



Regulatory Performance Improvement Practice

Optimize your regulatory operations through rapid assessment and strategy development

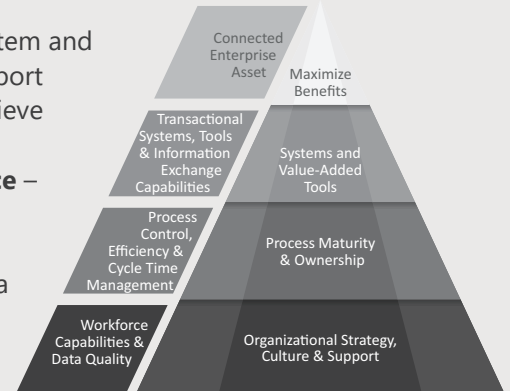
We have learned “what works to improve performance” from our extensive World Class RIM research and client projects with over 120 organizations. Our innovative method produces higher quality outcomes with reduced project time and cost (typically by 50%) while offering the best benefit realization.

We focus on these key levers from our performance pyramid to address your operational challenges and opportunities:

- 1. Organization** – Review your organization strategy, remits, skills to optimize your organization and elevate your team.
- 2. Process Maturity** – Identify barriers to effectiveness and efficiency to improve business outcomes by utilizing our process maturity diagnostic tool.
- 3. Metrics** – Identify outcomes you should be measuring to support continuous improvement from our KPI library and metrics maturity model.
- 4. Technology** – Optimize system and automation strategy to support business processes and achieve business benefits.
- 5. Data Quality & Governance** – Establish a plan to prepare for the future of structured data, including detailed data governance structure and practices leading to high data quality sustainability.



OBJECTIVES



Advanced RIM Practices

For more than 17 years, we have harnessed the most successful, progressive practices from across our community network, creating baselines of performance through the Gens & Associates research platform to accelerate RIM business outcomes.

Ready to improve your performance?

Get in touch with us:

www.gens-associates.com

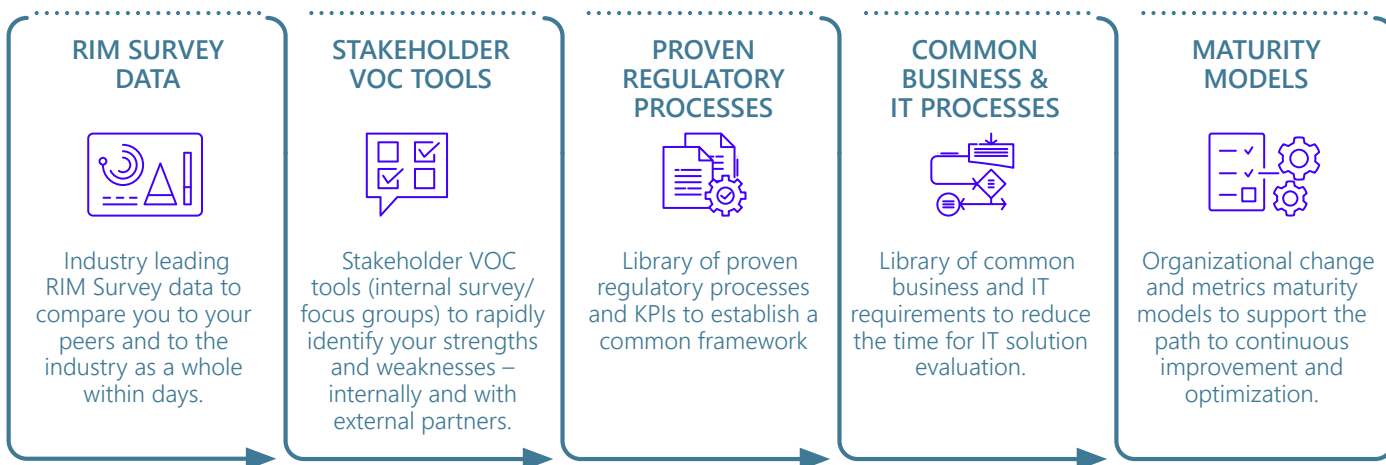
or email us directly at

corporate@gens-associates.com.

When do clients engage us?

Strategy Development (Establish baseline)	<ul style="list-style-type: none"> Develop initial performance improvement strategy, roadmap and business case Build or enhance performance measurement program and/or continuous improvement program that relies on “voice of customer”
Periodic Update (Benchmark to monitor progress)	<ul style="list-style-type: none"> Rapidly review and iterate performance improvement or optimization plan through our benchmarks and working sessions Partner to provide an unbiased interpretation of results and compare to industry peer group
Address Execution Challenges (Root cause diagnostic and improvement planning)	<ul style="list-style-type: none"> Organization failing to execute as planned leading to increased costs and delays threatening submission timelines and budgets (ROI) Customers and key stakeholders are frustrated; organization’s credibility impacted Rapid diagnostic and improvement planning

Our highly experienced team consists of proven regulatory, organization change/process management, and technology subject matter experts.



WE ARE COMMITTED TO TAKING THE REGULATORY COMMUNITY TO THE NEXT LEVEL by sharing expertise and knowledge. We approach our work with a spirit of generosity and integrity that is focused on making everyone better!

Together, Everyone Gets Better

As part of the Gens & Associates Community, you gain access to the Benchmark survey data and join an active community through which you learn and share global regulatory practices and trends.

Through our membership, you will receive updates and access to our specialized research, content, and private learning webinars and can tap into our network of experts.

The community is made up of:

- ✓ More than 160 global biopharmaceutical, medical device, consumer and generic drug companies and the providers that support them.
- ✓ Nearly 1,000 regulatory and business professionals.
- ✓ A group of life sciences leaders ranging from emerging, growth-stage companies to top 50 global leaders.



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