2023 Highlights and 2024 Projections

Steve Gens, Managing Partner

We have been researching and tracking how organizations are investing and managing their global regulatory information since 2005. We saw 2023 as the beginning of an interesting transition to fully realize what a digitally enabled regulatory division could achieve.

The past 10 years have been spent modernizing regulatory systems and processes with a clear goal of "simplifying" the number of systems and standardizing global processes. Many software providers contributed to this innovation by developing either an E2E RIM (End-2-End Regulatory Information Management) or unified approach. This new system strategy was fully adopted by 55% of industry in 2022 and we predict adoption will approach 75% in 2024.

What piqued our interest in 2023 was the degree of organization evolution as the need for data science skills accelerated to support growing investments in analytics, data fabrics, data governance, and enterprise data architecture. We believe two key questions for 2024 are "how will regulatory operations evolve and what will be the primary responsibilities in 3 – 4 years?"

This growing organizational investment is critical, in our opinion, as much of the "hype" has been on the potential of Generative AI and automation opportunities. We believe organizations having the right skills to experiment and apply this new wave of technology is foundational, while others who just follow the latest hype may be doing so without a practical or thoughtful strategy. We also believe reports of machines potentially replacing a significant number of staff are overblown as artificial intelligence, in our opinion, should be used as a research assistant or to prepare initial draft content at this point in time.

Our research in 2023 began with our local affiliate study in which 320 local affiliate offices representing 94 countries participated to quantify "the voice of the affiliate" in order to improve regulatory activities and global RIM programs. The key theme was the need for greater inclusion (by > 50% of the participants) to optimize global processes, to prioritize system enhancements, and improve resource forecasting. This take-away is important as we estimated $1.9 billion has been spent in the past 5 years improving global RIM programs across the industry. The study reported only 48% of affiliate time is spent managing regulatory information using global systems. This means spreadsheets, teamshares, and email folders are still being used extensively to manage key regulatory information in addition to or instead of using global systems.

We also conducted a pulse survey of 41 companies to identify the latest status and strategy for IDMP/SPOR and eCTD4 programs as strategies and plans to adopt health authority initiatives are constantly evolving. We closed out the year with two quick studies of large organizations to determine if: 1) a unified approach met their anticipated business benefits and requirements and 2) combining regulatory, safety/PV and R&D quality organizations realized operational synergies.

We look forward to a great 2024 and will be focused on the following areas:

1. Conducting our World Class RIM Benchmark focused on extending the power of RIM. We expect record setting industry participation in this benchmark study.

2. Preparing for the impact of Generative AI.
3. Evolving Organization Strategies (structure, remits, upskilling etc.) – through our OSEC forum and consulting projects.
4. Exploring how Medtech companies are investing to improve their RIM programs through a fall pulse survey in collaboration with Megha Sinha, Head of Kamet Consulting Group.
5. Helping organizations improve their global RIM programs.
6. Expanding our membership program which provides access to our detailed research and models, private member webinars, and access to our global experts. This membership allows us to conduct more pulse surveys through the year.

Have a great start to the new year and I'll be updating you in the beginning of the second quarter.

Best Regards

Steve