

“In chaos theory, the ‘butterfly effect’ is the sensitive dependence on ‘initial conditions’ in which a small change in one state of a ‘deterministic nonlinear system’ can result in large differences in a later state. The term, closely associated with the work of Edward Lorenz at MIT, is derived from the metaphorical example of the details of a tornado (the exact time of formation, the exact path taken) being influenced by minor perturbations such as the flapping of the wings of a distant butterfly several weeks earlier.” The business risk of not being compliant can have the similar tornado effect to disrupt businesses much more than the anticipation is a prime importance in today’s business.

Although we have been talking about digital transformation for years, the past 10 weeks of living through COVID-19 have accelerated our desire to transform into digital workplaces, which visionaries expected would not happen for at least another decade. Before the pandemic, companies large and small were still resisting the move to a digital workplace with cloud infrastructure-based applications. Now, as COVID-19 rages, the argument has reversed with employees and company leadership asking, “why can’t our business be all-digital, all-remote, all-cloud all of the time? Why should we return to our traditional work locations knowing the present dangers, while also knowing that a digital workplace is more productive and cost-efficient?”. In the compliance and risk management space, only about 50% of the practitioners were comfortable with the digital solution adoption that has become a near 100% digital now. This is the new normal of post-COVID business.

This is what Edward Lorenz defined as the “Butterfly Effect.” One disturbance (the virus) from one location (China) resulted in everybody working from home, utilizing internet-based tools. COVID-19 created a
“perfect storm” for digital transformation. **Mindsets have changed and resistances have fallen yet the old legacy systems remain.**

Multiple forces converged in a very short period of time driven by the COVID-19 pandemic’s exigent threat and accelerated the opportunity to transform to an all-digital compliance risk management for the operating businesses.

- Life sciences companies have the opportunity to expedite bringing in new discoveries to market faster than ever driven by COVID-19 and FDA’s record-breaking moves to expedite emergency approvals
- FDA and other similar global agencies have taken bold steps. FDA internal systems and technology and other innovation experience in several areas within the Agency appear to have been primed and ready for the post Covid-19 all-digital world
  - E-sourcing guideline for clinical trials
  - Third party accreditation-based Food Safety inspection regime across world
  - Experience with e-audit for GMP inspections

FDA has suspended in-person inspections to digital and many other serious moves are at play

- The AI, ML, RPA, Digital Video, Broadband/5G technology have matured significantly to drive all digital and all cloud operations. The life sciences industry has started realizing the benefits of digital solutions successfully tried in other industries.
- The evolution of internet-based businesses from web 1.0 to post-COVID-19 web X.0 is occurring.
- A cultural change and acceptance to digital transformation is seen across the board. This will be a missed opportunity without a change of mindset and elimination of resistance

**What benefits do the all-digital operating model create?**

The COVID-19 pandemic has created a “perfect storm” creating huge pressure on FDA Regulated industries, exposed weaknesses in the global drug supply chain requiring changes in suppliers and facilities of approved drugs, and hurdles to rapid introduction of new drugs and vaccines. Although FDA moved rapidly to eliminate a lot of barriers by Executive edicts, this time window provides an unique opportunity to accelerate digital transformation of compliance risk management process inside the life sciences companies to align with e-Audit, e-Inspection, e-Sourcing and e-Reporting processes already proposed by FDA which we believe will now be accelerated.

There are opportunities for all stakeholders:

- **Manufacturers:** rapid development & launch of new products and efficiently utilize the supply chain. However, over 80% of Compliance Officers believe that the compliance systems are too
complex and they are vulnerable internally and at 3rd party partners. They need technology solutions to enable e-Audit, e-Inspection, e-Sourcing and e-Reporting.

- **Regulators**: regulators are a lot more open to adapting digital initiatives and simplifying process steps to help manufacturers and the consumers. However, manual operating processes and lack of readiness at the manufacturer level are making it difficult for them to move things faster.

- **Software solution providers**: while there were several digital solutions in existence at various silos, it was a daunting task for them to move the manufacturers and regulatory agencies to adopt those solutions. The COVID situation has created a larger opportunity for them; however, they are challenged to ensure the digital solution works in compliance and does not add more non-conformance driven business risks.

- **Consumers**: digitization will simplify processes at every level of the drug supply chain. This will make drugs accessible faster and maybe at a more affordable price.

### Why are we in the current situation and not able to reap the benefit of digital transformation?

Most compliance practitioners believe that compliance processes are too complex. Regulatory agencies have various policies and guidelines that are interpreted by the industries differently which creates another layer of complexity. This gets further complicated with the broken processes and systems.

The top issues, as per a recent survey, are the following:

- Broken compliance & risk operating model
- Too much focus on process adherence that creates humongous amount of processes, SOPs, guidelines, work instructions, etc. They are optimized to implement locally
- Manual actions are still the prevailing way of managing compliance
  - Adoption of technologies and automations are not widely accepted
- Compliance work is sporadic. No real-time monitoring
- Very limited data and analytics driven decision making. Risk based decision making is still in its nascent stage
- Limited skilled bandwidth and fund drives the status quo

All of the above concerns have been brought to an even sharper focus for action in the post-Covid-19 world. In addition, the fear of US drug shortages for Life Science companies and the need for rapid drug development and approvals have highlighted the need to prepare for a broad range of risks as drug companies adapt their businesses to changing regulatory laws and market-driven pressures. This recent exogenous Covid-19 event exposed the far-reaching nature of the global drug supply chain ecosystem and amplified the need for adaptive and SMART digital compliance processes and compliant data integrity.

Life sciences companies are in need of new digital tools to enable remote e-Audits, e-Inspections, e-Sourcing, and e-Reporting as proposed by the FDA to minimize business disruptions.

### What does this all-digital operating model of the future look like and what needs to be done now?

Current operating models with a siloed collection of legacy systems and limited integrations among the systems, coupled with the lack of seamless integration with external systems, are not adaptive enough to
effectively manage compliance in today’s constantly changing world. For quality and compliance risk management to be effective in this new all-digital world, company operating business platforms and compliance risk management systems need to be migrated to an all-in-one digital cloud platform to be always ready to meet compliance needs, avoid 483s based on predictive modeling of compliance risks, protect data integrity and bring innovation to markets at rapid speeds with full regulatory compliance in the digital workplace. To support this, we need to:

1. Re-imagine all processes, systems and policies to enable continuous data integrity and the e-Chain of custody information, and in real-time chart a strategic digital workplace;
2. Create a new paradigm for the post-COVID-19 world of holistic digital management of compliance risk prediction and real-time compliance monitoring, and to be always ready for e-Audit, e-Sourcing and e-Inspections.

An end-to-end digital cloud platform must have the following functional capabilities:

- AI-driven risk prediction based on the current trend of FDA inspections and 483s, consent decrees, and penalties
- Internal audit, benchmarking and scoring the current state of compliance against the current compliance expectations of regulatory bodies
- A mechanism for executive decision support and the development of mitigation strategies and prioritization
- Digital tools to implement all the above; and
- Ongoing real-time compliance monitoring.

The all-in-one digital cloud platform of the future is already here today.

**Introducing Total Compliance Cloud Solution**: A Digital Web X.0 platform with compliance risk prediction and real-time compliance monitoring, available as an all-cloud-based execution system embedded in the operating platforms of core businesses.

Most companies lack real-time visibility into emerging regulatory changes and enforcement patterns, which inhibits their ability to ensure compliance with regulatory requirements. In addition, manual intervention in a conventional regulatory compliance review process is time-consuming, sporadic, inefficient, error-prone and expensive. Most company assessments are periodic by design and fail to consider compliance maturity levels in real-time. Accordingly, companies do not have the capabilities, bandwidth and systems to predict business risks associated with existing nonconformances associated with regulatory compliance standards.
All-in-One Total Compliance Risk Management Platform

At the core of the Compliance Risk Predictor™ module is Xybion’s proprietary industry index that analyzes multiple data sources, including 483 citation documents, internal audit databases, and Department of Justice fines and settlements database. Our unstructured data lake includes more than 35,000 records from the past years and continuously pulls in the latest information to make real-time reporting and trend analyses possible. The Compliance Risk Predictor determines your company’s Compliance Risk Maturity Index (RCMI) Score. The system identifies the regulatory compliance risk and guides users through a questionnaire that assesses your current state of maturity. Follow-up audits are conducted, based on identified areas of risk. During the audit stage, the system, which uses our XybionEye™ technology, automatically finds nonconformances in documents. The Compliance Risk Predictor classifies all nonconformances based upon the proprietary database and prioritizes actions based on the likelihood of a citation and financial impact.
The Compliance Risk Predictor™ provides a quantitative score for a company’s RCMI at the company level, country level and functional area level, and turns it into actionable information that empowers you to prioritize actions based on findings. The tool can be used internally as well as with your third-party vendors.

The RCMI Score: The RCMI score uses a 5-point scale that scores results by functional area and location so that you can easily identify and aggregate by function- or location-specific results. The ability to drill down into the report allows you to prioritize areas of focus.
Sample scorecard:
One can further drill into the functional reports. The system provides reports of risk areas based on functional area vs. control types. Our patent-pending Predictive Risk Algorithm assesses audit results against risk on external and internal data sources.

**Predictive Compliance Sample Report**

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<th>Process</th>
<th>People</th>
<th>Quality</th>
<th>Technology</th>
<th>Governance</th>
<th>Investigation</th>
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**Business Impact Summary**

A risk management-driven predictive compliance platform will not only lower compliance risk, it will also make the company more efficient and competitive by allowing it to dedicate more attention to the innovation process. Benefits include:

- A program for sustainable compliance can free up to 30% of the function’s capacity, improving the effectiveness of risk management.
- By implementing a best-in-class digital **GRCQ X.0** total compliance system, such as our **Total Compliance platform**, a life sciences company will be able to sustain and improve compliance standards and performance. At the same time, companies will be able to generate greater patient and business outcomes by focusing on transformation opportunities across the value chain and expediting drug discovery into commercialization.
• The low-code digital **Total Compliance XD** digital acceleration platform is adaptive and fully configurable so that compliance processes/SOPs are completed right the first time and adapt/change as mandated with proper data integrity and record controls.

• Enables your organization to fully participate in the evolving FDA digital regime of e-Audit, e-Inspection, e-Sourcing and e-Reporting functionalities.

• Provides complete visibility across all your organization’s facilities and suppliers, enabling life sciences companies to have a 360° closed-loop view across all global compliance documents, control measures and standard operating procedures within a single data lake, allowing you to

  • “Be Always Compliance Ready.”

**Future-Proof Your Technology Investments with a Clear Path on ROI**

Xybion’s Total Compliance Solution (TCS-XD) is built on the Xybion Digital Acceleration Platform (XDP) Cloud Platform. It is a low-code technology stack that leverages the core principles of a unified operational ecosystem, rapid configuration engine & intelligent digital workplace for true digital acceleration, not just transformation. TCS-XD provides a single, out-of-the box, yet highly configurable solution to holistically manage quality and compliance processes and information across an organization’s entire value chain. TCS-XD delivers immediate value without expensive customization, minimizing total cost of ownership over time. TCS-XD can scale rapidly with the company’s growth, improve process efficiency and manage the risks associated with inhouse and external distribution models, including changing regulations.

**About Xybion**

Xybion is the leading provider of software, services and consulting for global corporations operating in highly regulated industries. Xybion specializes in the development and delivery of flexible enterprise solutions that can be easily configured, integrated or deployed out of the box to deliver the capabilities you need. Leveraging our extensive global experience working with companies of all sizes, we offer deep domain knowledge of FDA regulations and have a long track record of helping clients build effective compliance and risk mitigation strategies and solutions.

Since 1977 Xybion has provided software, services and consulting for global corporations operating in highly regulated industries. Xybion’s holistic approach toward product life cycle, including R&D, clinical data, compliance risk, quality, contents and data integrity, are all maintained with a modular low-code application development. Clients can easily deploy the functionality they need and quickly adapt the Total Compliance platform to suit their unique business processes.

Since its founding in 1977, Xybion Corp. has provided software solutions and services for R&D and compliance to global pharmaceutical, medical technology and biopharma companies for the FDA approval process. Xybion has more than 150 customers in 16 countries on all five continents, including all the top 20 biopharmaceutical companies.