2030
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Where Quality and Regulatory Compliance Meet Technology:
Opportunities Facing Life Sciences Teams
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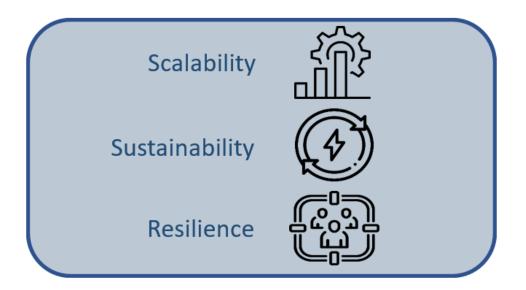SeanWinslow@2030Consulting.com

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Introduction – Improving Quality & Regulatory Compliance with Modern Technologies

The life sciences industry is a dynamic environment of science and technology. Quality and Regulatory Compliance (QRC) are foundational elements of this ecosystem that permit the thorough investigation of new medicines, precise manufacturing of new devices, and speedy development of innovative therapies. Rapid growth, dynamic teams, and frequent mergers & acquisitions within the Pharmaceutical, Biotech, and Medical Device communities are continuously stoking changes to business operations. Therefore, a QRC foundation must be able to adapt with confidence while also providing uninterrupted compliance.

There is a constant tug of war between the inertia of time-worn legacy systems and the frenetic energy and motivation of innovative teams to perform more effectively. This continuous tension creates a plethora of possibilities to improve QRC with robust new technologies. The 2030 Consulting team (pronounced Twenty-Thirty) has worked extensively in the QRC arena for decades. Based on our experience, we believe that three priorities should drive modern QRC technology efforts:

In this paper, we share our rationale for maintaining these priorities in QRC technology initiatives. We also share some of the project experiences that have shaped our approach and permeated discussions with Quality and Regulatory Compliance leaders.

The 2030 View: The Importance of a Solution's Scalability, Sustainability, and Resilience

Quality and Regulatory Compliance requirements can present impediments to progress. However, these requirements also reveal opportunities to re-envision a team's effectiveness, renovate processes, and enable newer technologies to revamp business-as-usual.

As teams begin a QRC project, the proposed solution's scalability, sustainability, and resilience should be top of mind. Regardless of what is required – a new or updated process, new technologies, a reorganization, or any combination – these three overlapping priorities provide reliable guiding principles for progress.

- **Scalability (adapting to demand)** – All aspects of the solution must provide the ability to adapt to increased needs. Such demands may take the form of an expanded pipeline of products, bigger teams in more locations, and processes that grow beyond traditional organizational boundaries. This principle also applies to organizations that need to reduce or end their use of a process or system.

- **Sustainability (future-proofing)** – All too often, when a software solution is implemented, there is a foregone assumption that it will meet the business needs indefinitely. A project's success must be measured in short and mid-term results required to support the implementation team's needs, the business, and end-users at go-live. The ongoing management of the solution should also be considered. The implemented applications or tools must meet users' needs over longer, sometimes 'indefinite' periods despite changing technologies or market conditions. Meeting these needs requires constant control of project and product scope, as well as proactive attention to the health of the solution for a sustained future. Sustainability metrics might include implementation and management costs, adoption rates, or the product's projected useful life.

- **Resilience (quick resolve)** – The larger the environment a solution must support, the more challenging it becomes to maintain acceptable service levels during abnormal operations. Predictable challenges can occur when creating a backup, on-boarding new user groups, or executing a planned data import. Unplanned challenges can range from simple administrative mistakes to large scale disasters or cyber-attacks. Systems and processes must be able to

accommodate such risks accordingly. Often, they require the re-evaluation of rigid legacy technologies and manual or paper-based processes that lead to errors.

2030 Client Success Stories

As experts in deploying quality management solutions, the 2030 Consulting team has achieved great success leading projects where scalability, sustainability, and resilience help drive decisions. **The 2030 team offers a unique combination of quality, regulatory, and compliance expertise interwoven with software development and implementation experience.** With each project, we add to our capabilities, expand our skill sets, and refine our perspectives. Our evolving knowledge is passed on to our clients and results in greater and recurring value for all.

Scalability for Rapid Growth

Case Study - Positioning a Client for Quick Expansion

2030 Consulting led a vendor selection initiative for a biopharmaceutical Contract Development and Manufacturing Organization (CDMO), experiencing substantial organizational growth. Management expected to increase the number of customers three-fold and employees by 50% by the end of the calendar year, with similar content and data increases. Manual paper-based document and training record processes were already causing a lag in productivity, posing multiple regulatory compliance risks, and

placing customer-relations in peril. They sought a single-vendor, cloud-based document management solution (DMS) that enabled 'anywhere-anytime-anyone' collaboration and approval with built-in training distribution and record-keeping.

The 2030 Consulting team facilitated the development of business and user requirements. Once we established the requirements, our consultants managed the RFI, vendor solicitation, RFP distribution, demonstrations, and assisted with contract negotiations. Throughout the project, 2030 aided the CDMO in evaluating eleven software vendors. Our approach systematically filtered for the best 'fit for purpose' solution by highlighting relevant strengths and weaknesses and ultimately selecting the most appropriate solution to meet their compliance and growth demands.

Our company earned the trust and privilege to help lead the implementation project. Our collaborative approach helped our client focus on priorities, respond to rapidly changing needs, and implement a scalable solution. We successfully delivered the software applications with a rapid deployment and on-boarding program that included reusable, cloud-based, computer-based training (CBT) courses. This remote, on-demand learning capability, combined with our efforts to integrate into the client's existing application service desk (i.e., helpdesk), enabled the client to seamlessly support its current and future employees. In fact, the number of users increased by 200% by the time the system was validated and deployed.

By introducing the virtually autonomous scalability and elasticity of a cloud-based solution, combined with a build-once/use-many configuration and on-boarding process, our CDMO client was fully prepared to meet its business scalability demands.

Case Study – Re-aligning a Solution with Evolving Business Needs

An early, clinical-stage biopharmaceutical company was naturally focusing much of its resources on its drug research, so they invested in a 'turnkey' or 'one size fits most' quality management solution. Initially, one administrator was able to manage the lifecycle of policies and procedures effectively. The solution met the needs of their small team of less than a dozen scientists and lab technologists, as long as the existing knowledgeable resources remained in their roles.

Over time, employee turnover and increased workloads resulted in disintegrated processes. The staff grew (and sometimes shrunk), including changes in the number and type of employees, contractors, and academic and consulting alliances. These revolving professionals contributed to an ever-growing database of content and frequent changes to processes. Eventually, the employees were no longer using the software as initially intended. Many tasks, such as record reviews and approvals, were occurring outside of the system. The client's changing needs called for the quick and efficient reconfiguration of the technology and supporting processes.

We helped the client better understand their evolved quality management needs and addressed many of their immediate requirements with configuration changes, updates to roles and responsibilities, and modifications to streamline processes. **By exposing scalable options within the software and business process, the client was able to renew their compliance efforts while getting more from their original technology investment.**

Sustainable Programs that Minimize Risk

Case Study – Urgent Need for Reliable and Repeatable Compliance

A major Pharmaceutical company received a Good Practice (GxP) Sponsor inspection by a regulatory agency. In the findings, the agency noted process issues with the management and control of GxP documentation. The issues included process defects, missing approval/acceptance signatures, and potential data privacy breaches when documents contained employee information.

The inspection findings resulted in a series of corrective action requirements. The company was mandated to perform an impact assessment of existing data protection compliance initiatives. They also needed to update policies, address process optimizations, and implement short-term fixes to ensure compliance stopgaps in specified time frames. Although the organization could address the required corrective actions, they knew these fixes would not sustain the business operations and compliance needs over an extended period; the solution was not 'future proof.' The organization was determined to produce a more permanent and reliable solution to ensure against future audit findings.

Leveraging our expertise on the subject, 2030 collaborated with the client team to develop business and user requirements. Although already deployed systems could be re-engineered to meet the new needs, the group unanimously agreed that these applications were not designed for such conditions. The adoption of such an approach was not viable or sustainable.

The 2030 consultants designed a software mock-up of a user-friendly, automated workflow portal that would leverage the client's already validated and deployed record management application. Upon acceptance by the business owners, we helped lead the implementation of the purpose-built integration. The development and implementation were focused on the Minimum Viable Product scope (MVP) of the client's needs. This approach enabled our developers to focus their activities on necessary work only and offered an opportunity for customers to provide feedback for future product development. Further, the reduced 'surface area' of an MVP inherently mitigates the introduction and severity of software bugs or design fails. Our approach helped increase compliance readiness, reduce costs and processing time, and stablished a working environment for core activities while providing a platform for further enhancements when needed.

We also supported development and validation activities, working with the business to develop and document Policies, Procedures, and Work Instructions. With these governing documents in place, we then

trained the first line support team and supported go-live. We then instituted hypercare operations to ensure seamless adoption of the new system.

Inspections and audits represent high costs for companies, even when inspectors find minimal or no deviations. They also represent an increased risk of negatively impacting a company's reputation. 2030 helped position the client for continuous compliance readiness through simplified design, which accelerates adoption and issue resolution, enabling a longer useful life of the solution.

Resilient Solutions that Restore Performance

Case Study - Quick Recovery from Difficult Conditions

A multinational biopharmaceutical company faced business crippling software application issues that required in-depth investigation. Collaboration was necessary among the application owners, helpdesk and infrastructure owners, and the vendor to resolve numerous issues.

2030 Consulting applied our troubleshooting, configuration, and project leadership experience. A full-time Technical Project Leader with expertise in Document and Learning Management (DMS/LMS) tools and processes was assigned to the project. With the assistance of other 2030 gurus, the project leader utilized industry best and common practices to guide the client's third-party application support team through investigation, root cause analysis, and remediation of critical issues.

Our crew acted as a direct liaison with the software vendors on behalf of the client. This relationship required the client's trust in our ability and willingness to act in their best interest. **A trusted partnership between the client and a specialty consulting firm like 2030 provides a key benefit for the client team. It ultimately enabled the client to focus on core responsibilities while we managed vendor interactions to ensure issue resolution and knowledge transfer.** A pivotal and exciting point of this relationship occurred when the vendor, recognizing its common interest in resolving the issues, agreed to share in the costs of our services to manage communications and troubleshooting. This act demonstrated how much both parties valued our contribution to their resilience initiative.

Opportunities to Optimize Acquired, Broken, or Abandoned Processes

Technology is omnipresent in Life Sciences organizations. Unfortunately, many are poorly implemented or outdated, resulting in performance degradation, workarounds, and other liabilities. 2030's brilliant team of professionals continues to see a huge opportunity to move toward sustainable solutions across QRC areas. The movement includes streamlining processes, re-evaluating compliance requirements, and off-loading non-core activities as part of any process improvement strategies. These efforts help extract more value from technology and transform capabilities.

One of the most considerable opportunities facing many organizations is to use frequent mergers and acquisitions as the fuel to revamp stale systems and processes. In December 2019, MarketWatch reported, "a record-setting year in which drug manufacturers and biotechs have spent $342 billion snapping up smaller companies to bolster their pipelines."[1]

M&A's and licensing deals bring new products to portfolios and robust pipelines of development projects. In most cases, they also require expanding teams beyond traditional company boundaries as contract resources are used (i.e., CROs, CDMOs, Contractors & Consultants), adding complexity and demanding scalability. Streamlining, renewing, and aligning QRC systems across such teams and processes is vital for high growth businesses. *Following an M&A, such restructuring is a specialty skill in which an organization is uniquely justified and served by outsourcing the services like those offered by 2030 and other niche providers.*

Antiquated systems and manual or paper-based processes also offer the chance to review current practices and significantly impact efficiency. For many organizations, rigid systems typically require increasing numbers of workarounds and manual interventions. Inflexible deployments such as paper-based processes, spreadsheets & file shares, or custom-developed applications stress compliance efforts

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[1] MarketWatch website https://www.marketwatch.com/story/drugmakers-have-spent-a-record-342-billion-on-ma-in-2019-2019-12-09, access November 11, 2020

and create system-wide vulnerabilities. When feasible, we facilitate improvement by introducing best-of-breed technologies, cloud-based solutions, and shared-cost managed services to subsidize or replace inefficiencies.

Regardless of what drives the change, the right technology will only be useful when paired with strong and manageable processes. Infusing quality and compliance early in a process delivers better output when and where it is needed. Leveraging technology to minimize manual errors reduces risk and increases efficiency.

How 2030 Helps Teams Achieve their Goals

In regulated industries, penalties including fines, Corporate Integrity Agreements (CIAs), damage to corporate reputation, and loss of federal grant funding can severely impact operations and the company's brand. 2030's Trusted Advisors have established reliable methods to create robust compliance programs that use technology to maintain consistent and reliable results, effectively support audits, and avoid these penalties.

2030 works with Chief Compliance Officers (CCOs), Chief Technology Officers (CTOs), Chief Quality Officers (CQOs), and their business teams to deliver SUSTAINABLE, SCALABLE and RESILIENT solutions.

We continually update our methods to support best and common practices and the use of modern technologies. Most importantly, our clients gain the advantage of working with experts who know the business. We see what others have done, what worked well, and what new technology is available. We recognize how to apply this input within the context of the client's unique environment to address their needs.

Our experienced resources foster a quick ramp-up and maintain focused efforts toward project objectives. Our practical knowledge helps clients avoid integration issues and other technical delays. We understand

the strategic importance and the operational impacts of implementing a new solution and can navigate complex scenarios and apply our learnings to shorten the client's path to success.

The 2030 Journey

2030 brings decades of experience designing and implementing QRC Technology solutions within the life sciences and other highly regulated industries. We help teams transform disjointed, disconnected, or antiquated processes into streamlined, technology-enabled processes that deliver superior value.

Our life sciences clients know us for our Quality & Regulatory Compliance Technology services. However, 2030 Consulting's underlying strength is identifying business process problems and implementing their solutions. Through our project work, we see many gaps in the technology marketplace. One gap we have begun addressing is the need for a robust, cloud-based worker qualification management solution. As a result, our sister company, 2030 Software Solutions, has been developing a commercial off the shelf, cloud-based solution for qualifying worker capabilities against job requirements. We are excited about the opportunity and are on track to release the solution in 2021.

We understand the capabilities of today's technologies. We are committed to working with our clients to achieve the greatest value for their enterprise technology investments. You will have confidence in our practical knowledge and our real-world solutions engineered to exploit the Quality, Regulatory, and Compliance opportunities that lie before us.

To learn more about 2030 Consulting Services, please visit our website at www.2030Consulting.com.

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