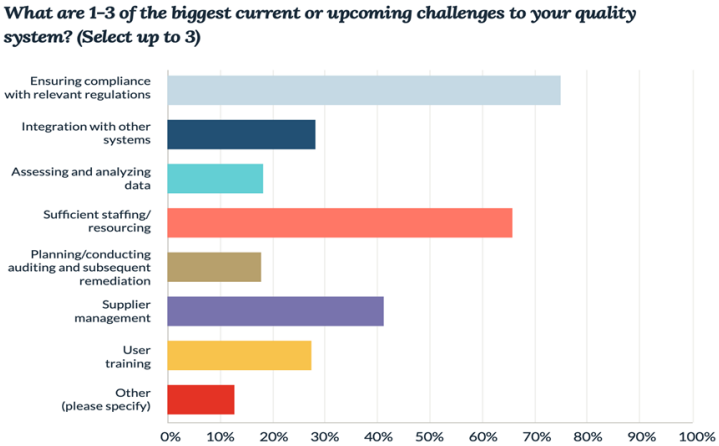

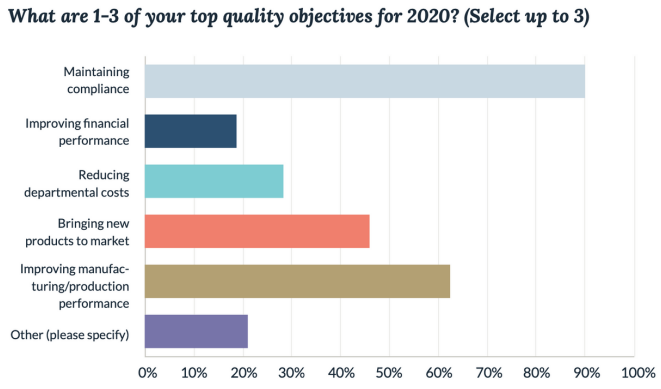

Source: FDA Group's Report - The Life Science Quality Leadership Report & Benchmark

The Full Potential of Digital Transformation

Digital quality management systems are capable of alerting about the deficit in resources when a sample is logged in. The alert mechanism helps save time and ensures that there is continuity in processes. When such benefits are overlooked and focus is laid solely on replicating SOPs (paper on glass), then it would lead to not using the systems to their full potential. The systems adopted may not support a fully paperless lab as well. Consequently, companies adopt hybrid systems consisting of both digital and paper documents.

Adopting a hybrid system could make it harder to pull insights from records, which are partly digital and partly paper. Audit trails, data integrity, and overall compliance can get affected. Even during audits, having everything digitally accessible is more convenient, while a hybrid system cannot make data retrieval easy. This approach also does not support deriving complete analytics and insights for decision-making. It only provides basic data. The wish list for a fully paperless QC lab thus remains unfulfilled despite having access to effective tools of digitalization.

The 3 Key Themes of Resilience

Resilient systems address the needs of not just today, but also take into account the needs of tomorrow. For life sciences, we recommend removing silos of data as a first step towards building resilience into systems. Data that cannot speak to each other is just data, not insights. Good decisions are made on the foundation of insights, and good decisions can make or break an organization.

When it comes to future-readiness, three key themes will influence today's digital decisions - a changing regulatory environment, a higher emphasis on quality driven by operational efficiency, and a critical role for digitalization in productivity.

The Three Key Themes of Future Readiness are

- **Compliance with Regulatory Requirements**
  - FDA demands more through quality metrics
  - FDA is asking for more quality data not just during audits but across the year
  - New SOPS as per the Technical Controls (Example Biometrics and Assignment)
  - Stronger data integrity
- **Quality through Operational Efficiency**
  - Better decision making for profitability, growth, and value creation
  - Adoption of Process Analytical Technology (PAT) and Real Time Release Testing
  - Remote equipment monitoring to reduce downtime and failures
- **Automation leading to Increased Productivity**
  - Human user experience
  - Data mining
  - Predictive Analysis for maintenance, release testing, stability testing, errors, deviations
  - Personalized experience to the users (personalized compliance)
  - Lab of the future, Operations of the future

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COMPLIANCE QUALITY AUTOMATION

Planning a Tomorrow-Ready Transformation

When companies put digital transformation on their strategic roadmap, they must consider how they plan to build resilience through this effort. To build resilience, organizations must start on a blank canvas and ask a few important questions that will shape their future.

- *What process efficiencies do you want to build?*
- *How do you ensure Quality by Design?*
- *What data gaps do you have now? Where is time & effort getting wasted in data retrieval and data analysis?*
- *How efficiently do you use your data now?*
- *How does our data interact? How should it interact in order to achieve your long-term goals?*
- *What are the key parameters for success? And what data do you need to collect to track success?*

What is not measured cannot be improved. An important element of this process of laying out the foundations of transformation to identify the key performance indicators, i.e. KPIs. KPIs traditionally measure efficiency, are specific to GMP guidelines, and are relatively reactive, not proactive.

The much-discussed Quality Metrics offer a great starting point. Quality metrics take into account parameters right from quality control to customer satisfaction. This serves as a good starting point to build KPIs. Resilience can be measured based on these holistic quality metrics in combination with the three themes of resilience - Automation, Quality, and Compliance. These three themes revolve around the current and future needs of the industry and the foresight of regulatory authorities. As we move towards a much-accelerated digital future, being prepared for what is about to change in the landscape is a great strategy towards not just survival, but also towards strong growth and readiness.

Quality management is a complex process by design. It requires that multiple departments work together seamlessly in order to create an environment that supports good quality product output. Therefore, another aspect to give keen attention to is how data interacts in the organization.

It is crucial to choose systems that integrate easily across departments, and that are cloud-ready, in order to plan for a digital transformation that ensures efficiency, compliance, and dependable resilience. In addition, systems should make it possible for Humans, Machines, and Data to interact in a compliant environment. This will offer the most solid foundation to derive the best value from technology.

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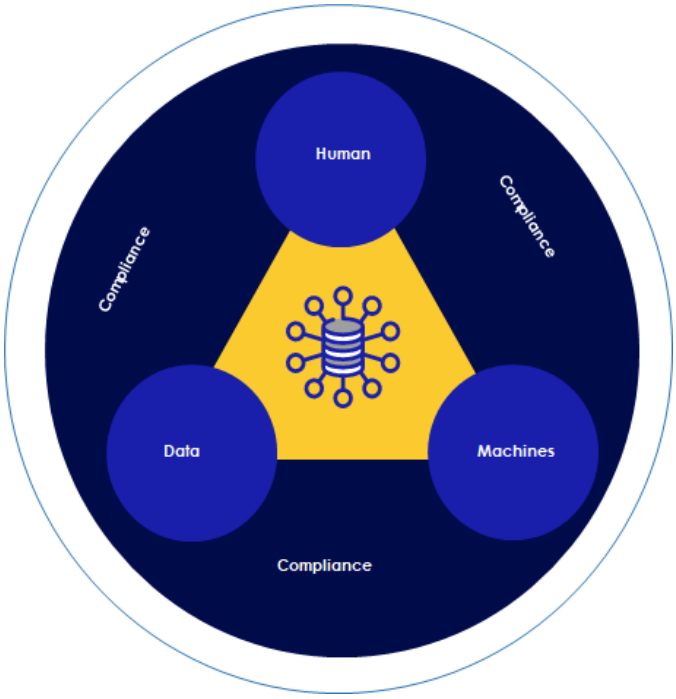

Deriving KPI for measuring LAB ROI

Once the decision has been made to implement digitalization, there should be a robust implementation process in place.

Plan

- Set clear goals & digital transformation roadmap
- Identify systems with redundant data capturing and high-risk prone areas
- Define robust business cases and have a scope finalization

Prepare

- Form a team of different stakeholders - business, IT, and compliance members developing a cross-functional vision
- Choose pilot site and get into execution mode

Execute

- Short term assessment and calculate manhours and tasks to estimate ROI
- Identify Repeated tasks that can be further automated with ML, RPA technologies
- Adopting CSA for validation

BUILDING A RESILIENT LAB

A revolutionary quality pyramid model developed by Caliber offers the approach of Integrated Quality Management (IQM) for life sciences organizations. Clean data is the first step to IQM for life sciences organizations. This allows for the interaction of clean data and can provide insights for decision-making.

These insights can be used to generate predictive analytics and crucial information for other statistical analyses. Further, the quality pyramid generates more complex outputs, including quality metrics, CPV, PQR and statistical insights. Overall, IQM offers an excellent roadmap for a resilient future.

Case Study - India's 1st 100% Paperless Lab

Adcock Ingram became the first 100% paperless lab in India built on the foundation of the CaliberLIMS application. They met their 100% paperless lab challenge with the integration of 25 Instruments and electronic notebooks operated on handheld systems with CaliberLIMS.

- Adcock Ingram achieved minimum inter-department paperwork with an integrated deviation handling system with QMS.
- LIMS-SAP real-time integration made seamless interaction possible between the warehouse and QC/QA department.
- Reviewers spent 60% less time on reviews and dedicated their free time to other essential works.
- 100% time was saved in COA preparations & approvals.
- More than 20% of Senior QA time was saved in preparing material quality trends.
- Good improvement in the planning of the team and increase in quality performance with a reduction in errors.
- As a result, on average 2000 samples per month were released from CaliberLIMS.

Moreover, the organization is now built on the foundation of a resilient system that can help them scale up easily, be fully compliant, and allow them to be tomorrow-ready.

Contact Us:

Write to:
sales@caliberuniversal.com

North America
1(412) 499 3442

India
91 95509 56829

Asia Pacific
86 (10) 86399268

Bangladesh
(880)-2-5881-0881

UK & Europe
(44) 07758792855

www.caliberuniversal.com

Caliber offers the widest range of solutions for Process Automation, Quality Management, and Regulatory Compliance for highly regulated industries. Our key differentiator is our product suite which gives companies the unique opportunity to achieve Integrated Quality Management with a single suite of products.

Contact us now for a demo!

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