Industry Brief

MasterControl™

Overcoming Pharma's Top 6 Quality and Compliance Oversights

Benefits of Platform Integration and Iterative Task Automation

MasterControl™

For companies doing business in the heavily regulated pharmaceutical industry, quality management and compliance are not just intimidating endeavors — they involve activities that are increasing in complexity as the industry accelerates. Quality successes can only be achieved in the modern regulatory environment when an extensive range of variables are continually monitored and appropriately handled. The prevention of quality oversights — whether they occur during document control activities, corrective action/preventive action (CAPA) management, audit initiatives, supplier relationships, or any other quality-related process — demands precise actions, informed decision-making, and connected processes, all of which can only be realistically achieved in accordance with regulatory requirements by using purpose-built digital solutions.

"Compliance failures can be costly, both in terms of fines, remediation costs and reputational damage. Therefore, identifying, analysing and mitigating compliance risks are essential in developing an effective compliance programme and ensuring the future sustainability of the industry."[v]

- Deloitte Centre for Health Solutions

Avoiding Quality and Compliance Oversights

This brief presents six common quality and compliance missteps that pharma companies either inadvertently enable or unknowingly perpetuate over time. It also recommends actions organizations can take today to help mitigate the long- and short-term problems caused by each oversight.

Oversight #1: Failure to Adapt to Regulators' Risk-Based Approach to Quality

Over the past decade, the regulations and standards that affect pharmaceutical companies have been trending toward a greater focus on risk management and risk-based thinking, a shift that has undoubtedly been accelerated by the COVID-19 pandemic. With each update to an existing standard or new regulation that goes into effect, regulatory agencies are placing more emphasis on risk management and mitigation. Regulators across the globe are shifting from what was once a one-size-fits-all regulatory mentality to a more segmented approach that is primarily driven by data. This compliance trend is expected to become more prevalent, as indicated by the U.S. Food and Drug Administration (FDA) Q9

Quality Risk Management guidance which specifies that greater assurance of a company's ability to deal with potential risks "might affect the extent and level of direct regulatory oversight."[i]

As the role of good quality data (and auditors' access to it) becomes increasingly vital to the enforcement of regulatory policies, effective risk management is emerging as the cornerstone of compliance. But risk-based quality management isn't just important for compliance reasons — it is essential for neutralizing the effects (and potential effects) of quality events that commonly occur in pharma environments.

"Many pharma companies admit they feel poorly prepared to navigate these choppy waters because their risk analysis and management is not as robust, data driven, action oriented, or far-reaching as they would wish,"

- McKinsey & Company

"Risk management and risk mitigation are part of the continual improvement process," said Erin Wright, MasterControl data and compliance senior manager, noting that regulatory bodies have clearly stated that the ALARP (as low as reasonably practicable) approach to risk management is no longer acceptable in the life sciences. Since even low-risk items must now be continually mitigated, she said that pharma companies' "risk will never be low enough, particularly when you are dealing with patient safety and the safety of your product."[ii]

Coinciding with regulators' amplified attention to risk is an increase in the magnitude and frequency of the risks pharma companies must manage, particularly as they pertain to product quality, drug approvals, and clinical trial design and execution, according to McKinsey & Company.

"Many pharma companies admit they feel poorly prepared to navigate these choppy waters because their risk analysis and management is not as robust, data driven, action oriented, or far-reaching as they would wish ," McKinsey's researchers report.[iii]

A pharma company's focus on documents over data — which has historically been the industry's standard approach — is no longer a tenable compliance model in the modern regulatory landscape. Yet, as many pharma organizations attempt to adopt a more data-driven approach to risk management, unstructured data dilemmas are surfacing as the most significant roadblock to data centricity. Risk-related data that could help a company identify and mitigate risks before they cause larger problems down the road are too frequently trapped in unsearchable paper documents, inaccessible reports, or disconnected information silos.

The Deloitte Centre for Health Solutions predicts that regulatory agencies will create some form of digital platform by 2025 that will enable companies to exercise more self-regulation, which should move the management of risk closer to those most affected by it.[iv] Deloitte analysts postulate that regulation will continue to become more outcome-based, data-driven, and segmented, and that it will increasingly rely on advanced analytics to detect patterns and trends to ensure the safety and effectiveness of pharmaceutical products.

The data-fueled future of risk management will require pharma companies to adopt a continuous-readiness quality model that is supported by digital technology, according to Deloitte.[v] Such a model will drive efficiency and is expected to lower overall compliance costs dramatically. Combining this continuous-readiness model with robust digital tools that facilitate effective risk assessments/management will further improve the effectiveness of a company's compliance function.

Proactive Response: Digitize More Risk-Related Processes

To stay competitive and agile in a shifting regulatory environment, pharma companies should consider implementing an advanced software solution that can automate and more effectively manage risk-related processes. Although some pharma executives worry that the efficiencies gained from advanced risk management technologies might make their companies susceptible to running afoul of regulators, the opposite is actually true, according to Sue Marchant, product management director at MasterControl.

"We're finding that regulators are adopting new data-driven approaches and that they are at the forefront of this trend," Marchant said. "They are taking an approach that favors assessing risk in a more intelligent way. That regulatory stance will place added importance on life sciences companies' quality data while also increasing its value."

"There are fundamental building blocks that will have to be put in place, whether that's from a technology standpoint or an operating model, and so digital transformation really becomes an enabler. It becomes a bit of a risk mitigator on one hand and an accelerator of strategies on the other."[xxix]

- Greg Reh, US Life Sciences Sector Leader, Deloitte Consulting LLP

Advanced risk management solutions substantially improve an organization's capacity to track and trend risk data. Additionally, they can also enhance an organization's ability to demonstrate the effectiveness of risk management efforts to auditors. Moving forward, digital technologies will be the central modality through which a pharma company can prove that risk can be managed according to regulatory guidelines.

Deloitte researchers point to two technology-related steps pharma companies can take that will help them successfully navigate compliance challenges in the future:

- Integrate a single, enterprise-wide view of compliance risk.
- Build data analytics capabilities to predict key risks.[vi]

As regulators lean harder into risk, innovative digital tools that connect data across the enterprise and include predictive analytics capabilities are poised to be core mechanisms for generating value from risk management efforts. The use of advanced analytics and machine learning to boost risk management efforts is rapidly gaining traction across the industry, according to McKinsey & Company research. In one case study cited by McKinsey, a global pharma company adopted an advanced analytics approach to improve its prioritization of clinical trial sites for quality audits. The new approach allowed the company to identify issues that would have gone undetected using its old manual process while also freeing up 30% of its quality resources.[vii]

"In order to thrive, manufacturers should ensure that they are capitalizing on the momentum gained in accelerating digital transformation programs, strategic shifts, and commercial reorganization — it is imperative to remain competitive in the future and build resiliency into the operating model."[x]

- Deloitte Insights

"Risk is all about putting a plan in place, executing on that plan, and being able to show that plan," said Kim Jackson, MasterControl's senior product manager overseeing risk and quality event solutions. "At the end of the day, what matters is being able to mitigate those risks because you've thought of them ahead of time. Tracking all of that on a spreadsheet is very difficult, but a lot of people are still doing it that way these days."[viii]

Companies that consolidate smarter risk-management principles with the latest performance monitoring/enhancing digital technologies will gain the following advantages, according to McKinsey's extrapolations:

- A comprehensive view of quality management in real time.
- The ability to quickly identify areas of potential risk and emerging trends, as well as review their underlying metrics and connections to different areas.
- Automatic collection, analysis, and visualization of leading indicators and outcomes on intuitive dashboards.
- The capacity to make rapid decisions to address existing or emerging issues and monitor the results.
- The ability to adjust metrics and targets to further improve performance as goals are achieved.
- A view of the entire value chain that creates transparency for all functions throughout the enterprise, not just the quality department.[ix]

To learn more about the many ways pharma organizations can benefit from risk management software with advanced analytics capabilities, visit mastercontrol.com/quality/risk-software/.

Oversight #2: Failure to Invest in Catalyzing Technologies

"Best-in-class companies understand and develop the most important capabilities while actively rolling out digital use cases."[xv]

- Deloitte Insights

One of the most consequential oversights a pharma company can make is the tendency to play it safe with advanced tools that can improve efficiency. Waiting to adopt innovative technologies until they've been established as industry cornerstones can severely stifle a company's competitive positioning. Some pharma companies have waited so long to pursue digital initiatives that they are still managing documents with paper-based or hybrid systems that literally require hundreds or even thousands of administrative work hours each year to maintain.

During the COVID-19 pandemic, companies with manual, disconnected systems learned the hard way that quality flexibility, process digitization, and data connectivity in the cloud are critical to surviving in the modern pharmaceutical industry. The pandemic caused many companies to revise or scale back drug launches, and market responses to new drug launches were lackluster, according to industry leaders surveyed by Deloitte.[x] Digital, cloud-based solutions were vital to withstanding such setbacks.

The pandemic forever changed the way we can and must work when crises have global and/or local complications. For example, it's impossible to perform many quality processes manually in instances where employees are required to work remotely or maintain social distance. Furthermore, it makes little sense to even attempt to do so when there are proven software solutions capable of streamlining administrative work and connecting quality processes with the personnel responsible for executing them via a secure internet connection. Technology is the key to adaptability.

Proactive Response: Embrace Optimizing Technologies

Pharma companies that haven't already implemented technologies to streamline and integrate their quality processes should consider increasing investments in technologies that will ease the burdens of quality and compliance management. That being said, the trepidation of pharma executives that are hesitant to make large investments in quality management technologies is understandable when taking into account the sheer number of solutions on the market and their respective costs. But the value provided by proven software solutions that have been specifically designed to streamline quality and compliance processes far outweighs any difficulties incurred in selecting, implementing, and paying for them. Process automation and data connectivity are worth the price if the digital tools provide value greater than the investment, especially if the turnaround time for realizing returns on the investment is short.

"Data is becoming the new water. And AI is helping healthcare professionals and patients get more insights into how they can translate what we already knew in different silos into something that's useful. As we start going further down this technology pathway, you will see better and different techniques emerge."

- Bakul Patel, FDA Digital Health Center of Excellence Director

Advanced digital tools — particularly those that already incorporate or are positioned to integrate machine learning (ML) or other artificial intelligence (AI) components — are revolutionizing the way pharma companies connect data with processes. The significance of this trend is not lost on regulators.

"Data is becoming the new water," said Bakul Patel, director of the FDA Digital Health Center of Excellence. "And AI is helping healthcare professionals and patients get more insights into how they can translate what we already knew in different silos into something that's useful. ...As we start going further down this technology pathway, you will see better and different techniques emerge." Patel said that advanced software, algorithms, and ML technologies are opening access to information and evidence that was once inaccessible or scattered throughout disconnected data silos, which is leading the entire industry "to a place where we are all better informed."[xi]

Smarter tools facilitate a smarter approach to quality. And a digital, risk-based quality management system (QMS) is the most effective mechanism for integrating a "smart quality" approach across the entire value chain, according to the latest McKinsey & Company industry research.[xii] McKinsey's analysis points to three critical benefits provided by digital QMS platforms that cannot be replicated using manual, disconnected systems:

- End-to-end connected product data for product life cycle management and digital change control.
- Automated quality performance tracking and quality management review.
- Digital quality training/learning management system.

Evaluating QMS Solutions

"Prior to COVID-19, manufacturers viewed digital transformation as a long-term objective; today, it is a necessity. We are seeing rapid uptake of digital technologies by the biopharma sector in order to facilitate internal and external operations."[x]

- Deloitte Insights

When evaluating which digital QMS solution is the right fit for your business needs, there are two fundamental steps your organization should take.

1. **Analyze Peer Performance:** Review industry analyses of QMS vendors and, if possible, speak with similarly sized companies in comparable sectors that have implemented digital QMS solutions to determine whether the same solution(s) would be well-suited for your environment. There's no shortage of use-case analyses that illustrate how different pharma companies have made quantifiable improvements in their quality metrics by digitizing quality processes and centralizing data. For example, there are multiple case studies highlighting how companies' implementation of the MasterControl Quality Excellence™ solution has led to impressive gains such as:
    - Reduction in signature approval times for standard operating procedures (SOPs) from weeks/months to less than 24 hours.
    - Decrease in data input and other human errors by 50%.
    - Reduction of CAPAs related to employee training by 50%.
    - Acceleration of the tracking and reporting of adverse events and deviations by 30%.
    - Saving more than 450 hours per year in time employees spent preparing training documents.
2. **Determine Return on Investment (ROI):** Before investing in a QMS upgrade, companies should be able to estimate the ROI a QMS solution can help them achieve as well as the speed with which they'll be able to realize the investment's time to value. A recent evaluation of MasterControl clients showed that companies are saving an average of $284,813 annually by digitizing processes and streamlining document management and training processes with the Quality Excellence solution.[xiii] In addition, the average time it takes for the MasterControl system to completely pay for itself is just 15.4 months. When calculating the potential returns on a QMS investment, be sure to account for the time required to install, configure, deploy, and educate employees on the use of the solution. The software vendor (and possibly its client references) should be able to help you approximate the time it will take to get a new system up and running.

Pharma companies with geographically dispersed groups of suppliers and/or research and manufacturing contractors must also consider the importance of investing in a cloud-based QMS solution. Such companies require a platform capable of:

- Providing authorized sites with access to relevant data.
- Standardizing quality processes.
- Producing reports in applicable languages and routing those reports on global and/or local levels.

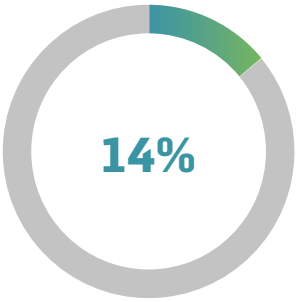
Integrating all of the quality activities above within a single cloud-based platform enables a company to align quality across all sites, vendors, and contractors,

regardless of their geographic location. Fagron, a pharmaceutical compounding and personalized medicine company with 49 locations around the world, is an ideal example of global quality alignment. Since implementing a cloud-based MasterControl QMS solution to maintain quality uniformity across globally dispersed sites, Fagron has saved approximately 1,000 hours of work annually at each site that has access to the platform and is now efficiently administering 3,500 training tasks each month to designated personnel. Authorized employees at the 13 cloud QMS-enabled Fagron sites can instantaneously access the most current version of a document or training protocol whenever they need to execute a task. And the advantages continue to mount as Fagron expands access to the QMS platform to more sites around the world, according to Matt Seitz-Paquette, the company's North America quality specialist.

"We're all working from one source of truth on one platform, so everybody around the world is together," Seitz-Paquette said. "Now I can see the documents that Poland is working on and vice versa. We haven't had that flexibility until now."[xiv]

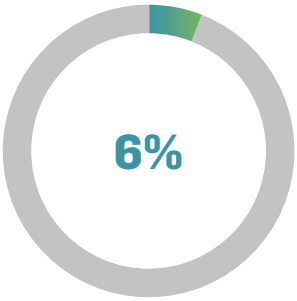
Oversight #3: Lack of Quality Transparency

Too many pharma companies are hamstrung by quality visibility issues like lack of access to pertinent and timely information and gaps in data that could be used to boost improvement if it were available for analysis. These impediments are common when quality isn't prioritized along each step of a pharmaceutical product's life cycle.



Executives and quality managers that believe individuals across their organizations understand their roles in achieving quality goals.

The research firm Boston Consulting Group (BCG) reported an alarming quality statistic: only 6% of executives and quality managers believe their entire company contributes to meeting quality standards. Perhaps even more shocking, the same study revealed that just 14% of those surveyed don't believe that individuals across their respective organizations understand their roles in achieving quality goals.[xv] In environments like these, quality is only an afterthought to most personnel. It is commonly viewed as a necessary evil that must be enforced, and quality compliance is therefore superficial, passive, and only involved in the late stages of decision-making processes. Conversely, in companies where quality is holistic and conspicuous as a top priority at every level of the enterprise, compliance is a fully integrated endeavor and a culture exists that can be measured and recognized as a compliance risk factor, according to Deloitte's industry research.[xvi]



Executives and quality managers that believe the entire organization contributes to meeting quality standards.

"Quality is a mentality, not just a department," said MasterControl's Kim Jackson. "It should be baked into everything that you do. When that happens, you start to get a culture shift where quality doesn't make it hard to do your job — quality is your job. Then you end up with a better product at the end of the day."[xvii]

A strong quality culture is also fundamental to attracting the highest performing employees, according to Deloitte, which projects that the most successful pharma companies in the future will be those that can "sustain a compliance talent pipeline that enables them to meet the increasing demand for, and changing nature of, compliance skills."[xviii]

"Successful companies will be those that are able to sustain their compliance talent pipeline to meet the increasing demand for, and changing nature of, compliance skills. Those with a strong compliance culture will attract more high performing employees."[xviii]

- Deloitte Centre for Health Solutions

Proactive Response: Establish a Quality Culture that Spans the Enterprise

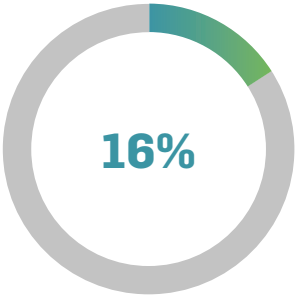
To develop a culture of quality, a pharma company must have systems capable of embedding a quality mindset and unifying compliance efforts throughout all the organization's functions. This need, coupled with the overall industry's acceleration and the accompanying increased focus on data, has propelled software platforms to the forefront. Cloud platforms are playing an increasingly larger role in quality management because they provide greater real-time visibility into data while also allowing companies to exert greater control, even as complexity increases and change occurs more rapidly.

Rather than piecing together disparate applications to coordinate multiple processes and data streams, a unified platform offers the reassurance of native connectivity and integrates all essential applications and processes within a common architecture and database. Plus, a pharma company can achieve greater governance over its quality management processes by running multiple applications within an inherently integrated operating system.

Software platforms facilitate innovation and enable pharma organizations to take their culture of quality to the next level by providing an integrated set of tools that tightly correlate data and processes across the enterprise. By design, platforms enable multiple interrelated processes to operate and synchronize within the same digitized framework, which is the primary reason they are proving to be the most effective mechanism for mapping data and process connections across product life cycles.

Employing software platforms to automate administrative tasks such as follow-ups and signoffs does a great deal to strengthen the quality culture. In addition to embracing a platform approach to quality, a pharma company can further bolster its quality culture by increasing budgets and support for quality assurance (QA). Greater support for pharma QA groups will likely require the following:

- Increased planning of workloads and resource allocation.
- Elimination of paper-based processes.
- Harmonization of separate QA groups.



Only 16% of companies currently enhance quality management best practices with digital technologies.[xix]

A pharma company's implementation of QA improvements and platform technologies are steps toward becoming a "digital frontrunner," an organization in which quality enhancement initiatives are viewed as long-term investments and a total quality management culture is prevalent. It's worth noting that digital frontrunners are far outnumbered by the number of organizations whose modernization efforts are still lagging, according to BCG's studies. In fact, only 16% of respondents to BCG surveys reported that they are currently applying advanced digital technologies to enhance traditional best practices in quality management.[xix] Pharma companies on the leading edge, on the other hand, are already past the planning stages and have implemented digital technologies that are helping them realize critical gains in the areas of quality governance, performance management, and training.

Platforms are also instrumental tools for offsetting rising research and development (R&D) costs, which have been rising faster than revenues throughout the pharmaceutical world.[xx] New integrative platforms are sparking a fundamental shift in pharma R&D models, according to Deloitte's industry analysis.

"Digital technologies are starting to transform how biopharma companies approach clinical development by incorporating insights from multiple sources of data, providing an opportunity to improve the patient experience, enhance clinical trial productivity, and increase the amount and quality of data collected in trials."[xxi]

- Deloitte Centre for Health Solutions

"Digital technologies are starting to transform how biopharma companies approach clinical development by incorporating insights from multiple sources of data, providing an opportunity to improve the patient experience, enhance clinical trial productivity, and increase the amount and quality of data collected in trials," the Deloitte Centre for Health Solutions stated in its most recent pharmaceutical innovation report. "However, digital transformation is not just about technologies, platforms, and advanced analytics; it is a way of doing things differently. Consequently, adopting a digital mind-set is a new business imperative."[xxi]

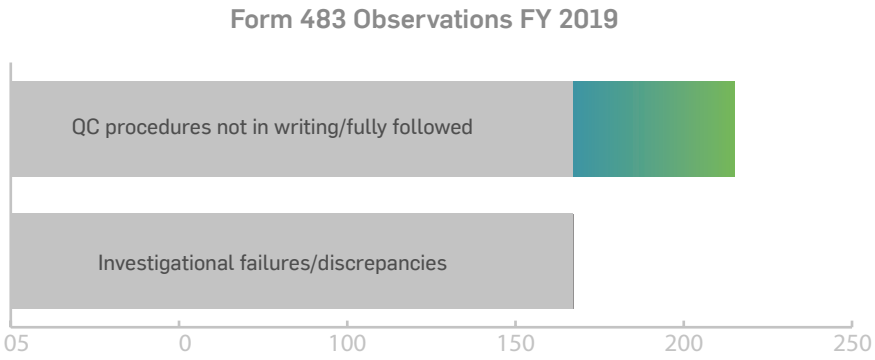
To learn more about the many benefits of adopting a digital-first, platform-based approach to quality, visit mastercontrol.com/platform.

Oversight #4: Inadequate or Ineffective Personnel Training Programs

Though most corporations support training at some level, it is often surprisingly inadequate in regulated life sciences environments. In fact, the most common reason the FDA issues Form 483 inspection observations to pharma companies — in most years by a longshot — is because the procedures applicable to the company's quality control unit are not in writing and/or are not fully followed. In FY2019, for example, 215 Form 483 observations were issued to drug companies, which was 48 more observations than the next most common infraction (investigational failures/discrepancies).[xxii]

The most common reason pharma companies receive Form 483 Observations from the FDA:

Quality control procedures not in writing and/or not fully followed.



Training "weak spots" lead to a variety of complications that cause hitches in even the most carefully planned quality systems. Problems related to incomplete or ineffective training (or the utter lack thereof) in pharma manufacturing frequently include:

- Tasks are performed incorrectly or not fulfilled at all as a result of manual management of training materials, SOPs, and exams (all of which have a tendency to be outdated or inadequately controlled in paper-based systems).
- Retraining on revised documents is ineffective (or fails to occur) because document revision procedures and training programs are maintained within disparate systems, which inevitably leads to training gaps or work being performed from outdated instructions.
- Training coordinators spend countless hours routing and tracking training assignments (not to mention the time and effort it takes for them to track the completion of tasks and verify the results).
- Managers have difficulties finding and retrieving training records and documentation requested by auditors and inspectors.
- Employee competency is impossible to assess with any degree of reliability and accuracy.

"Human error is the cause of substantial variation across the industry. It can be prevented by analyzing process for failure modes and increasing automation."[xxiii]

- Rick Friedman, FDA Deputy Director, Office of Manufacturing Quality

Proactive Response: Automate Training

Training is not a one-time event — it is a continuous and dynamic effort. That not only means that a pharma company's training program itself must be dynamic, but that the documentation and certification of the individuals being trained must be dynamic as well. To stay competitive and compliant, pharma organizations that have been reliant on disconnected, largely paper-based systems to manage their training programs must adopt more robust tools and methodologies for training and record keeping.

Preventable human errors — problems that could be avoided with better training programs — contribute to the most common root causes of quality issues. Such errors are the cause of substantial variation across the pharma industry and can be avoided by increasing the use of automation and analyzing process for failure modes, said Rick Friedman , deputy director of the FDA's Office of Manufacturing Quality.[xxiii]

A digitized system that integrates training processes with correlated quality activities can catalyze dramatic improvements like:

- Training that directly connects to and is triggered by revisions to critical documents.
- Simplified routing, follow-up, and escalation of training tasks.
- Meticulous audit preparedness.
- More accurate competency assessments.
- An overall reduction in administrative burdens, which allows training coordinators to focus on training effectiveness and the quality of curricula.

The outsourced pharma research market will soon reach a value of

$55 BILLION

The MasterControl Training™ software solution automates all training activities, from the distribution of tasks, materials, and exams to the follow-up, tracking, escalation, and verification of completed courses. The solution provides managers with an up-to-date snapshot of employee training statuses and even offers a view of statuses grouped by job code. Each employee can view their past training, course due dates, and upcoming training requirements, ensuring that all personnel are always up to speed. All training records are maintained in a cloud repository, so users and auditors alike can easily retrieve documents whenever they are needed.

To learn more about the benefits of digitized training programs, visit www.mastercontrol.com/training-software/.

Oversight #5: Inefficient CRO Management

Pharma companies are always searching for ways to accelerate clinical trials without jeopardizing trial accuracy. To achieve those goals, companies are increasingly outsourcing at least a portion of their clinical research activities to contract research organizations (CROs). With the number of drug development projects multiplying, the demand for CRO services continues to skyrocket. In fact, the exploding outsourced pharma research market has a projected acceleration of up to 12% through 2022 with a total value that will likely soon reach more than $55 billion , according to the Clearwater International Healthcare forecasts.[xxiv] Despite the increasing reliance on CROs, however, most pharma companies fail to manage CRO resources effectively and in a manner that would allow them to fully realize their drug development and financial goals.

"It's cheaper for a sponsor to contract out to the CRO rather than have trained employees do the job internally. However, although the financial benefit is there in the short term, pharmaceutical sponsors risk a damaged reputation in the long term."

- Dr. Andrew Wei, Monash University and Alfred Hospital Researcher

CRO-related pitfalls inevitably arise when pharmaceutical sponsor companies place too much focus on outsourcing as a money-saving scheme rather than as a means of effectively extending their own policies and initiatives. The industry is plagued by sponsors that value financial gain above quality, according to Dr. Andrew Wei, an acute myeloid leukemia researcher at Monash University and Alfred Hospital in Melbourne, Australia.

"It's cheaper for a sponsor to contract out to the CRO rather than have trained employees do the job internally," Wei said. "However, although the financial benefit is there in the short term, pharmaceutical sponsors risk a damaged reputation in the long term."[xxv]

Companies that outsource research must not lose sight of the fact that quality cannot effectively operate in isolation. Quality must be pervasive and uniformly enforced throughout a sponsor's network of CROs for quality consistency and compliance to be maintained. Quality is especially difficult to manage — particularly for organizations with geographically broad CRO networks — when the quality management processes in place are reliant on paper-based systems.

Some of the compliance failures that result from ineffective and/or inconsistent management of quality across CROs include:

- Critical information can't be accessed when needed (i.e., because it is located at a different site, obscured in unsearchable paper documents, segregated in a disconnected system, etc.).
- Procedures are inflexible or don't align with regulatory expectations.
- Audits are problematic due to difficulties and inefficiencies experienced when retrieving requested data.

Proactive Response: Centralize and Streamline CRO Management

77% of CROs and sponsors struggle to load information into data capture systems because of

- Compatibility issues
- Technical demands
- Integration challenges

- Tufts Center for the Study of Drug Development

Employing a network of CROs allows pharma organizations to save money and speed up product-to-market times. But managing quality processes and enforcing policies across an assortment of CROs is messy work if the organization lacks a centralized framework for control. A recent analysis by the Tufts Center for the Study of Drug Development (CSDD) found that the increasing volume of clinical trial data is causing delays in drug development times and causing considerable technical and integration problems for personnel who manage clinical data.

The analysis showed that more than two-thirds of CROs and sponsors experience difficulties loading data into their data collection systems due to compatibility issues, technical demands, and integration challenges.[xxvi] Significantly, the Tufts CSDD research revealed that two process changes can simplify these efforts and accelerate study initiation:

- Clearly integrated CRO/sponsor processes.
- Electronic documents, workflows, and visibility.[xxvii]

To maintain comprehensive control and complete oversight over quality, sponsor organizations must have continual visibility into all relevant data and be able to track quality activities in real time across the entire CRO ecosystem. Pharma organizations that currently lack these capabilities should invest in technology that enables them to effectively monitor, audit, and standardize quality across their various CROs. At a minimum, the technology should allow the organization to:

- Effectively manage trial master file (TMF) documents and integrate them with training and other compliance-critical processes.
- Improve communication channels between corporate management and CRO staff.
- Assign a status (e.g., assessed, assessment in progress, approved, etc.) to any given CRO or supplier.
- Generate approval subcategories (i.e., if a CRO is approved to produce x, y, and/or z) to give clinical trial personnel more control over their choice of the appropriate CRO.
- Archive audit information and accurately track any outstanding actions.
- Improve inspection readiness.

The cloud-based MasterControl Clinical Excellence™ trial management solution offers these benefits and more. It centralizes data collection, integrates quality processes, and empowers sponsors to treat each CRO as an extension of the organization rather than a solitary external entity. The Clinical Excellence solution provides a single system within which pharma companies can collect, control, and orchestrate TMF documents, artifacts, tasks, and site data for any number of CROs throughout the entire clinical life cycle.

To learn more about MasterControl clinical management solutions, visit www.mastercontrol.com/clinical/.

3 Keys to PV

Transparency.

Evidence-based postmarket decision-making.

High levels of accountability.

Oversight #6: Insufficient Understanding of and/or Investment in Pharmacovigilance

Pharmacovigilance (PV), which is the unifying term for the activities related to detecting, assessing, understanding, and preventing adverse effects and other drug-related problems, is an essential series of processes that every pharma company must master to ensure regulatory compliance. The regulatory definition of what is entailed by PV varies by agency and region. For instance, the FDA and the European Medicines Agency (EMA) have different interpretations of PV best practices. Yet both agencies share an emphasis on three essential components of PV:

- Transparency.
- Evidence-based-postmarket decision-making.
- High levels of accountability

Since a compliant PV program hinges on the ability to effectively gather, maintain, and report on premarket and postmarket safety data, pharma companies need the right set of tools to manage, track, and connect consumer feedback and study information. Companies that are unable to successfully procure, analyze, and report on optimal PV data typically fail to do the following:

- Centrally maintain quality and compliance information relating to global, regional, or local PV audit programs. For the sake of accessibility, this information should be stored electronically.
- Generate up-to-date PV-related trending information.
- Ensure rapid resolution and follow-up of any PV issues. Some type of software control will always be required for timely resolution.
- Harmonize PV auditing procedures.
- Expedite the handling of PV-related regulatory inspections.

Preventive Action: Automate Postmarket Activities

As with other quality and compliance procedures, pharmacovigilance activities are far more effective when processes are automated and harmonized with the overall quality system. A digitized solution that reliably integrates quality, customer complaint, and postmarket surveillance processes can help a company

enhance its management of product safety risks and facilitate compliance. The next level of smart quality, according to McKinsey & Company, involves digital applications that offer risk-tailored investigation pathways and automated reporting and customer response solutions.[xxviii]

The MasterControl Postmarket Excellence™ solution is specifically designed to help pharma companies achieve intelligent quality. It collects data from customer complaints, surveys, internal quality control activities, post-clinical studies, or any other monitoring source within a centralized platform. Linking postmarket activities within the MasterControl platform enables pharma companies to:

- Close the quality loop with a risk-based surveillance and complaint management system.
- Automatically incorporate feedback back into related quality processes such as CAPA and nonconformance.
- Establish continual visibility into postmarket activities and statuses with robust reporting tools that classify feedback according to product groupings, elapsed time, average time, and responses pending acknowledgement from regulatory authorities.
- Reduce complaint resolution times.
- Take a more coordinated and comprehensive approach to regulatory reporting.

"How do you put a price on having the peace of mind that everything you need is in one place in terms of documentation, complaints, audits, and training records? That peace of mind you cannot really put a price tag on." [xxx]

- Jorge Kalil, Chief Information Officer, New Jersey Organ and Tissue

To learn more about software solutions that can help you better manage PV activities, visit www.mastercontrol.com/postmarket.

Conclusion

Pharmaceutical companies are pressed for time and under extreme pressure to get safe products to consumers quickly. Those constraints can lead to oversights — lapses that are avoidable with process automation. There's no greater competitive advantage a pharma company can obtain than the efficiency that comes from automating iterative and administrative tasks and integrating quality and compliance processes within a unified digital platform. The benefits of advanced digital quality management platforms go beyond merely connecting and accelerating compliance-critical processes — they are fundamental to generating value and building a foundation for long-term quality efficiency and compliance continuity.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organizations digitize, automate and connect critical processes across the regulated product development life cycle.

Learn more at mastercontrol.com.

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