2023 Optimizing Affiliate Engagement to Improve Performance of Key Regulatory Activities

Study Whitepaper

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Introduction

The 2023 Optimizing Affiliate Engagement Regulatory Survey marks our 42nd Industry study and was designed to capture the "voice of the affiliate". It examines the current affiliate status and explores performance improvement opportunities in how critical regulatory information is managed and utilized to support key regulatory activities at the local affiliate level.

Improving affiliate engagement, referred to as going the 'last mile', was one of four key insights from our 2022 World Class Regulatory Information Management (RIM) study of 76 companies where we determined most participants were at the later stages of their RIM modernization cycle and had not reached the goal of global RIM adoption with the associated business benefits.

This study reviews many dimensions of the affiliate work environment including regulatory activity efficiency, effectiveness of global systems, and confidence in regulatory data quality levels. In our opinion, improving global regulatory performance requires uniform usage of global systems and processes, addressing the complexity of unique local affiliate requirements, higher affiliate inclusion in global system and process design, and better training for diverse roles at the affiliate level.

This paper provides insights from the participating 320 affiliates representing 94 countries across 20 organizations (both biopharmaceutical and medtech). Key study findings we explore include:

1) What global systems and local tools do affiliates use and how much time are they spending weekly on managing information in nine key regulatory activities?
2) Affiliate's perspective on process efficiencies, confidence in data quality levels, system health and effectiveness, affiliate satisfaction with system and process design, support and training, and the overall impact of global technology and system investments.
3) Understanding key barriers and opportunities for improved global performance.

The paper structure is:

- Executive Summary
- Survey Design and Demographics
- Industry Status and Challenges
- Considering the Affiliate Perspective and Experience
- Improvement Opportunities
- Study Summary – The Path to Global Excellence

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


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Executive Summary

Life Science companies are making substantial investments to change how key regulatory information is managed and leveraged on a global scale. One critical dimension is improving how affiliates work and how headquarters interact, collaborate, and support those affiliates.

There has been significant investment in technology and process optimization, but this does not quite match the expected benefits to date where only 68% of affiliates report that technology and process implementations by the central regulatory organization have "improved" or "somewhat improved" efficiency. We estimate $1.9 billion has been spent over the past 5 years on RIM Modernization (according to the 2022 Gens & Associates Total Addressable Market Analysis of Regulatory System Spend), yet 32% of affiliate participants do not agree these types of investments are paying off to date.

The study data shows that although there is progress in terms of affiliates spending more time in global regulatory systems, an increase from 13% in 2015 to 48% in our current study, they continue to spend a significant amount of time in local and regional tools (e.g., spreadsheets, teamshare, email folders) to manage all regulatory requirements and processes. This highlights the type of daily complexity at the affiliate level. The research also reveals the desire for more engagement with central headquarters and teams where over 50% of affiliates want to be more involved with activities such as resource planning, process design, and system enhancement decisions (governance). Optimizing affiliate engagement is a key priority for all companies.

Although the study results provide a general overview of where industry is at with affiliates at a point in time (May-July 2023), we find the details of the results vary from company to company. For companies that participated in the study, their individual affiliate cohort results provide a more accurate portrayal of their affiliate work environment and experience. While this paper reviews the results for the full study, each participating company received two sets of results: full study results and results of just their own affiliate cohort.

Ultimately the path to global excellence requires implementing and optimizing end-to-end processes, improving system capabilities and usability, increasing data quality levels, and utilizing process automation to improve efficiency and effectiveness. These actions pave the path for excellence which improves regulatory strategy, time to Health Authority submission, and existing marketed product compliance.

Survey Design and Demographics

Several survey design sessions were held in the spring of 2023 to refine the overall study design with the support of Gens & Associates membership and several participating companies. We asked each participating company to nominate between 8 - 25 affiliate representatives (based on company size) to enroll in the study. We accepted one completed survey for each affiliate from May through July of 2023 and required a "consensus response".

Figure 1 represents the distribution of large, mid-tier, and small organizations who participated in the survey. We also assigned each country or group into one of four macro regions based on the United Nations *Standard Country or Area Codes for Statistical Use (M49)*[1]: Middle East and Africa, Americas, Europe, and Asia and Asia Pacific. For the study, an affiliate is defined as a team or an individual at a specific country office. For medical device participants it may also include a design center.

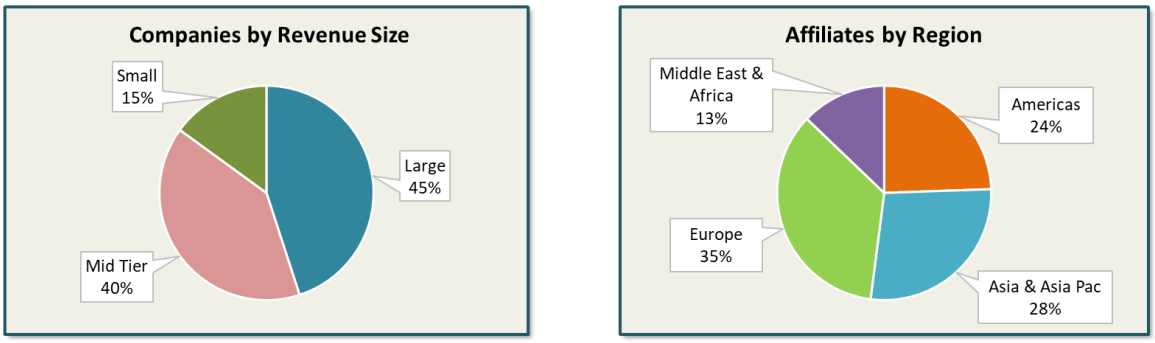


Figure 1: 2023 Affiliate Engagement Study Demographics

The survey consists of 26 questions divided into four sections:

A. Demographics
B. Affiliate Perspective on Managing Regulatory Information
C. Affiliate Perspective on Improving Efficiency of Key Regulatory Activities and Processes
D. Affiliate Perspective on Overall Engagement with Headquarters

The nine target regulatory activities measured and assessed in the survey were:

1. Submission Forecast and Planning
2. Submission Content Management
3. Product Registration Management
4. Health Authority Commitment Management
5. Heath Authority Interaction Management
6. Submission Archiving
7. Local Label Management
8. Regulatory Intelligence Management
9. Promotional Material

[1] https://unstats.un.org/unsd/methodology/m49/

Industry Status and Challenges

The participant performance comparison scatter graph (Figure 2) provides an overall score for each participating company based on 27 data points. It is calculated by the efficiency of the nine regulatory activities, global RIM system effectiveness and usability, and data quality confidence levels.

The participant company names are blinded and shown as "Cx". "x" is randomly assigned, and the "n" number indicates the number of affiliate responses for that corresponding company. The position of each diamond represents the average score of all affiliate responses for that participating company.

The peer comparison shows most companies have similar performance levels and are grouped closely with the tier average (orange line) but are much lower than the strong performance level (green line which is based on our World Class RIM methodology). This tells us that there are many opportunities to improve for all companies, however the analysis for each individual company showed different strengths and improvement opportunities.

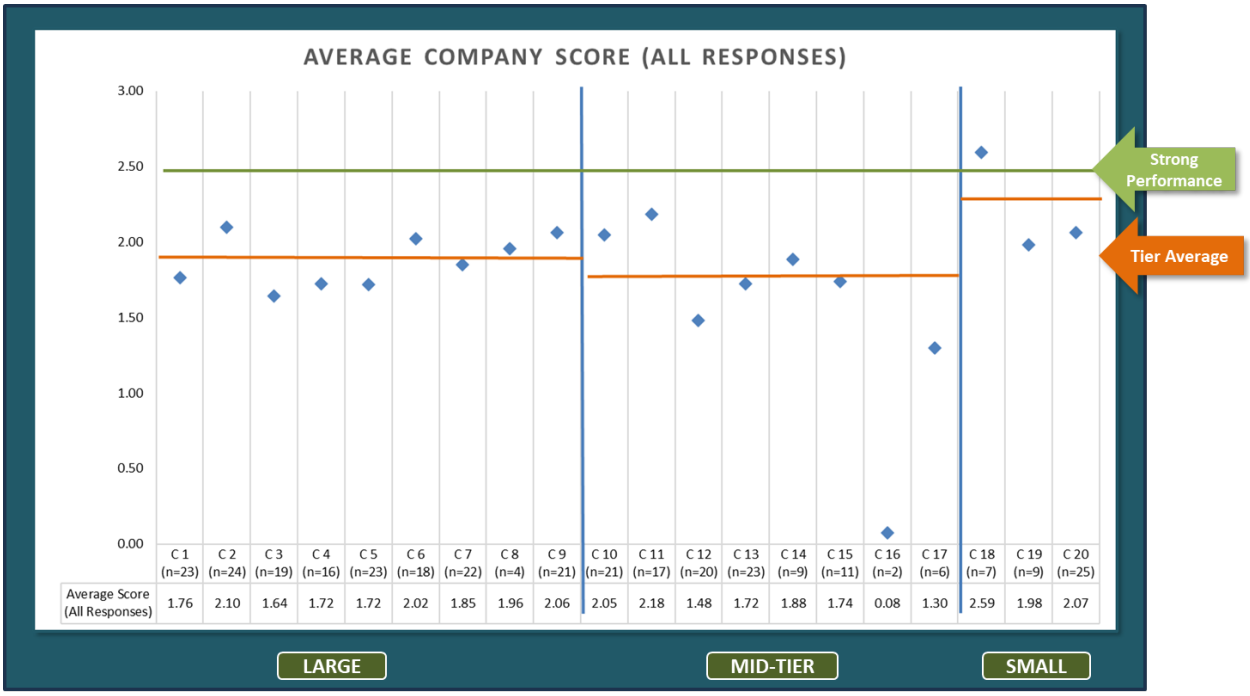


Figure 2: Company Performance Peer Comparison

The complexity of managing regulatory information with unique local country requirements can make it difficult for companies to consolidate and rely solely on one global system. We found that affiliates are using global systems more often, an increase from 13% in 2015 (of the average reported hours per week affiliates spend in global systems) to 48% in 2023. However, the other 52% of time was spent in local tools such as Excel, SharePoint, email folders, and local systems to manage key regulatory activities. Whether the continued reliance on local tools is due to comfort or necessity (i.e., global systems do not meet their full local requirement), the existing dilemma is whether or not it is possible to find a

comprehensive solution to fulfill 100% of unique local requirements. Furthermore, the regulatory workforce, which sometimes can just be a single person, at many small local affiliates must perform multiple roles, which may include quality, safety, or other tasks in addition to their regulatory responsibilities. This would require yet another set of global systems and local tracking tools to satisfy those jobs.

Figure 3 summarizes the global system vs. local / regional tools usage for all companies. Content related activities such as Submission Content Management, Ad Promo, and Submission Archiving Management have the highest usage of global systems, while Health Authority Commitments and Interactions have the lowest global system utilization which carries risks including compliance and potential incomplete information to inform strategy. Most organizations are still developing a global capability for Regulatory Intelligence Management due to limited offerings from solution providers, so the low usage of global systems in that category is unsurprising.

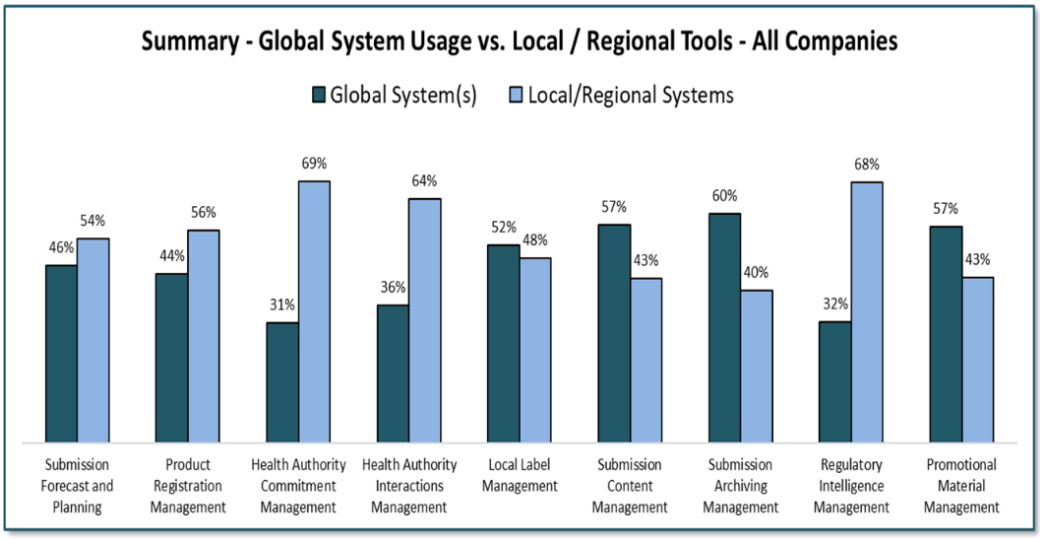


Figure 3: Time spent in systems and tools – Global vs. Local summary for all companies.

In addition to the full study results, each individual participating company receives their affiliate cohort report with a breakdown of affiliate time in global systems and local tools compared to peers for the nine key regulatory activities. Figure 4 is an example of the Product Registration activity for one of the study participants. It follows a pattern of high local tool utilization (50% of the time) versus 50% in the global system even though 100% of the affiliates utilized the global RIM system. This is likely due to partial tracking of unique regulatory requirements not available in the global system and also having to manage registration data in multiple systems (e.g., regulatory, ERP, safety).

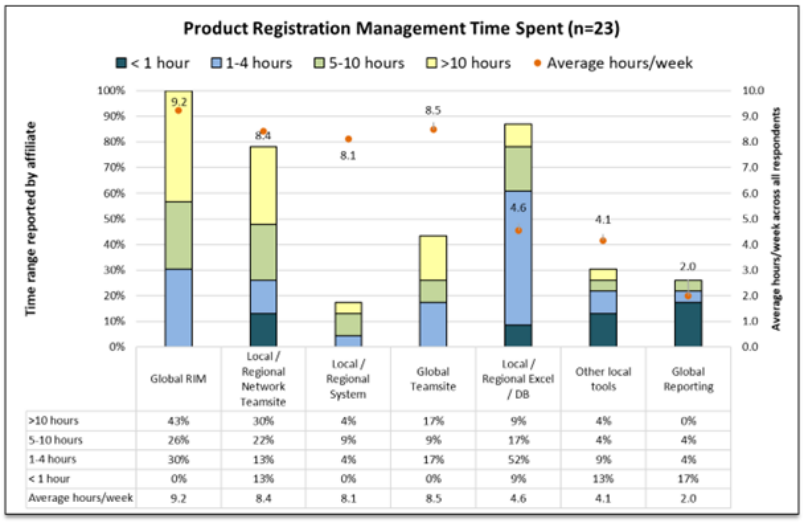


Figure 4: Time in Tools for Product Registration Management

Another area making progress in the right direction is the amount of time during an average week affiliate teams spend researching and responding to regional or central regulatory requests (e.g., phone, email, text, instant message) to provide, verify, or understand regulatory data maintained in the global RIM system. Over half of affiliate offices (52%) spent 10 hours or less during the average week which is a significant decrease compared to our historical data where 67% of affiliates spent 11 hours or more in 2013-2015. We believe this suggests global system usage improves information sharing, thus reducing the time to verify information.

Considering the Affiliate Perspective and Experience

Understanding the affiliates' perspective on process efficiencies of key regulatory activities, data quality levels in key systems, and what they think about the impact of global RIM technology and system investments can reveal opportunities for strengthening the interactions between headquarters and affiliates. Table 1 below summarizes affiliate responses from all companies for a variety of performance dimensions such as average efficiencies of key regulatory activities, % of high data quality confidence, % of affiliates with a positive view of current engagement with headquarters, etc. When we sort the data by size of affiliate, we find smaller affiliates (those having 1-4 or 5-9 team members) fared slightly better than larger affiliates (those with 10 or more team members). We believe this is driven by varying levels of complexity as team size increases. We also examined the data sorted by the 4 macro regions but found no significant difference in overall performance between the regions. In general, local affiliate and headquarters offices have similar experiences for efficiency and data quality levels which suggest alignment of RIM program performance levels.

Survey Question	Performance Dimension	All Participants (n = 320)	Number of Individuals (Employee and Contractor) who perform Regulatory Activities			
			1 – 4 (n = 138)	5 – 9 (n = 74)	10 – 15 (n = 51)	16+ (n = 57)
7 – 15	% of time in working in global systems (remainder in local tools)	46%	42%	44%	49%	51%
18	Average efficiency % of the 9 regulatory activities	72%	76%	72%	67%	64%
19	% who have a positive overall system usability view	65%	67%	69%	58%	61%
20	% of having "High" Data Quality Confidence	41%	47%	37%	36%	37%
21	% who view the primary global RIM system as effective	66%	70%	67%	62%	62%
24	% who have a positive view of central / affiliate engagement	68%	71%	72%	64%	62%
25	% who believe central process and system implementation have improved overall efficiency	68%	63%	75%	67%	70%

Table 1: Performance Dimensions by size of Affiliate
(Green = highest % for corresponding performance dimension)

When affiliates were asked about their involvement with activities related to implementation and ongoing improvement of regulatory systems and processes, the results show a large percentage of affiliates are currently 'not involved but would like to be' (Figure 5). The results show most affiliates expressed the desire to be more involved in the earlier phase activities such as process design, resource planning, and change management vs. later phases where decisions have been made with activities such as configuration, training, and testing. During our study debriefs, many affiliate participants expressed the challenge of not having enough resources to work on the opportunities for improvement that headquarters prioritized so being able to provide input for resource planning during those initial conversations would be a good start.

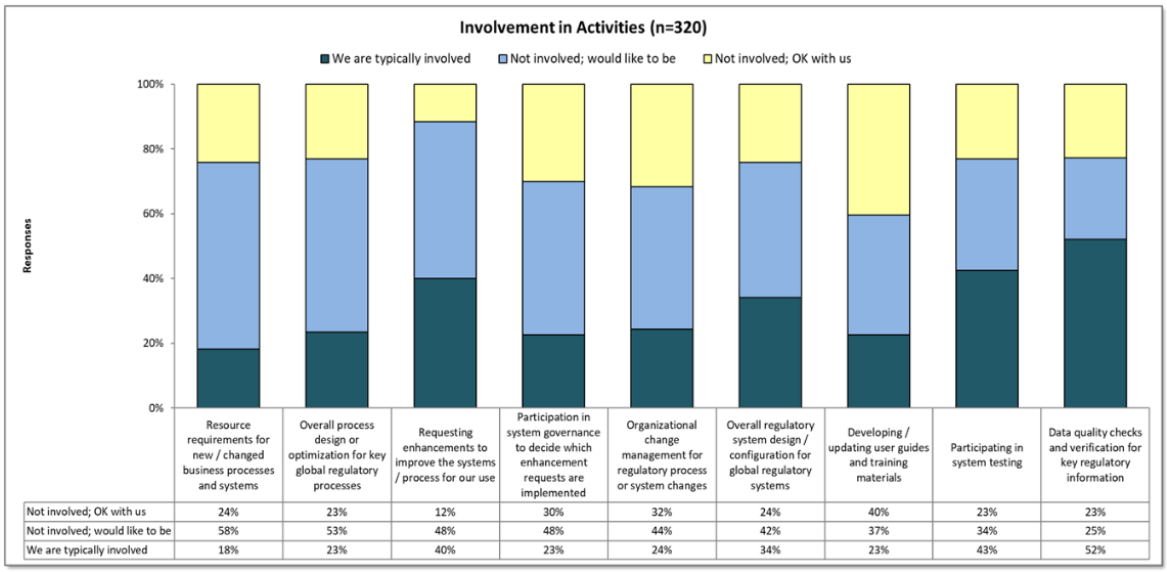
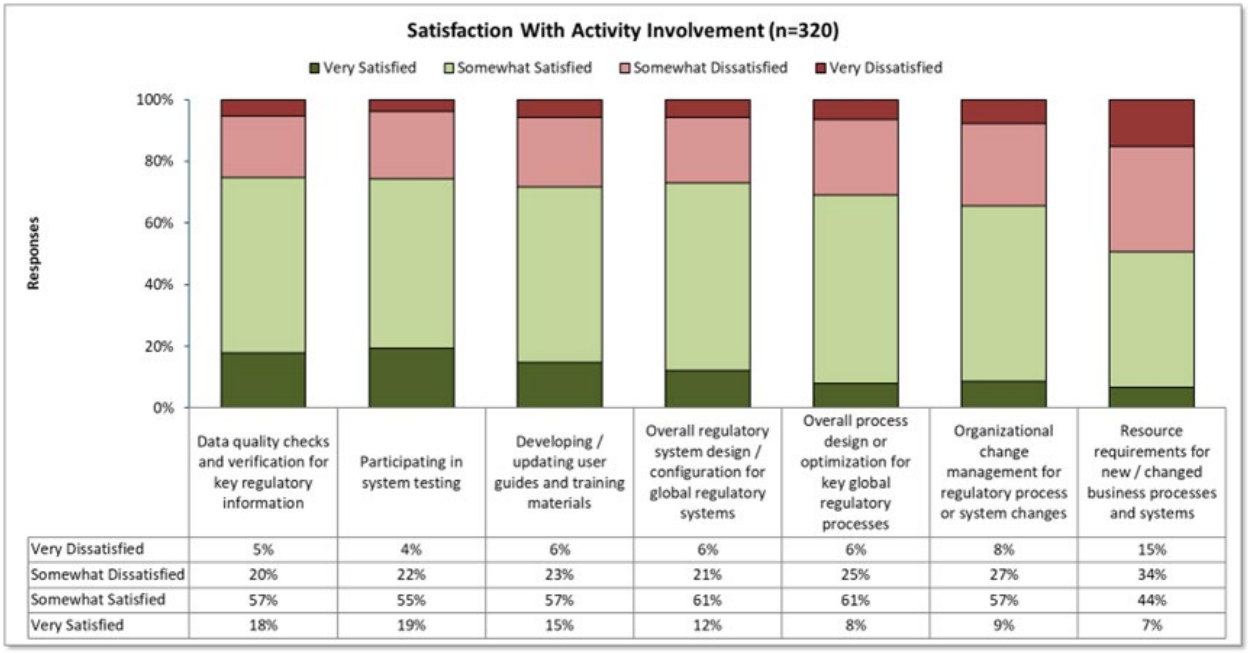


Figure 5: Affiliate Involvement with Regulatory-related activities in their company

The survey also asked affiliates if they were satisfied with the overall results from their team's involvement with the corresponding activities (Figure 6). The majority response for every category measured was a 'somewhat satisfied' response (light green bars in Figure 6) rather than a 'very satisfied' response, which we viewed as a call to action for headquarters to improve the quality of these interactions and engagement for better outputs. In our opinion, affiliates want greater collaboration and partnership where they can provide valuable feedback and knowledge, share their local expertise, and have their ideas and input be considered and used for important process and system decisions impacting work at their local level.



	Data quality checks and verification for key regulatory information	Participating in system testing	Developing / updating user guides and training materials	Overall regulatory system design / configuration for global regulatory systems	Overall process design or optimization for key global regulatory processes	Organizational change management for regulatory process or system changes	Resource requirements for new / changed business processes and systems
Very Dissatisfied	5%	4%	6%	6%	6%	8%	15%
Somewhat Dissatisfied	20%	22%	23%	21%	25%	27%	34%
Somewhat Satisfied	57%	55%	57%	61%	61%	57%	44%
Very Satisfied	18%	19%	15%	12%	8%	9%	7%

Figure 6: Satisfaction with affiliate Involvement with Regulatory-related activities

IMPROVEMENT OPPORTUNITIES

While progress is being made, there are still many opportunities for both industry (affiliates and headquarters) and the software providers to strengthen global performance.

In our study report we identified the following opportunities for industry:

1) Create or optimize a regional structure to improve representation of countries in process optimization and system governance
    a. Formalize advocacy for global system improvements such as usability (most local users are "infrequent users"), tailored training (more relevant, make it easy to consume, accessible and timely), and identifying unique required local information
    b. Use feedback loops - ensure the local countries that regions represent are informed of decisions and the rationale for the decisions

2) Manage 'truly local' information responsibly (i.e., apply consistent processes, standards, and governance)
3) Expand communication channels with change management mechanisms to support affiliate involvement and continuous improvement (not just on a project basis)
4) Create incentives for affiliates to decommission local systems / tools
5) Improve or incorporate regional data quality reporting
6) Provide automation capabilities to improve efficiency, effectiveness, and data quality

Software provider opportunities were also identified:

1. Deepen knowledge of "a day in the life of a local affiliate" to better design solutions (as opposed to HQ view of what the local affiliate needs)
2. Integration of Reg Intelligence content (requirements) into workflows and search (more for Med Device)
3. Advanced Automation – e.g. data capture from health authority correspondence, integration of generative AI to assist search
4. Real-Time Business Metrics – Volume, Quality, and Cycle Time Metrics to provide "real-time" KPI reporting
5. Improve Capabilities – to support local information management requirements – Reduce reliance of local and regional systems / tools, improve entry and information consumption for infrequent users or those who only utilize a few features of the global system

The final question in the survey asked each affiliate: *What one thing would your team want improved about how your company manages regulatory information that would improve the performance of your affiliate team*? Out of the 320 participating affiliates, 266 responded with the overarching theme of "simplification and connected systems". The top 5 themes from the comments are summarized in the graph below (Figure 7) support this conclusion. Some of these requests require significant work (e.g., integrated systems, system functionality) while many are tactical and can be accomplished in the near term (e.g., tailored training, role clarity, process optimization).

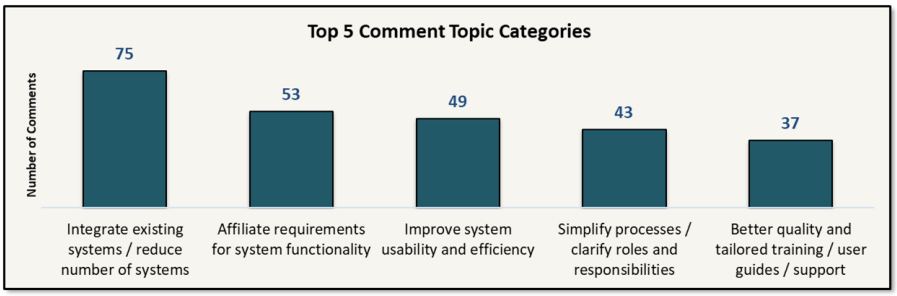


Figure 7: Affiliate comments for improving performance

Study Conclusion – Inclusion Leads the Way for Optimized Affiliate Engagement

The role of the local regulatory affiliate plays an integral part in any life science company, therefore understanding the uniqueness of what their jobs require is best viewed and assessed from their perspective. The nuances of their jobs are about managing local requirements such as maintaining effective work relationships with local health authorities and managing evolving regulatory requirements in their specific countries. To be successful in their roles requires collaboration with headquarters to set forth processes and procedures that make sense for their location, such as understanding the size of the affiliate, how many hats does the affiliate wear, what kind of training or learning must the affiliate take on and identifying any capability oversights or gaps (system, tools, processes, and skills). It is not easy for companies to streamline processes and reduce complexity across tens or hundreds of affiliate offices, however, it helps to start the conversation. This study was designed to capture the voice of those affiliates for each participating company. In return, the central regulatory headquarters can examine their responses and initiate a plan for the last mile as companies continue their journey towards having an effective and efficient global RIM capability.

What we learned from the study is that everyone has a part in paving the path, from global headquarters to local affiliates, and even the solution providers. This group effort, achieved through optimizing affiliate engagement, is the key to going that ‘last mile’.

White Paper Author

Katherine Yang-Iott is a core member of the Gens & Associates team with 20 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.

Steve Gens is the Managing Partner and Survey founder of Gens & Associates. He has over 30 years of business experience, with the majority of it in the biopharmaceutical and healthcare industries. His early career was spent at Johnson & Johnson, after which he moved into the area of consulting by managing 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, and facilitation of strategic change. He consults with all sizes of life sciences companies, especially those that are growing and scaling. Steve has a Master of Science in Organization Development from American University, with distinction for his fieldwork, and a Bachelor of Science in business computer science from Lock Haven University. He is a frequent speaker at conferences and workshops and was named to the 2017 PharmaVoice 100 entrepreneur category for his contributions to industry.

Kelly Hnat of K2 Consulting (supporting G&A research since 2019) has over 25 years' experience in the biopharmaceutical industry leading both IT and RIM/Reg Ops organizations in several companies. She has led implementation of large-scale global systems and processes, and is passionate about the potential for pharma companies to raise the bar on productivity and compliance through process-focused management of critical data. She is a globally recognized expert in IDMP and has served as a key SME supporting the EU implementation of IDMP as a member of the EMA SPOR Task Force, the SPOR PMS subteam, and the SPOR EU Implementation Guide Focus Groups. Additionally, Kelly serves on the Board of Directors for IRISS Forum, a global nonprofit organization that brings together industry, vendors, and health authorities to address topics related to submission standards. Her company, K2 Consulting, is a specialty firm focused on Regulatory Affairs and an alliance partner of Gens & Associates.

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