

What ‘Operational Excellence’ Looks Like for the Evolving Regulatory Organization

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Introduction

The regulatory function in the life sciences industry is under increasing pressure to deliver faster, smarter, and more predictable outcomes. Global complexity and evolving health authority expectations continue to be the norm for regulatory, yet today, an accelerating pace of innovation is placing new demands on regulatory leaders. Historically, regulatory operations have been measured primarily through efficiency—speed, compliance, and cost control. But evolution is not just about efficiency; as environments change, performance metrics alone are no longer sufficient to evaluate regulatory excellence.

Our hypothesis is that true regulatory operational excellence is best achieved through the combination of improving operational performance while planning ahead - what we view as ‘future readiness’. High performance today, without the ability to adapt and lead tomorrow, leaves organizations vulnerable. Conversely, forward-looking strategies and new investments without consistent operational execution risk undermining trust with regulators and internal stakeholders. The winning formula integrates both dimensions.

This position paper shares our current point of view, what we’ve learned from clients, highlights key survey design elements of the 2025 Regulatory Operational Excellence and World Class RIMSM Study, and explores what the results may reveal about the path forward for regulatory organizations. A subsequent white paper will detail findings and insights, to be released in early 2026.

Defining and Measuring Regulatory Operational Excellence

The 2025 Regulatory Operational Excellence and World Class RIMSM study design defines operational excellence as the organization's ability to align the right capabilities—across people, processes, data, and technology—to deliver high-quality, timely, and compliant regulatory outputs that support business objectives and improve product lifecycle management. We view excellence as not merely the efficiency of capabilities or processes, but the consistent achievement of strategic outcomes. The study aims to learn how regulatory organizations are evolving toward operational excellence by identifying the critical enablers, performance metrics, and emerging practices that drive sustainable, result-oriented success. The study is designed so that the output helps us better understand the status and balance of “what organizations achieve today” (operational performance) and “how organizations prepare for tomorrow” (future readiness) to ensure continuous growth and success.

The study’s World Class RIMSM (WCRIM) rating is a score we’ve calculated and trended since 2016 that provide companies with a measurement of their regulatory organization’s *current* state operational performance (capability efficiency, business outcomes, information speed,

continuous improvement, and data quality). Although data collected on cultural and leadership dimensions, organizational strategies, strategic initiatives, and data governance practices are not included in our World Class RIMSM score, the information consistently shows a strong correlation to the WRIM rating.

This time around, we introduced new questions aimed at exploring:

1) Maturity levels of key regulatory processes such as regulatory intelligence, major marketing submission management, and health authority interactions.

2) Change management as a core capability in regulatory – this includes changes related to systems and technology updates, process optimizations, organizational changes, and data initiative specific changes.

Process and change management maturity along with expanding our examination of information connectivity, cultural adaptability and innovation leadership provides a more complete story. We believe these factors and corresponding data reveal future readiness status that can help companies, along with their WCRIM rating, better understand their organization's evolution towards operational excellence.

This 'future readiness' measurement could be a key differentiator that indicates regulatory organizations abilities to adapt, evolve, and lead. By integrating these perspectives along with the standard WCRIM performance rating, the study creates a dual profile of each organization: one that reflects current execution and another that signals preparedness for tomorrow's demands – useful for building a practical roadmap for regulatory operational excellence.

Conclusion

Operational excellence in regulatory is not a fixed endpoint but an evolving capability that enables and sustains the organization. Achieving this requires more than efficiency—it demands a new digital strategy, adaptive operating models, a willingness and commitment for change, and a workforce prepared for the future. The 2025 Regulatory Operational Excellence and World Class RIMSM study, closing in December, builds on this perspective by examining both operational performance and future readiness. By integrating these dimensions, the study aims to establish a new benchmark level for regulatory operational excellence and provide insights into how organizations balance today's demands with tomorrow's challenges. Study results will provide a better understanding of which factors most strongly influence excellence and what strategies distinguish leaders from laggards.

Performing today, ready for what's next – we believe this thinking is the path to operational excellence – truly elevating your regulatory operations from service provider to a strategic capability.