

Gens & Associates launches latest World Class RIM study – the largest yet – to define & hone “industry standard” practice

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Stakeholders across the global Life Sciences industry & regulatory provider community are invited to play their part in cementing the ultimate approach to regulatory information management

Newtown, Pennsylvania, USA – October 4th, 2023 - Leading Life Science benchmarking and advisory firm Gens & Associates (<http://www.gens-associates.com/>) has launched its largest World Class RIM Benchmark study to date. The 2024 global study of Life Sciences regulatory information management programs – the 6th in the firm’s World-Class RIM series (which dates back to 2015) – will be the farthest reaching and most inclusive in terms of respondents. It will also be the deepest dive yet into hot topics such as structured data submission programs, advanced technology application to key regulatory processes, and regulatory digitization strategies.

The 2024 survey, which will help define and hone the industry standard for ultimate regulatory information management (RIM), is expected to attract record-breaking participation from 80-100 organizations. These will represent all corners of the Life Sciences industry, including small startups in the clinical stage, biotechs, medtech, generic, consumer, and combination product companies, as well as traditional pharma organizations.

Over the last five years, Life Sciences companies across the world have collectively spent over \$1.9 billion on improving regulatory information management, Gens & Associates estimates. The latest study will explore the impact of that investment, for instance in tangibly transforming organizations’ regulatory intelligence and cross-function process efficiency.

As in previous years the World Class RIM research will delve into companies’ evolving RIM strategies; peer performance status; investment priorities; advanced technology application; cross-functional connectivity; and organizational strategies to improve performance. It will also provide a comprehensive, up-to-date review of the software and service provider landscape.

Crucially, the Gens & Associates 2024 World Class RIM Benchmark study is co-designed with the Life Sciences industry, for the Life Sciences industry – ensuring that it asks the questions and secures the insights that matter most to companies as they finesse their own RIM strategies and investments tactically and strategically.

Seven industry survey design sessions will be conducted between October and December 2023, incorporating the feedback from 35-40 organizations. In the US the survey tour will take in Lambertville, New Jersey; Boston; Chicago; and San Francisco. European sessions include Copenhagen; Zurich; and London. For Asia-Pacific colleagues, collaborative survey design may take place virtually to maximize inclusion and convenience.

Commenting on the launch of the 2024 World Class RIM Benchmark study, Steve Gens, founder and managing partner of Gens & Associates, said: “This important new research will be the largest, broadest and

deepest study we have done to date, in terms of the participants and our outreach to include more companies of different sizes and origins. Inclusivity is paramount, as the whole aim of this research program is to empower everyone to improve the performance of their regulatory information management program (and for the providers, of their products and services), by harnessing the latest leading practices and supporting tools.

“Our mission at Gens & Associates is ‘Everybody Gets Better’ – by which we mean everyone across the regulatory ecosystem (industry players, IT/service providers, and health authorities). That same philosophy is also at the heart of our World Class RIM Benchmark study. The more companies that are involved in the design of the study, and the more survey participants we attract, the more powerful the actionable insights that everyone can draw on.”

Companies participating in the new study will gain access to this latest industry-recognized RIM research (typically running to 100+ pages) into key trends and practices; in addition to insights into their own performance position relative to their industry peers and the latest observed World Class RIM performance levels. They will also benefit from actionable insights, and a detailed view of the current status and emerging trends across the Regulatory software and service provider landscape.

There is no cost to take part in this blinded study. In addition to receiving the full results, participants will also have the opportunity to be part of a community debrief. First-time survey participants are invited to watch a short video covering Gens & Associates’ benchmark history and value, the 2024 study focus, as well as research policy and rules. The link can be found on the Gens & Associate web site at <https://gens-associates.com/world-class-rim-research/> (<https://gens-associates.com/world-class-rim-research/>).

The 2024 World Class RIM Benchmark study is Gens & Associates’ 43rd comprehensive research project in 17 years. The firm’s most recent findings from 320 local affiliates representing 94 countries, which are about to be published, explore the evolving role of country Affiliates as part of efforts to centralize, streamline, and advance global regulatory information management.

About Gens & Associates

Founded in 2005, Gens & Associates Inc is a Life Science benchmarking and advisory firm specializing in improving client performance, developing clear and pragmatic strategic plans and implementation roadmaps, and supporting organizational transition. Gens & Associates’ regulatory benchmark data is the industry standard – quoted by industry analysts, software and service providers, thought leaders, and utilized extensively by industry.

Gens & Associates’ global network consists of seasoned professionals typically possessing 20+ years of experience and advanced degrees and certifications. Many are industry-recognized consultants having substantial experience in industry, government health agencies, or top-tier consulting firms. Gens’ associates and partner organizations are located primarily in Europe and North America. In 2017, Gens & Associates was recognized in the PharmaVoice 100 as one of the most influential and inspiring organizations in the Life Sciences industry.

Gens & Associates’ Membership Programs combines strategic performance improvement advisory service

with access to Gens & Associates' private survey content and market reports through an Executive Lounge. More at www.gens-associates.com

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