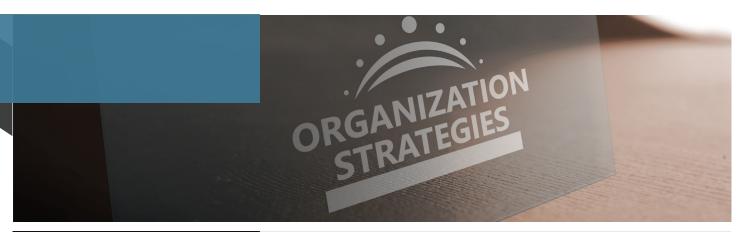


ORGANIZATION STRATEGIES - EVOLUTION AND CHANGE PRACTICE





Deep Organization Expertise

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 improve regulatory performance.

Ready to improve your performance?

Get in touch with us:

www.gens-associates.com

or email us directly at

corporate@gens-associates.com.

Optimizing Change is the Key to Performance Improvement We focus on preparing your team for transition readiness on both a tactical and strategic level

Globalization and pandemic impact have fundamentally shifted the ways in which industry functions and how teams work. Organizations are skilled at identifying 'what' has to change, but typically struggle with the "how". Our expertise focuses on delivering "how", not just effectively and efficiently but with a thoughtful approach using targeted change models and frameworks to guide organizations, teams, and leaders through a structured approach throughout their transition. We strongly believe any change effort comes down to people and teams, which must be closely tied to business goals with meaningful and quantifiable metrics.

Developing and sharpening change agent skills and improving practice effectiveness has never been so critical. Our highly collaborative approach leverages the best of the client and consulting teams to fast-track change optimization in any environment.

Our proven methodology, benchmarks and team experience is unparalleled. We specialize in navigating complex change and transitions by taking a structured approach, simplifying organizational thinking, and focusing on key actionable steps. Our diagnostic tools, organizational frameworks, and facilitated thinking creates the foundation for sustainable success. Our change practitioners are highly skilled and educated – most have a Master of Science in Organization Development, are published authors and researchers in change management – and have extensive experience helping life science organizations optimize change. We not only support your transition progress, but enhance the skill of key change agents in your team as part of the process.

Organizational Services



Evolving the Regulatory Organization: Structure, Roles, Skills, and Remit



Developing the Change Management Playbook for Your Organization



Review and Improve Strategic KPI and Metrics Program



Achieving World Class RIM: The Path to High Performance



Establishing/ Enhancing Data Governance and Data Quality Sustainability Practices



Improving Regulatory Process Maturity



Overcoming Barriers to Regulatory System and Process Adoption

Benchmarking data can inform key decisions by getting everyone on the same page and help teams focus on what needs to change. Our expert team uses the power of research data, change models, and industry know-how to help your organization through continuous improvements and ease change initiatives. Gens & Associates is the recognized industry leader in regulatory benchmarking with over 40 studies since 2007 touching over 160 sponsor organizations with a solid distribution of large, mid-tier, small and very small organizations. We focus on multiple dimensions of organization strategy to deliver on simple, systematic and sustainable solutions. Our 'start, learn, adjust' methodology means the quickest start to improving work.

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.

