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# Introduction

Our 2020 pulse survey focused on the effects of the Coronavirus Pandemic (COVID-19) on regulatory organizations across the globe. The research was designed to explore different short- and long-term regulatory impacts that organizations may have been experiencing and aimed to explore how those companies were responding during the fall of 2020. As the evolution of the pandemic continued, the pulse survey measured how companies were adapting by understanding the practices and tactics employed by the regulatory teams to sustain or develop organizational resiliency and agility. The study also explored what companies learned to help them plan for their future.

This white paper provides insights from the 2020 pulse study, explores our viewpoint on how organizations were evolving during the pandemic while highlighting the impact of the current global health crisis on business operations, regulatory activities and on the ways of working for regulatory organizations. We reviewed the study results alongside our findings from our 2020 World Class Regulatory Information Management (RIM)<sup>sM</sup> study to better understand how key trends and priorities were being affected. Key study take-aways to be explored include:

- 1) A focus on organizational agility and resilience as most were forced to immediately shift and adapt to operate in a socially distanced and virtual world, allowing companies to experience organization-wide changes much quicker and rethink "what is possible"
- 2) Growing organizational dilemmas may complicate resolutions as short-term adaptive behaviors become set habits, challenging established organizational cultures
- 3) Significant RIM investments in global capabilities over the past 5-7 years have made it possible, or at least easier, for organizations to endure industry-wide challenges caused by the pandemic

#### Whitepaper structure:

- Executive Summary and Study Demographics
- Organizational Evolution During the COVID-19 Crisis
- Breaking Free of "Time to Change" Beliefs and Mindsets
- Accelerating Organizational Agility Innovations from Within
- Growing Organizational Dilemmas Workforce Flexibility and Productivity
- Study Summary

We hope you find this information insightful and valuable. Please contact us with any questions.



#### **EXECUTIVE SUMMARY**

The COVID-19 Pandemic has changed the world overnight. Life Sciences industry, as a whole, transformed in many ways to develop, produce, and deploy several novel and effective treatments to treat this disease that was unknown over a year ago. Regulatory organizations played a major role each step of the way, ensuring the quality, confidence, and integrity of the products developed to combat the virus.

Our pulse study examined the effects of the pandemic on regulatory organizations in 3 focused areas during the fall of 2020. We measured the impact of the pandemic on business operations, regulatory activities and on the regulatory workforce. From our data, we made observations on how organizations were adapting during the start and height of the pandemic as well as shared a model that showed our thinking on how organizations would continue to evolve past the end of the pandemic.

The 4 key themes emerged from our research focused on organizational resiliency and their abilities to adapt and change in the challenging environment. Pandemic conditions have helped organizations realize that they have the ability to do things much faster than they originally thought, helping them break free of 'time to change' beliefs and mindsets. Significant shifts in organizational behaviors were also starting to show. The longer the pandemic continued, the easier it became to consider keeping temporary norms, such as having flexible workdays and virtual business meetings. Companies had new considerations for their approach on future policies and procedures: would they find ways to support the newfound flexibilities or would they request their workforce to revert back to performing their roles and responsibilities as they did pre-pandemic, such as being on site with a structured workday? These organizational dilemmas continue to grow as companies recover from the global health crisis and shift into their *next* normal.

Throughout the study, there was a broader theme of resilience and agility highlighting how companies were finding innovations from within their own organizations to adapt to all the immediate challenges. The final theme of maximizing global and virtual investments came from combining these survey findings with other insights and the recently completed 2020 World Class Regulatory Information Management (RIM)<sup>SM</sup> study of 70 companies. Global system and process investments over the past 5-7 years have made a significant impact on how companies have been able to adjust and adapt to the pandemic environment. Those with strong foundations had an easier time maintaining stability and experienced less interference when shifting to remote work settings.

Ultimately, what we learned from the study participants was the pandemic created a perfect storm where regulatory organizations were put to the test and forced to meet challenges head on. Companies have been able to maintain stability and survive these tests with many shifting their mindset to 'what is possible in a shorter timeframe' after living through it and experiencing the possibilities firsthand.



# SURVEY DEMOGRAPHICS AND DESIGN STRATEGY

Our survey design process started with interviewing both industry and provider networks to explore different learning opportunities, followed by several working design sessions to establish and test those priorities in focus groups (see figure 1). We appreciate the organizations, consulting partners and our advisory board member who all contributed to strengthening the study design.

The virtual design sessions and focus groups took place from June-August 2020. The final pulse survey design was locked in early fall 2020 with a total of 18 questions focusing on regulatory impact to Business operations, Ways of Working and Regulatory Activities. Given the pandemic circumstances, the study team felt it was important to recognize the personal experiences and individual perspectives as opposed to a company consensus response. Survey responses were collected over a 6-week period from September 14 – October 31, 2020.



Figure 1: 2020 Pulse Survey Approach and Timeline

For this study, 183 individual responses were processed across 52 unique companies (see Figure 2). The companies, representing large, mid-tier and smaller organizations, were headquartered worldwide, allowing us to capture a true global perspective of the COVID-19 pandemic. Although the participating companies were distributed globally, the work locations of the individual study participants were mainly within North America and Western Europe (see Figure 2). We asked this question in anticipation that work location, work environment and connectivity to the internet would impact how individual participants responded to different questions in the survey.

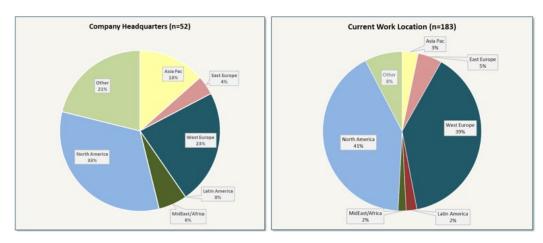


Figure 2: 2020 Pulse Survey Demographics

We requested each company to encourage multiple individual responses from their organization, 10 - 15 individual responses for larger companies and 5 - 7 for smaller companies. We strived to get a fair



representation of the many departments that exist in a typical regulatory function. Figure 3 shows the demographics of roles and functions including individuals heading regulatory affairs, regulatory strategy and operations, RIM and IT groups as well as marketing, certain clinical functions and even some special task forces. Notably, Figure 3 also shows the population of study participants who were actively involved with a COVID-19 related product during the time of the study (54%) vs. those that were not (39%). Throughout our research, we found that those working on a COVID-19 related product had different experiences than those not working on a COVID-19 product, particularly and as expected with regulatory activities.

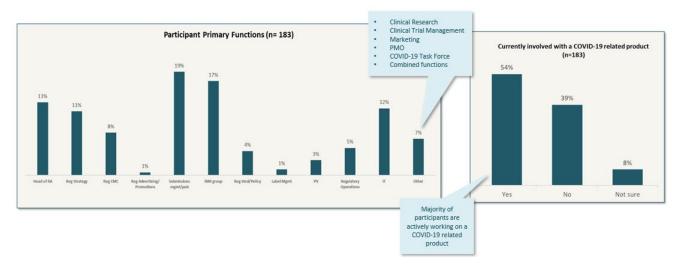


Figure 3: 2020 Pulse Survey Demographics

#### ORGANIZATIONAL EVOLUTION DURING THE COVID-19 CRISIS

One of the study's main priorities was to see what organizations would learn about how they were reacting during the pandemic and to envision how they might plan out next steps post pandemic. From our conversations with multiple organizations, we knew that companies were all having different experiences, however, the *way* companies were thinking about and processing the changes and challenges facing them had similarities. These commonalities fell into 3 distinct phases within a pandemic timeline. We saw organizations evolving through the initial crisis mode, shifting into a recovery phase, and finally evolving through the renewal phase (see Figure 4).



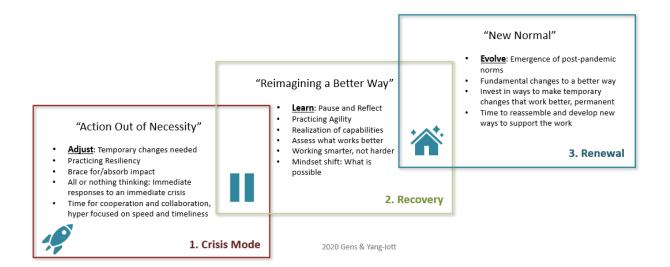


Figure 4: Organizational Evolution Framework

During the initial **Crisis Model Phase**, companies were often taking actions out of necessity and adjusting to find stability from all the immediate challenges. There was a sharp focus on speed with teams determined to focus on what was needed to be done in order to maintain control. Teams focused more on collaborating and cooperating rather than going through an exhaustive list of pros and cons on why something should be done a particular way, marking this phase with many changes seen mostly as temporary. Companies also demonstrated organizational resiliency during this time by taking steps to rebound from any initial setbacks caused by the pandemic, such as re-strategizing correspondence with health authorities due to new limitations in interacting/communicating with them.

Our study responses were collected from mid-September 2020 to the end of October 2020. The global pandemic lock-down started in the first quarter for some regions while most were in full lockdown by April 2020. Following the logic of our evolution framework, our survey results indicated that many participant's companies were still in the initial Crisis Mode phase during the study. For instance, the survey tested 6 common business-related priorities to measure the impact the pandemic had on them. The priorities were: new product development, core system and advanced technology investments, business process optimization, organizational change initiatives and continuous improvement programs. The majority of responses saw little impact to any of the priorities, however 29% did say their companies were accelerating business process optimization but that coincided with the findings from our 2020 WC RIM study, where 60% of participating companies were working on end-to end Label Management, Variation Management and Global Dossier Strategy. The initial Crisis Mode phase of our organizational evolution model was all about maintaining stability while also allowing companies to reevaluate and question how long activities should take. The lack of any significant accelerations, postponements or cancellations of business priorities confirmed our hypothesis that most companies had yet to move out of the crisis mode.



The **Recovery Phase** is the second phase of our organizational evolution throughout the pandemic. Once organizations recovered from the initial shock of the global health crisis and found their footing, they were able to start shifting their mindset and transition into the Recovery phase. During this period, resilient organizations took the time to pause and reflect on what happened in the initial phase. How can their actions and behaviors during the crisis mode inform them to be better in the future? What solutions were implemented, and did they work? Furthermore, could they continue to work even after the pandemic? Learning is the key focus during the Recovery Phase. Our observation from the study was the pandemic created a unique and challenging environment that revealed to many companies what they could accomplish in a short amount time and with the resources they had. This profound experience made it possible for them to reimagine a better way moving forward. The shift in mindset to what was possible was one of the key characteristics of practicing agility that the study revealed.

We see the potential of real fundamental changes fully emerging in the **Renewal Phase**. While change is constant and experienced in the Crisis and Recovery Phase, companies can evolve only after they had the time to learn from their experiences. In this last phase, organizations start to invest in ways to convert the temporary changes that worked better for them into something more permanent; this is the time when prevailing norms integrate as part of the organization's culture. Not all post-pandemic norms can be accurately predicted but there is a general consensus that most industries will emerge stronger and for the better. The final question in our study asked participants to share what they have learned and experienced during the pandemic that would contribute to performance improvements for their companies in the future. Many of the comments hinted at which practices they hoped would become the prevailing norms, such as work from home practices, and a lot had to do with how they performed and behaved during this unique time. We sense more flexibility, better technological and data connections, and more rapid decision making as part of the fundamental changes that will emerge post-pandemic.

## BREAKING FREE OF 'TIME TO CHANGE' BELIEFS AND MINDSETS

Comments such as "things can get done really quickly" and "not everything has to be that complicated" were often reiterated and emphasized from conversations with companies and what survey participants shared during the survey. One of the clear themes that emerged from this study is the pandemic environment allowed many organizations to start breaking free of expectations, specifically 'time to change' beliefs and mindsets. For many companies, they have been conditioned, based on historical experiences, to accept the conventional mindset that change takes time. However, during the pandemic environment, time was no longer a luxury.

Seemingly overnight, organizations were able to successfully shift entire workforces to remote and virtual environments. In one instance, a study participant's company took their planned corporate conversion to Microsoft Teams project, estimated to take 6 months pre-pandemic, and successfully implemented the platform and onboarded their workforce in just 3 weeks. The set of historic norms in



the life sciences industry, in terms of how long it took to implement a project, go through an approval process, or how complicated an application might be, is being challenged by the COVID-19 pandemic. The unprecedented speed, for which we have all witnessed, in vaccine development, production, and deployment can attest to the shift in what people believe is now possible due to the pandemic.

In the study, participants were asked about additional regulatory support needed in various areas. All tested categories, including Supply Chain Disruptions, Customs/Border/Transportation Challenges and Virtual Clinical Trials, saw at least a 38% increase of work as a result of the pandemic. The combination of compressed time frames and more actions and support needed for these Regulatory activities contributed to the measure of 'more work' requirements. When the data was broken out to compare responses from those working on a COVID-19 related product to those who were not, the level of extra work required was significantly higher for those working on a COVID-19 product, across all categories (see Figure 5). Companies developing a COVID-19 product measured more than twice as high for additional support needed in Trial Medication, Virtual Clinical Trials, and Government Affairs, which was expected given the global race for effective vaccinations.

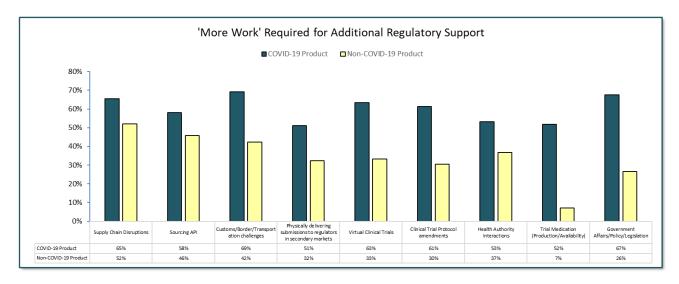


Figure 5: Increase in work required for additional regulatory support

Regardless of what products companies were working on, the study results showed that the regulatory workforce was experiencing more work during the pandemic, not less. Given how highly regulated the life science industry is, we knew that no steps were skipped, and no short cuts were taken in terms of safety, efficacy, quality, and compliance. Even with all the additional work, the work was being completed *and* in record time. This speaks to the key theme of breaking free of expectations and mindsets. In crisis mode, organizations found quicker paths without sacrificing quality and ended up challenging the status quo.



# ACCELERATING ORGANIZATIONAL AGILITY - INNOVATIONS FROM WITHIN

The study's approach to measuring company responses to changes during the pandemic included an observation on different organizational statuses. We asked our respondents to best characterize their organization by choosing from 3 statements (see Figure 6). 34% are 'using the pandemic as an opportunity to reassess our systems and processes to function more efficiently and improve our performance', which we saw as an indicator of agility. 57% have 'maintained the status quo and are operating effectively with minimal disruptions', which we described as showcasing resiliency. These two main themes of resiliency and agility appeared throughout our research and work with clients. It is our belief that there would be a shift from the 57% showcasing resiliency and maintaining the status quo to the 34% that were working to improve their systems and processes as organizations evolved from operating in their Crisis Mode into the Recovery Phase, as described earlier in our framework. The transition from focusing on stability to practicing agility can occur in the Recovery phase as organizations incorporate their learnings into actions and decisions that favors performance improvements for their company's future.

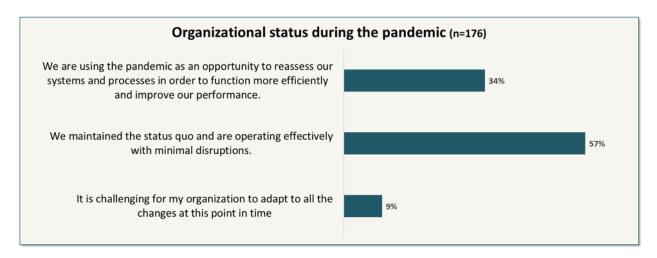


Figure 6: Pandemic Organizational Status

Our data also indicated a different investment in speed for many companies, such as the creation of internal pandemic taskforces focused on accelerating decisions and actions. Several organizations set up special taskforces specifically to bypass their norms, which were characterized as more bureaucratic, rigid in their hierarchical structures and often contributed to slowing things down. COVID-19 has induced a general sense of urgency, forcing companies to focus on tasks at hand and what is necessary, resulting in that realization of 'what is possible'.

Another observation was a growing sense of community and shared organizational mission. Although the pandemic forced people to become more isolated and physically distant from one another in the workforce, it also impacted how people developed and nurtured relationships by bringing more clarity to the different roles and made them see the reliance of those roles with one another. Social distancing and virtual teaming allowed colleagues to better understand what other teams were responsible for and



how all the work was interconnected. 48% of participants experienced an increase of building and maintaining relationships with internal co-workers during the pandemic compared to pre-COVID days. One area that we expected to be negatively impacted by a remote and virtual environment was the ability to build new relationships; this was an instance where the value of having face-to-face interactions was hard to replicate in a virtual environment, even with webcams. For those that had to interact with new hires or those who joined new teams, the lack of in-person interactions was sometimes difficult to overcome. In the survey, we asked how the inability to meet in person impacted the ability to build new relationships with new providers and found that 10% of participants answered, 'Positively Impacted', which we saw as a great learning opportunity indicating that there were innovations even with relationship developments during the COVID-19 crisis.

Overall, the behavioral impact of the pandemic was significant because organizations were experiencing and realizing what they were capable of during a global health crisis. During our interviews with organizations, we heard numerous stories about teams stepping in to fill roles when necessary. For example, a few companies described how regulatory submission associates packed and prepared shipments in their warehouses during the beginning of the pandemic when there was a shortage of workers. Between evidence of much quicker decision making, faster rollouts and adoption of new processes and systems and the fluidity of roles and communications, demonstrations of organizational agility were often on display. In the near future, as companies move through the later phases of our evolution framework, will they choose to sustain these innovations from within or will these newfound efficiencies become just a symptom of the times?

# GROWING ORGANIZATIONAL DILEMMAS - WORKFORCE FLEXIBILITY AND PRODUCTIVITY

The study results set up an interesting observation about growing organizational dilemmas and challenges to what the future of regulatory workforce will look like and how people will operate. In Figure 7, we asked 2 different questions about remote working. When asked about the expectation for employees to return back to work, onsite when possible, 63% of study participants agreed there was an expectation for them to be back onsite, post-pandemic. When asked about their ability to effectively work remotely, an even larger population, 78%, said that work locations do not make a difference in their ability to be effective at their jobs.



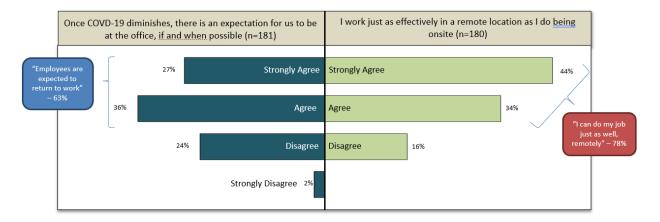


Figure 7: Workplace Flexibility and Productivity

This tension between the expectations of returning onsite vs. people's expressed desires to have flexibility through remote work created a conflict in terms of what emerges when the pandemic is over. On one hand, companies are familiar with and feel comfortable with their deeply embedded, in-person cultures. Many organizations often talked about the importance of in-person collaborations and the value of face-to-face interactions. Fostering that environment was very much a part of the company's DNA, built with intent. On the other hand, a growing number of employees were saying that they could do their job just fine, without having to physically be together in one location. Even more, the data showed a preference for this flexibility and convenience. Companies will have to come to some consensus to respond to these dilemmas: will teams be requested back to the office because it suits the organization? Has the future of work permanently shifted where flexibility and convenience for the employee jumped from being a 'nice to have' to now a 'must have'? What are other long-standing work cultures that will shift post-pandemic? And how will organizations evolve to support the changes?

The impact of COVID-19 on the Ways of Working was a specific section in the study. This was the first time, on a global scale, that entire industries shifted to virtual works environments. The combination of remote working while juggling all other aspects of one's personal life means that the pandemic has had a massive impact on how people work. Not only were employees expected to continue their roles and functions, but most had to do so in addition to many other personal responsibilities such as giving care to others while navigating a new pandemic existence. As organizations quickly adopted new policies and procedures to support their altered realities, we were more interested in thinking about permanent shifts post pandemic. ~40% of our study participants believed that remote working and flexible work hours will become a permanent change, but 47%-55% predict that other common policies and events put on hold during the pandemic, such as in person conferences or business travel for meetings, will resume post-pandemic. The longer the workforce stays socially distanced, the easier it becomes to both justify and realize the benefits of doing some of these things virtually because teams are figuring out not just how to do thing differently, but also how to improve on them. The likely reality is a combination of old and new approaches; however, even seemingly insignificant developments could drastically impact downstream effects on business norms and implications for one's personal life.



In the study's review of different work conditions, the data shows the impact of remote working on communications and collaborations along with the consequences of these adapted behaviors. There were benefits: 80% stated they had the ability to work flexible hours, and also challenges: working in a virtual environment led to a substantial decrease of both formal and impromptu meetings (66% and 42% decrease, respectively). Without having the ability to stop by a colleague's desk to resolve quick issues or effectively exchanging ideas over lunch, 52% stated that they experienced a decrease in personal work productivity and 50% are experiencing challenges with managing relations with coworkers. During interview sessions, we learned the importance of visual cues, such as people physically leaving the office at the end of a workday, to help employees log off and separate their personal lives from their professional lives. In the virtual environment, where many of these visual cues were missing, people had a much harder time disconnecting from work. 76% of participants saw a decrease in their ability to disconnect from work, many stating that the lack of communication or fluctuating work hours for different team members resulted in them staying logged in at all hours to keep up with 'appearances'.

The research provides compelling arguments for both sides of the growing organizational dilemmas (see Figure 9). There is evidence supporting people's preference for remote working and their desire to continue workplace flexibility, yet they also were experiencing decreased personal work productivity due to the pandemic conditions. But the organizational dilemmas do not just end with the people.

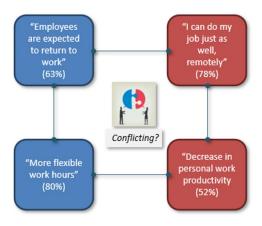


Figure 8: Organizational Dilemmas

Once companies figure out how to manage their people in this shifting environment, they will also have to find ways to provide resources to support the new policies and practices for the new workforce environment. Whatever companies decide to do, whether providing software upgrades and internet connections or access to more mental health or dependent care resources, these will all come at an additional cost for the organization.



# MAXIMIZING GLOBAL AND VIRTUAL INVESTMENTS

We believe the significant investment in regulatory organizations focused on end-to-end processes, global systems, and data quality since 2014 has resulted in the ability to rapidly shift and adapt to a virtual and remote environment. For the past 7 years, industry has been investing to improve "global processes and systems". Based on the 2020 World Class Regulatory Information Management (RIM)<sup>SM</sup> Survey of 70 companies, the top priorities included: Global Dossier Strategy and Dossier Management Operations, End to end Label Management, End to end Variation Management, and Registration and Health Authority Commitment Management.

In the COVID-19 Pandemic pulse survey, we asked participants to rate their organization's RIM capability effectiveness (processes and tools) in supporting remote work. Study results showed that 80%-90% of survey participants acknowledged that their organizations' RIM capabilities were effective or very effective (see Figure 9). Participants working on COVID-19 related products scored even higher for 'Very Effective' compared to those that were not, for all RIM capabilities listed.

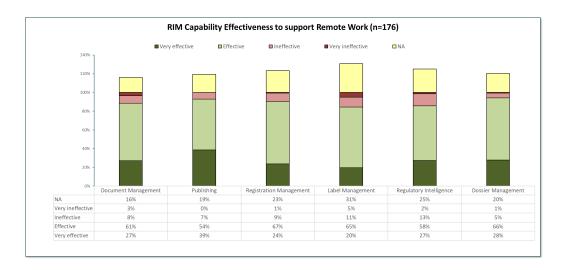


Figure 9: RIM Capability Effectiveness

A cohort of top performing companies emerged from the 2020 World Class RIM benchmark research that achieved global improvement for many key regulatory processes and systems. They have high RIM capability efficiency supported by mature processes and standardized ways of working, more access to real-time information, much higher data quality confidence scores, and have continuous improvement programs. Our benchmark research shows how companies continue to improve their performance, from systems and processes to organizational strategies and RIM capabilities. These improvements have made it possible for the organizational resiliency that this pulse study highlighted.



### STUDY CONCLUSION

The COVID-19 pandemic impact on regulatory organizations is significant. The study results told us a story of stability, resiliency, and the acceleration of organizational agility. Business operations and regulatory activities were not drastically impacted, though an important observation can be made about the workforce and the many changes in the ways of working that *will* impact business operations and regulatory activities in the near future. The next 6-12 months becomes a critical period as companies start to shift out from the Recovery Phase to the Renewal Phase, where fundamental changes materialize to best support the post-pandemic industry.

In the end, study participants shared close to 100 comments focused on benefits from swift changes in organizational behaviors, to technological advancements and on the overall spirit of the regulatory workforce. Shared comments such as one about new interactions with regulators that allowed faster incremental submissions and how 'Regulatory Authorities are discussing how to preserve COVID-19 era efficiencies, post the pandemic", demonstrated the kind of agility and innovation realized in a relatively short amount of time. Transformations will continue to be observed and these learnings and new practices will continue to shape the real, more permanent changes that will come to fruition after the pandemic is over. Ultimately, the comments illustrate how companies and teams stepped up to challenges, big and small, and adapted when needed to. The speed in which they were able to overcome the challenges surprised even them and set the stage to view "what is possible" through a new organizational performance lens!



# White Paper Authors



Katherine Yang-lott is a core member of the Gens & Associates team with over 15 years of experience in the healthcare and pharmaceutical industry leading and managing complex interdisciplinary projects. She worked as a research scientist at Regeneron Pharmaceuticals and The Children's Hospital of Philadelphia before transitioning to consulting work, where she focused on strategy development and continuous improvement projects to support research operations. Katherine has a Master of Science in Organizational Dynamics from the University of Pennsylvania

and a Bachelors of Science in Biochemistry.



Steve Gens is the survey co-founder with the first industry survey conducted in 2007. The COVID-19 Regulatory Impact survey was the 36<sup>th</sup> survey conducted under Steve's leadership. He has over 30 years of business experience with the majority in the biopharmaceutical and healthcare industries. His early career was spent at Johnson and Johnson and then moved into consulting where he managed several healthcare consulting practices for Booz Allen Hamilton and First Consulting Group.

Steve has deep experience in strategy formulation and implementation, organization development and performance, industry benchmarking, information management strategy, and facilitating strategic change. He consults with all sized companies and those that are growing and scaling. He has a Master of Science in Organization Development from American University with distinction for his field work and a BS in Business Computer Science. Steve is a frequent speaker and was named to both the 2017 PharmaVoice 100 entrepreneur category and the 2020 Innovations in Pharmaceutical Development for his contributions to industry.



# GENS AND ASSOCIATES INC. BENCHMARK HISTORY

- 1) 2007 eCTD/Electronic Document Management Survey, (with ILSS)
- 2) 2007 Promotional Material Process Metric
- 3) 2007 Labeling Pulse Survey
- 4) 2008 eCTD and Organizational Implications
- 5) 2008 Labeling Best Practices Survey
- 6) 2008 Regulatory Core Dossier Submission Strategy
- 7) 2009 Electronic Document Management/Collaboration (with ILSS)
- 8) 2009 Industry Engagement
- 9) 2009 Regulatory Submission Management and Production Planning
- 10) 2010 Global Pharmaceutical Regulatory Affiliate Strategy
- 11) 2010 Regulatory Information Management & Health Authority Trends
- 12) 2010 Vendor Market Share Update
- 13) 2011 Collaboration and Content Management Trends (with ILSS)
- 14) 2011 Regulatory Futures
- 15) 2011 Publishing and Dossier Management (organization and outsourcing)
- 16) 2011 Labeling and Promotional Material Organization Strategy
- 17) 2012 Regulatory Information Management Trends
- 18) 2012 Vendor Market Share Update
- 19) 2013 Managing Regulatory Information as a Corporate Asset (n = 37)
- 20) 2013 Regulatory Operations Pulse
- 21) 2013 CTA Pulse
- 22) 2013 EDMS and Digital Archive: One in the same?
- 23) 2014 Regulatory IT Resource Pulse
- 24) 2014 Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)
- 25) 2015 Product Registration Investment Pulse
- 26) 2015 Next Generation Content Management (n = 21)
- 27) 2015 Addressable Market update (solution and services)
- 28) 2015 Legacy Product Outsourcing Pulse Survey
- 29) 2016 Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)
- 30) 2016 Enterprise Content Management Governance Structure Pulse Survey
- 31) 2017 Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)
- 32) 2017 Regulatory Services and Software Addressable Market Analysis Update (top 500)
- 33) 2018 Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)
- 34) 2018 Submission Content Management Capability Change Investment Pulse (n = 10) Top 30
- 35) 2020 World Class RIM: IS Industry at a Performance Tipping Point (n = 70)
- 36) 2020 COVID-19 Regulatory Impact Pulse Survey (n = 183 Individual Response Survey)

