2022 COVID-19 Regulatory Impact Follow-up Survey Whitepaper

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GENS
& ASSOCIATES

Introduction

In the spring of 2022, we followed up on our 2020 Covid-19 Regulatory Impact research to see how regulatory organizations were evolving with the ongoing pandemic. In our original study, conducted 6 months into the pandemic, we learned how companies tapped into their organizational agility and resiliency as they were forced to quickly shift and adapt to a socially distanced and virtual world. It enabled them to rethink "time to change" preconceptions and endure industry wide challenges while making significant RIM investments in global capabilities.

This white paper provides insights from the 2022 follow-up pulse study, explores our viewpoint on how organizations continue evolving throughout the pandemic while highlighting what strategies and implementations were adopted and the shifting norms of company culture and ways of working. We also review the study results alongside our findings from our 2022 World Class Regulatory Information Management (RIM)℠ study to better understand how key trends and priorities are being affected. Key study take-aways we explore in this paper include:

1. Shifts in strategies and priorities in the regulatory organization
2. The impact of pandemic on working relationships with health authorities
3. The evolution of relationships between sponsors and providers
4. Planned vs. actual implementations in the past 12-18 months
5. Evolution of Team Effectiveness with new ways of working

The paper structure is:

- ■ Executive Summary and Study Demographics

- ■ A Continuous New Normal

- ■ Organizational Agility Driven by a Crisis Environment

- ■ Evolving Organizational Dilemmas – How People *Want* to Work

- ■ Study Summary

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

2022 Pulse Survey Research Team

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EXECUTIVE SUMMARY

In the follow-up study, we see both the trends and predictions from the original research evolve and intensify as the pandemic carries on, likely due to the early timing of the previous survey where companies had yet to experience the full impact of the pandemic. Between the gained experiences from tapping into organizational agility, leveraging existing capabilities, and the adopted broad use of technology to collaborate, we want to continue emphasizing the importance for companies to find ways to make these temporary changes more permanent as the pandemic may prove to be an opportunistic time to adopt cultural shifts in support of performance improvement for Regulatory organizations.

The results of the current study reveal how many of the shifting habits are becoming normalized as most people have accepted that covid-era trends will be integrated as part of industry existence moving ahead. The most obvious shifts in norms have to do with how people work. Flexibility and autonomy continue to be highly valued and here to stay as teams have adjusted to the new team dynamics: collaboration with vast cooperation enables the development of more trust in virtual workspaces which allows high quality work to be accomplished and offers better conveniences than the pre-Covid era. Product acceleration is another realization, particularly for companies working on Covid-19 related products since many of those companies were able to deliver on their promises without sacrificing safety or quality of their products. The speed in which some of these vaccines, therapies, and diagnostic tests were developed for market was both unprecedented and remarkable.

Pandemic conditions have accelerated many areas for Regulatory: Interactions with health authorities are becoming more efficient, activities such as inspections and 3rd party provider management are more sophisticated, even the use of technology for virtual inspections is more mature today than compared to just a few years ago. Overall, the past couple of years helped to level the playing field in terms of access and convenience, largely due to the removal of physical constraints (geographical location and even offices and work sites) and inspiring companies to become more innovative. With all the good comes new challenges as well, such as defining work boundaries in the absence of physical ones or developing infrastructures to support technological advancements. The Covid-19 pandemic has had a significant impact on regulatory organizations, pushing organizations to rethink how work gets done and what's possible, and for many organizations, offering a realistic alternative.

SURVEY DEMOGRAPHICS AND DESIGN STRATEGY

The purpose of the follow-up survey is to continue measuring the impact of the pandemic on regulatory organizations and the providers that serve them to learn about emerging norms born from pandemic trends.

For this research, we included a second survey version designed specifically for service and solution providers, alongside the updated survey version for industry. As with the original pulse study, this survey was designed to collect responses from individuals, rather than one response per company, to recognize

the personal experiences and perspectives of survey participants. We processed 173 responses from 60 unique global companies. The general spirit of the question sets is similar amongst both versions. The industry version of the survey consists of 19 questions and the provider version consists of 14 questions, all focusing on the pandemic impact. Survey responses were collected during Spring 2022.

The 60 unique organizations, including those across industry and provider companies, are headquartered worldwide which allows us to capture a true global perspective of the Covid-19 pandemic. The responses across 38 companies in industry (Figure 1) represents large, mid-tier and smaller organizations, where most of the participants are working from North America and Western Europe. There is a balanced distribution of companies with and without Covid-19 related products in the study.
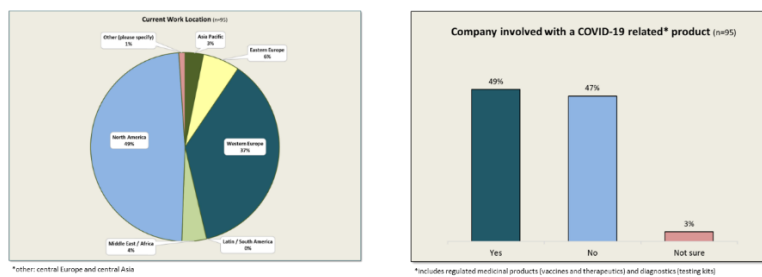

Figure 1: 2022 Pulse Survey Industry Demographics

22 unique Regulatory service and solution provider companies are represented in this study. About half of the responses (51%) are from software providers while the other half (49%) include services, management consultancies, and other commercialization services (Figure 2).
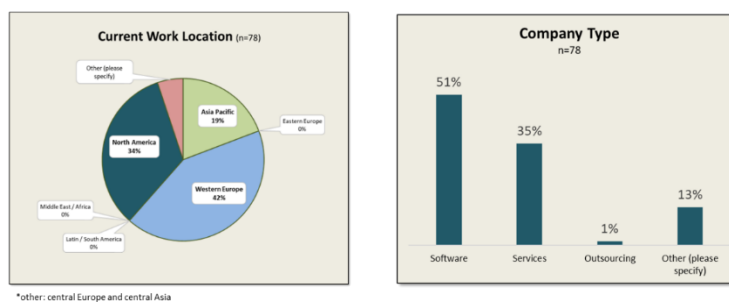

Figure 2: 2022 Pulse Survey Provider Demographics

A CONTINUOUS NEW NORMAL

We developed the model shown in Figure 3 in 2020, hypothesizing how organizations would evolve out of the pandemic. We expected 3 distinct phases: the crisis phase, a recovery phase and finally, a renewal phase. We believe most organizations were just coming out of the crisis mode into recovery at the time of our 2020 survey but have now entered the 'New Normal' as companies are adjusting to a continuous pandemic existence. In 2020, with very little information or experience with any global pandemic, the

general sentiment was that work life, company culture and policies would snap back to pre-pandemic terms once the pandemic ended. However, that viewpoint has now shifted to a wide acceptance that the pre-pandemic existence is in the past; anything moving forward is the new normal.
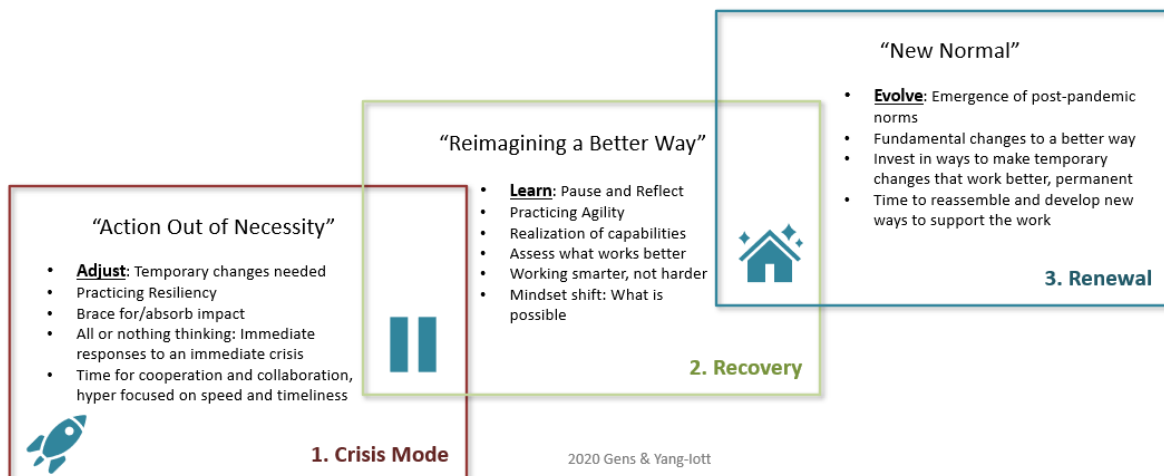

Figure 3: 2020 Organizational Evolution Framework

Study results show that the overall perceptions of organizations' innovation and flexibility have remained steadfast in the past 12-18 months. In general, the biggest adjustments were dealt with in the first few months of Covid-19 to address the immediate challenges and hurdles of global wide shutdowns (home schooling, home officing, etc.). In the 'New Normal' phase, perceptions from the pandemic impact have endured long enough and now people are used to the ways things have been over the last 2½ years.

Generally, the pandemic has had very little impact on priorities in regulatory organizations, as shown in Figure 4. Certain priorities for investment opportunities such as Regulatory System or Advanced Technology investments may have already decided on prior to the pandemic, but the pandemic environment did not significantly disrupt those plans. Digitalization efforts are accelerating the most (43%), along with business process optimization (37%), such as CMC Change and Health Authority commitment and correspondence management which we saw an uptick starting in 2018 before the pandemic. Survey participants also noted the acceleration of organizational change priorities (26%) which aligns with the shift to virtual work and an opportunity to do things a new way. Recruitment and retention during the pandemic have also been highly impacted but the data shows that even if hirings were postponed due to pandemic conditions, most have been reinstated. The challenges with hiring have less to do with organizational stability, budgets, and resources and instead more due to organizational culture and work-life preferences and the workforce themselves, which is evident in the recruitment data where 97% (n = 95) of respondents indicate that the market is very competitive to hire new talent with specific skills and expertise.
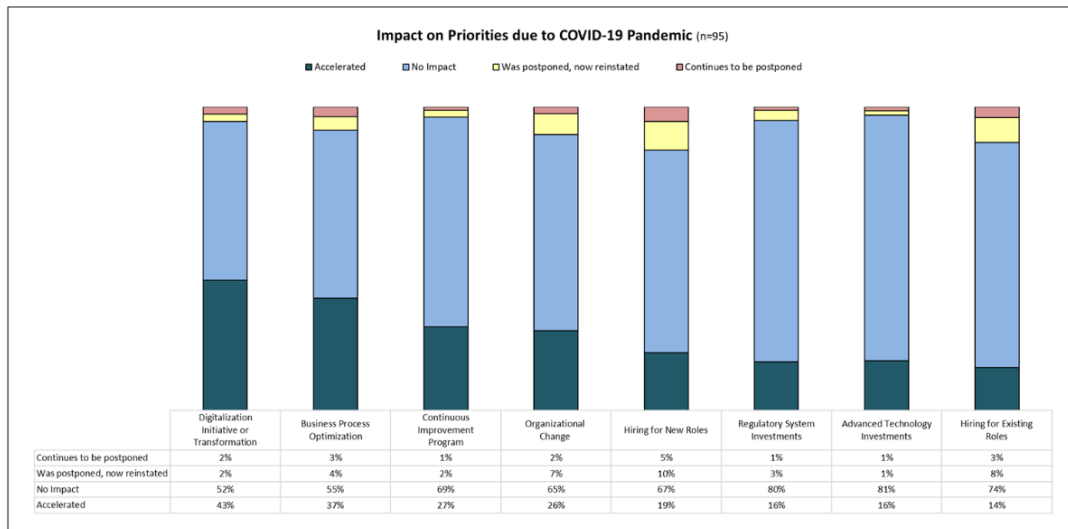
Impact on Priorities due to COVID-19 Pandemic (n=95)

■ Accelerated   □ No Impact   □ Was postponed, now reinstated   ■ Continues to be postponed

	Digitalization Initiative or Transformation	Business Process Optimization	Continuous Improvement Program	Organizational Change	Hiring for New Roles	Regulatory System Investments	Advanced Technology Investments	Hiring for Existing Roles
Continues to be postponed	2%	3%	1%	2%	5%	1%	1%	3%
Was postponed, now reinstated	2%	4%	2%	7%	10%	3%	1%	8%
No Impact	52%	55%	69%	65%	67%	80%	81%	74%
Accelerated	43%	37%	27%	26%	19%	16%	16%	14%

Figure 4: Pandemic Impact on Regulatory Priorities

Team Effectiveness improved immensely over the past 12-18 months and the study finds recurring themes around the growth of team trust, teamwork appreciation and healthy team dynamics. In Figure 5, we show the impact of the pandemic on team effectiveness for both industry and providers, where team effectiveness for all the activities is generally high. Even for activities not optimal in virtual workplaces such as onboarding new team members, managing conflict, and group brainstorming, many have found ways to make it work. These activities will only become easier with time as teams practice and develop their new skills working and collaborating virtually.
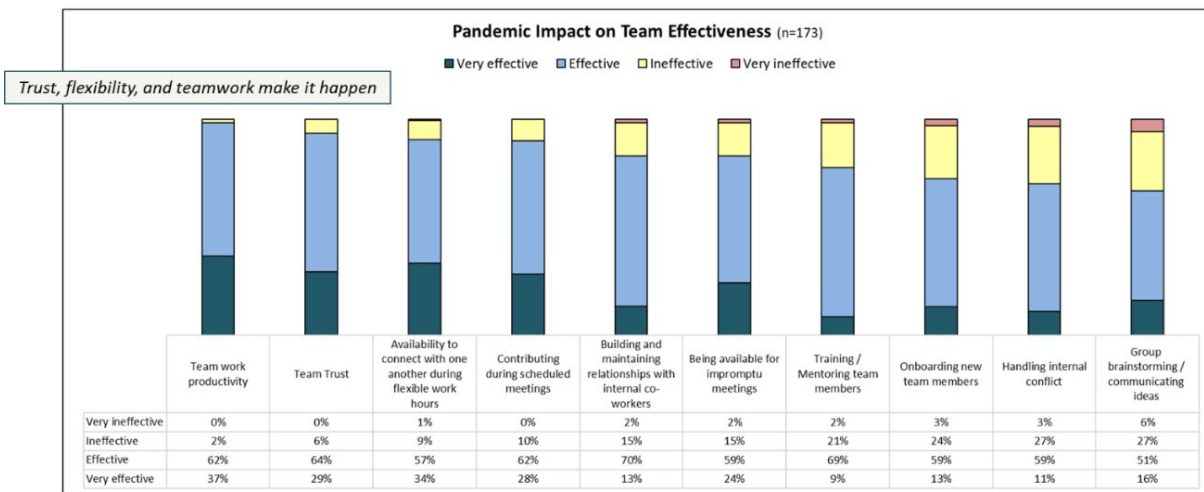
Pandemic Impact on Team Effectiveness (n=173)

■ Very effective   □ Effective   □ Ineffective   ■ Very ineffective

Trust, flexibility, and teamwork make it happen

	Team work productivity	Team Trust	Availability to connect with one another during flexible work hours	Contributing during scheduled meetings	Building and maintaining relationships with internal co-workers	Being available for impromptu meetings	Training / Mentoring team members	Onboarding new team members	Handling internal conflict	Group brainstorming / communicating ideas
Very ineffective	0%	0%	1%	0%	2%	2%	2%	3%	3%	6%
Ineffective	2%	6%	9%	10%	15%	15%	21%	24%	27%	27%
Effective	62%	64%	57%	62%	70%	59%	69%	59%	59%	51%
Very effective	37%	29%	34%	28%	13%	24%	9%	13%	11%	16%

Figure 5: Pandemic Impact on Team Effectiveness

Pandemic norms are now just new norms as companies adopt and develop skills for the current ways of working, gradually shifting industry culture with each new practiced experience.

Organizational Agility Driven by Crisis Environment

One of our key learnings in 2020 was, "In crisis mode, organizations could find quicker paths without sacrificing quality, often challenging the status quo". This time around, the findings are reemphasized with data that shows how a crisis environment pushes companies to change up how they get things done with the same set of standards.

Figure 6 details the findings on product development during the past 12-18 months. The data shows significant difference between companies with and without a Covid-19 related product; companies with a Covid-19 product benefits from process (43% with Covid-19 product vs. 7% without Covid-19 product) and technology (28% with Covid-19 product vs. 2% without Covid-19 product) changes. For companies with a Covid-19 product, the organizations were able to implement new processes (streamlined interactions with Health Authorities), adopt new technologies or leverage their tools (virtual inspection capabilities) while embracing new virtual collaboration efforts (remote teaming) to truly accelerate product development required to deliver critical unmet needs. A small percentage of companies without a Covid-19 product were also able to leverage the environment to progress how they develop new therapies and products, which showcases what is possible in a crisis environment or perhaps even more true, what becomes possible *because* of a crisis environment.
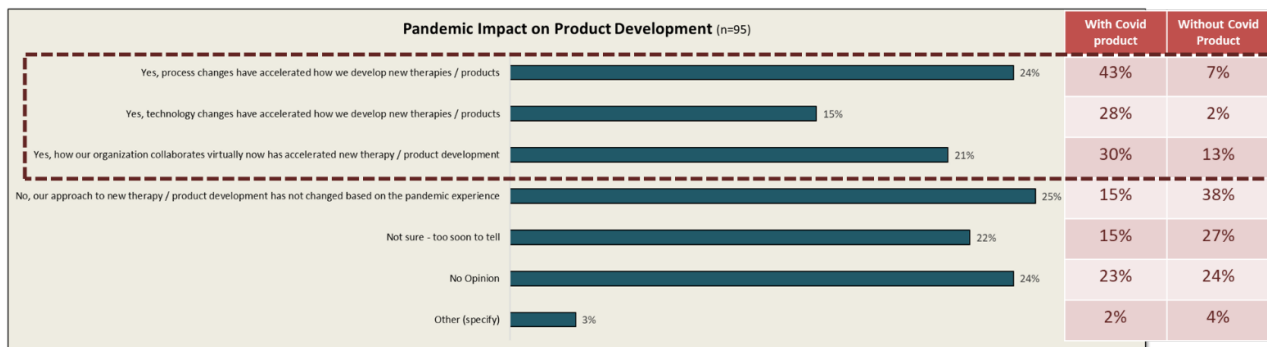

Pandemic Impact on Product Development (n=95)		With Covid product	Without Covid Product
Yes, process changes have accelerated how we develop new therapies / products	24%	43%	7%
Yes, technology changes have accelerated how we develop new therapies / products	15%	28%	2%
Yes, how our organization collaborates virtually now has accelerated new therapy / product development	21%	30%	13%
No, our approach to new therapy / product development has not changed based on the pandemic experience	25%	15%	38%
Not sure - too soon to tell	22%	15%	27%
No Opinion	24%	23%	24%
Other (specify)	3%	2%	4%

Figure 6: Pandemic Impact on Product Development

In our 2022 WCRIM study, we investigate how culture makes a difference by measuring organizational characteristics that support performance improvement such as viewpoints and beliefs about innovation and agility. We find that character and effort could be formulated in a way that aspirational characteristics are grounded in practicality through processes, practices and fostering the 'right' environment. Culture is often shaped by the environment, and we believe the pandemic environment forced a call for action that enabled companies to activate new processes, new ways of thinking and new ways of working to develop products at a speed that is truly unprecedented. Sustaining the changes remains a question about practicality and urgency but companies are proving something to themselves with their achievements throughout the pandemic and those are lessons will pave the way for continuous improvement and progress.

The Covid-19 pulse research also examines the impact of the pandemic on relationships with Health Authorities and finds that they remain strong throughout the pandemic. We included an open text question for participants to share with us how pandemic conditions resulted in innovative or improved Health Authority interactions (n=55). For some companies, interactions with Health Authorities became simpler, quicker, and more effective using virtual platforms and having less reliance on paper often resulted in much faster communications. Quarantine policies also restricted many in person or onsite interactions causing inspection rates to drop dramatically. Participants share how the collective goal to fast-track approvals harmonized the interactions between health authorities and regulatory organizations, the need to approve a product so quickly had never been done before and so everyone involved had to find ways to facilitate the process as efficiently as possible while applying the same quality and safety standards as always.

Regulatory operations and performance also remained steady over the past 12-18 months. RIM Capability Effectiveness (processes and tools) ranks high across the board: Publishing, Dossier Management, Document Management, Registration Management, Label Management and Regulatory Intelligence, are all above 87% for effectiveness, however, our 2022 World Class RIM study (n = 76 companies) cites lower "efficiency" in each of these 6 areas (79%, 48%, 70%, 59%, 57%, 48% respectively) which makes us question how new ways of working and team dynamics are impacting the respective processes and use of tools. Technology can be used in a way to ensure capability effectiveness (does it get done or not?) but efficiency (how much effort is required and how fast?) is more often dependent on coordination and collaboration.

In terms of the shifts in requirements and risks, Figure 7 represents the pandemic impact on Regulatory activities. The Top 3 regulatory activities requiring more work are the same from 2020 but have increased even more so in 2022: Supply chain disruptions (60% → 68%), Customs/Borders (57% → 79%), Virtual Clinical trials (55% → 63%). We believe these increases are related to the timing of the 2020 study: at the time, companies had not yet felt the major impacts of the pandemic. Even so, the data shows that the pandemic ultimately created much more work for Regulatory organizations.
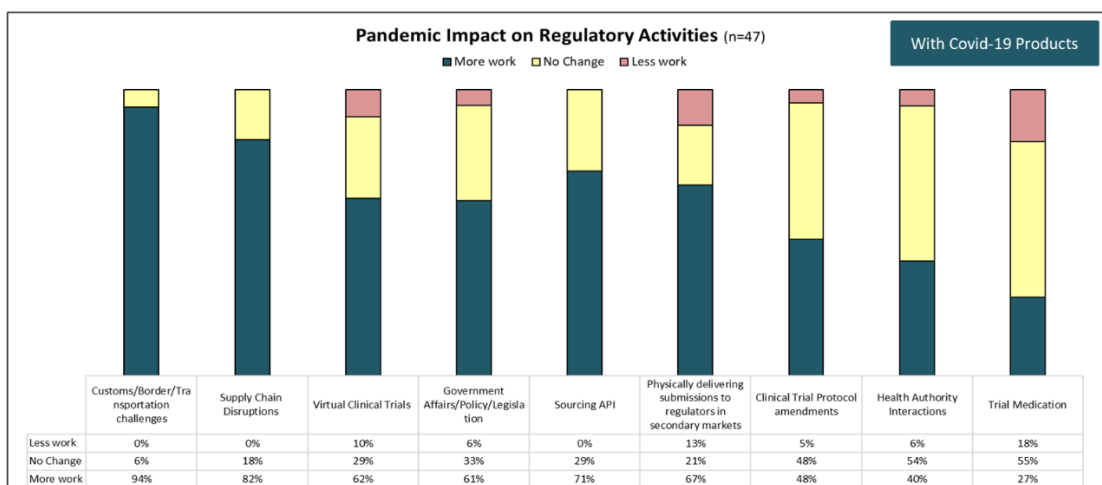

	Customs/Border/Transportation challenges	Supply Chain Disruptions	Virtual Clinical Trials	Government Affairs/Policy/Legislation	Sourcing API	Physically delivering submissions to regulators in secondary markets	Clinical Trial Protocol amendments	Health Authority Interactions	Trial Medication
Less work	0%	0%	10%	6%	0%	13%	5%	6%	18%
No Change	6%	18%	29%	33%	29%	21%	48%	54%	55%
More work	94%	82%	62%	61%	71%	67%	48%	40%	27%

Figure 7: Pandemic Impact on Regulatory Activities

There has been much focus on supply chain management during the pandemic as companies consider all the new risks made evident by pandemic conditions such as border shutdowns, customs challenges, and extensive drug shortages. Companies with Covid-19 products faced additional challenges since they were tasked to deliver large quantities of product across the globe on very short timelines. This data is significant because organizations found a path to do the nearly impossible; so, what implications could that have on the future of regulatory work? There are distinct possibilities that the acceleration of advanced technology and new processes to support and accommodate these areas of increased regulatory work will ultimately reshape the landscape.

More Work Required	Custom/ Border/ Transportation challenges	Supply Chain Disruptions	Virtual Clinical Trials	GA / Policy/ Legislation	Sourcing API	Physically delivering submissions to regulators in 2nd markets	Clinical Trial Protocol amendments	HA Interactions	Trial Medication
With Covid-19 Product	94%	82%	62%	61%	71%	67%	48%	40%	27%
Without Covid-19 Product	62%	53%	64%	40%	11%	26%	38%	27%	17%

Table 1: More Work Requirements for Companies with Covid-19 Product vs. without Covid-19 Products

Table 1 above shows the distinct differences of the pandemic impact on regulatory activities between companies with a Covid-19 related product compared to those without. Respondents from companies with a Covid-19 product report that 'more work' is required for all the regulatory activities tested in the survey at a higher rate than companies that did not have Covid-19 products; this is especially true for sourcing API (71% vs. 11% respectively) and physically delivering submissions to regulators in secondary markets (67% vs. 26% respectively) where the amount of extra work was significantly higher. Again, this is likely due to immediate global reach and short timelines for delivery of these critical products.

Evolving Organizational Dilemmas – How People Want to Work

In 2020, we observed the 'organizational dilemma' as a remote work debate (Figure 8). While people enjoyed the flexibilities of remote work, they also expected many companies would enforce a 'back to the office' norm when the pandemic was over. The conflict was that many people felt they were able to do their jobs just as effectively remotely and preferred the benefits of remote work, *but* their companies had long-standing and deeply embedded in-person cultures that valued face-to-face interactions.
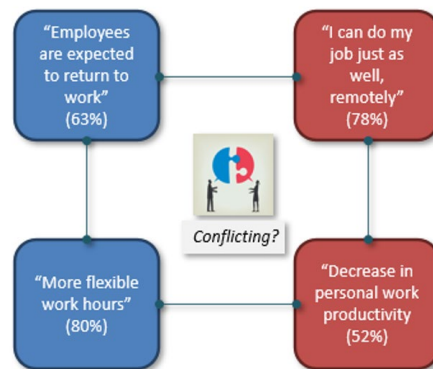
Figure 8: Organizational Dilemmas from 2020

In 2022, the shift in favor of remote work and expectations with it are evident (Figure 9). From the survey responses, the workforce values the benefits in flexibility while also recognizing the benefits for their organization such as strong workforce expectations and more access for talent. Only 33% of participants say there is an expectation for them to return to offices vs. 63% in 2020, which suggests changes to company policy about work conditions and could indicate significant changes in attitude about one's organizational culture, especially given the responses in 2020 about in-person culture being part of their company's DNA. We believe this shift invites other deeply imbedded cultural and organizational practices to be adjusted for current times, such as meeting culture, client interactions, and trainings. In the study, we find that 76% of engagements with service and solution providers are not yet in person but most organizations *and* providers stated they were finding ways to optimize the relationship with one another. Traditionally, being able to meet in person is a critical competitive advantage for providers to gain new clients but perhaps the pandemic proves to also be an opportunity to innovate client interactions. Trainings and onboardings are another area where in-person interactions are highly valued, paused during quarantine, but still accomplished over the past few years. These provisional practices, especially ones proving to be effective, could replace their pre-pandemic counterparts.
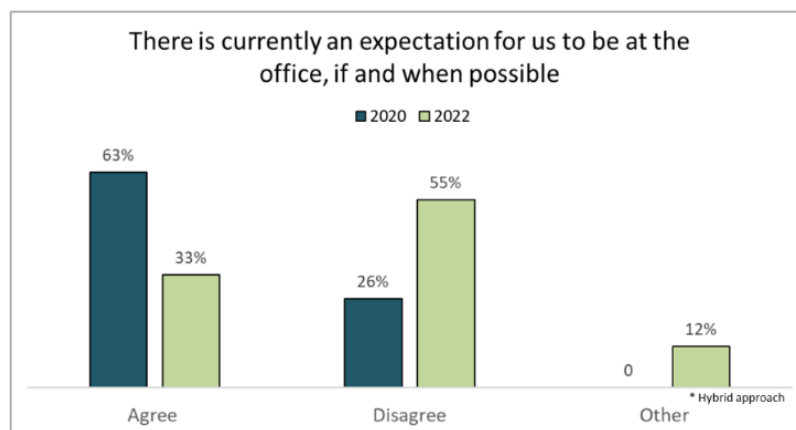

Figure 9: 2022 In Person Workplace Expectations

The question about remote work effectiveness is shifting from 'am I effective at my job working remotely?' (98% answered yes) to 'what are the unintended consequences of being effective at my job working remotely?'. With the remote work debate diminishing, we see the emerging dilemma focused on challenges with defining individual boundaries in a virtual work environment (Figure 10). The study data reveals that people are having difficulties disconnecting from work because their home life exists within the physical boundaries of their work life, leading to the feeling of being constantly 'on call' for the job. When asked about their abilities to disconnect from work and balance work life/personal life, participants (n = 94) answered 'Decreased' 57% and 40% respectively, over the past 12 months. The change of frame for the new organizational dilemma overrides the original company-centric cultural dilemma and puts the focus on individual perspectives and experiences. One participant shared, "Flexible work hours = Everyone is available all the time!". This new dilemma has a significant impact on how people feel about the way they want to work and could do work. While some have adjusted and negotiated what they personally need, many still need help and practice with how to manage their day to day. We see the global conversations about the 'Great Resignation' being driven by this dilemma as workers reevaluate what they are giving up vs. gaining from their professional lives.

1. Work Flexibility
2. Continued Remote Work
3. Personal Productivity
4. Team Effectiveness

1. Ability to disconnect from work
2. Building and maintaining relationships
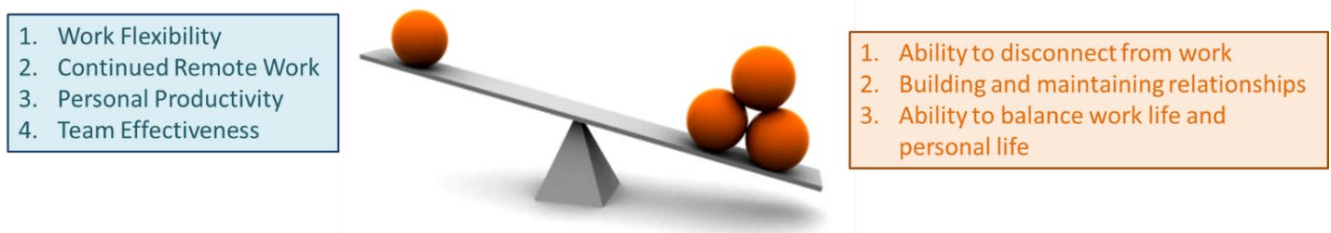3. Ability to balance work life and personal life

Figure 10: 2022 Organizational Dilemmas

This data is also significant for retention since both employees and competitors realize they can work and recruit from anywhere, further signaling an increase of control and power for the workforce and away from enterprise-driven enforcement of traditional organizational policies. In our survey, we ask participants about talent recruitment and retention at their companies during the pandemic. 65% of responses (n = 95) agreed that retention has been a challenge during the pandemic, which is surprising because historically, people tend to stay in their companies and positions during times of instability or unpredictability. 82% (n = 95) stated that recruitment is also challenging during this time, where many shared that new talent had higher demands for flexibility and virtual work conditions. The pandemic has accelerated the normalization of remote work erasing boundaries for where people can work, allowing people to go where they want which has a very significant effect on company culture on a global scale as organizations shift their ways of thinking about workforce expectations and development.

With time, these changing organizational dilemmas will acclimate to the norms of an adjusting environment; socialization and in-person contact will remain a big part of 'doing' work, but what that looks like will be very different from pre-pandemic times. The shift in favor of remote work is resetting many expectations about how work gets done and in turn, are forcing companies to change up how they

define both the workplace and a workday. What remains to be seen is just how much will the pandemic shake up traditional workplace dynamics.

STUDY CONCLUSION

Emerging norms born from pandemic trends can be seen on a global scale, not just in Regulatory organizations. The pandemic set off a chain reaction by creating a crisis environment activating the call for action to drive changes in how things are usually done. In doing so, companies were able to prove their own capabilities and experience a realistic alternative. The 'new' way does not automatically mean the 'better' way, but neither is the 'old' way. Instead, what the pandemic offers is the chance to do something different, learn and relearn from the experience, and have the option of choosing the best path forward for the organization.

2 ½ years into the pandemic, regulatory organizations are adjusting well to new challenges such as engaging in virtual environments with service and solution providers, evolving working relationships with Health Authorities, improving team dynamics across a global workforce, and adopting new processes, technology, and tools to improve RIM capabilities and support regulatory activities. The Covid-19 pandemic has pulled the curtain back on the view of what is possible, and the future looks bright.

White Paper Author

Katherine Yang-Iott is a core member of the Gens and Associates team with over 18 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 organizational consulting work, focusing on strategy development, change management and continuous improvement projects to support team development and business operations. Katherine has a Master of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelor of Science in Biochemistry from Virginia Tech.

GENS AND ASSOCIATES INC. RECENT BENCHMARK HISTORY

1) **2013 *Managing Regulatory Information as a Corporate Asset (n = 37)***
2) 2013 *Regulatory Operations Pulse*
3) 2013 *CTA Pulse*
4) 2013 *EDMS and Digital Archive: One in the same?*
5) 2014 *Regulatory IT Resource Pulse*
6) **2014 *Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)***
7) 2015 *Product Registration Investment Pulse*
8) 2015 *Next Generation Content Management (n = 21)*
9) 2015 *Addressable Market update (solution and services)*
10) 2015 *Legacy Product Outsourcing Pulse Survey*
11) **2016 *Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)***
12) 2016 *Enterprise Content Management Governance Structure Pulse Survey*
13) 2017 *Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)*
14) 2017 *Regulatory Services and Software Addressable Market Analysis Update (top 500)*
15) **2018 *Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)***
16) 2018 *Submission Content Management Capability Change Investment Pulse (n = 10) – Top 30*
17) **2020 *World Class RIM: IS Industry at a Performance Tipping Point (n = 70)***
18) 2020 *COVID-19 Regulatory Impact Pulse Survey (n = 245) – Individual Response Survey*
19) 2021 *Structure Content Authoring (n = 25) Pulse Survey*
20) 2021 *IDMP/SPOR Architecture Pulse Survey and Software Provider Review*
21) **2022 *World Class RIM: Accelerating Business Value (n = 76)***