



2021 Quality Industry Survey

*Enhancing Quality
Beyond Compliance:
Exploring Key
Dimensions to Elevate
Performance*

*Study Fast Facts and Entry
Support Guide*

Prepared by:

Katherine Yang-Iott (Study Lead)

Steve Gens (Managing Partner)

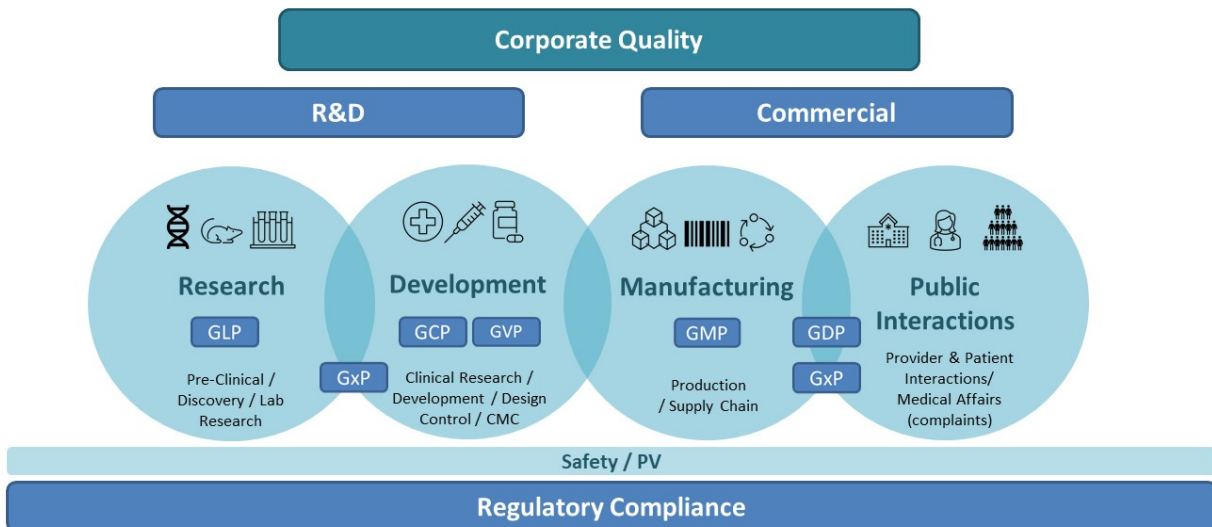
GENS
& ASSOCIATES

SURVEY BACKGROUND AND INTRODUCTION

Gens & Associates Life Science research projects are renowned for their quality, insights, and precision by providing a unique perspective on industry status, challenges and opportunities, investment priorities, key trends, and the solution/service provider landscape. All surveys are blinded, there is no cost to participate, and all participating companies will receive the full study results report.

The 2021 Quality benchmark (opening May 24th and closing around September 20th) will be the 37th study since our first landmark Regulatory benchmark conducted in 2007 and is expected to attract between 35 – 50 sponsor organizations. The survey purpose is to explore multiple quality dimensions coupled with strategic initiatives to help companies identify the steps and strategies towards enhancing quality beyond compliance.

Since quality permeates all phases of the product lifecycle, we have dedicated domain specific sections (see figure 1) to examine the functions and performance features of the individual Quality domains: *Corporate Quality*, *R&D Quality*, *Commercial Quality*, and *Regulatory Compliance*



* Our framing of organizational quality domains is represented in this simplified image and serves as the basis for our study structure and survey questions. The domain frame is not representative of all Quality elements or organizational structures and is not meant to be exclusive.

Figure 1: Quality Domains under Analysis

During the first quarter of 2021, we partnered with several Quality experts (sponsors, consultancies, and solution providers) to explore and establish the research framework. Industry design sessions, with 15 companies, were held in April and May to finalize the survey design. We ensured diversity of company size, product type and geography in these sessions to ensure a broad industry representation.

SURVEY PARTICIPATION BENEFITS

By participating in our survey, your company will gain the latest Quality-focused research including both a business and technology perspective and a peer comparison. Survey participant can use the survey data and debrief sessions in many ways, including:

- ✓ *Confirm or discover organizational, technology, and process / metric improvement strategies to improve Quality performance by domain (Corporate Quality, R&D Quality, Commercial Quality, Regulatory Compliance)*
- ✓ *Understand ranking to peers and between internal Quality Domains*
- ✓ *Understand the status and investment timeline to optimize QMS elements by company size to boost operational effectiveness and efficiency*
- ✓ *Gain detailed knowledge of the software provider landscape (market share, satisfaction, likelihood to change, and standing in our software provider innovation index)*
- ✓ *Educate senior leadership on quality related trends, peer strategic initiatives and organizational reporting trends, and strategies to move to a more proactive, predictive, and preventative Quality by Design culture*

Our study findings will be the foundation for our Opportunity Tool Kit (see figure 2), which can be used as a diagnostic tool for companies to improve their quality performance journey. The survey design also allows both external company peer-to-peer comparisons and internal cross-domain comparisons within companies.



Figure 2: Quality Improvement Spectrum

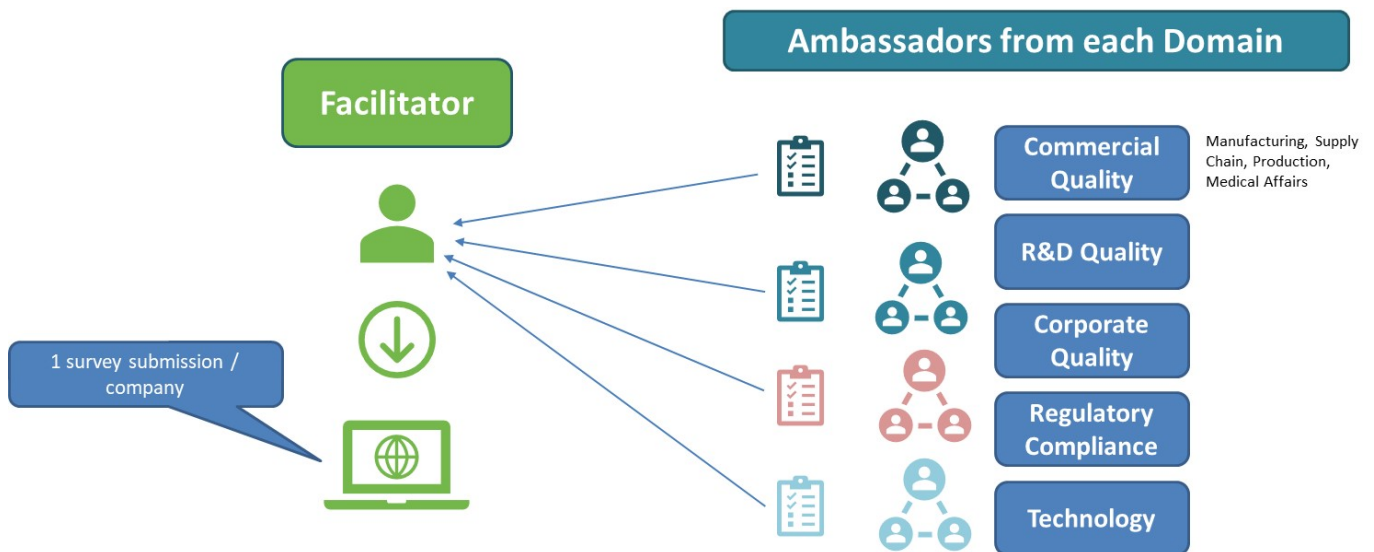
SURVEY LINK

The full survey PDF provided in the final enrollment package for enrolled participants is for reference only. Please submit the final survey answers into SurveyMonkey through this link:

<https://www.surveymonkey.com/r/GensQualitystudy2021>

TIME AND PROCESS TO COMPLETE THE SURVEY

Completing the survey requires a group effort with 2 defined roles to successfully complete the full survey response. We recommend that each company have an overall study “Facilitator” and each Quality area have a domain “Ambassador”. The study also requires a colleague or two from Information Technology to complete technology related questions. The Facilitator will be registered as the main point of contact for Gens & Associates. Please view our support videos at: <http://gens-associates.com/2021-enhancing-quality-beyond-compliance-benchmark-study/>



Please keep in mind that the ‘Facilitator’ of the study will submit the completed survey in its entirety for their company. Only one completed survey will be accepted per company, unless previously agreed upon with Gens & Associates (e.g., different ‘independent’ divisions such as consumer, pharma, vaccine, device within a company). Here are our recommendations for approaching this study:

1. **Identify each Quality Domain ‘Ambassador’ for completing specific sections** (refer to Figure 1 for Quality Domain frame)
 - a. The ‘Facilitator’ will identify and coordinate with a group of Quality ‘Ambassadors’ to complete each section of the survey. The 5 main survey sections are: Corporate Quality, R&D Quality, Commercial Quality, Regulatory Compliance, and Technology. Choose a representative Ambassador from each domain to be responsible for providing answers for their corresponding sections.

- b. Quality Ambassadors from R&D will complete the R&D Quality section, Quality Ambassadors from Commercial will complete the Commercial Quality section and so forth.

2. Filling out the survey

- a. We are providing the Facilitator with fillable PDF's for each section of the survey. The Facilitator is responsible for assigning and giving the section-specific PDFs to corresponding Ambassadors to complete. Please refer to the emailed survey package for all materials.
- b. The Facilitator should provide a 'due date' for Ambassadors. Each section has questions that will require time to gather and agree on the proper response from the different Quality domains. The time it takes to fill out each section will be unique for every team; however, a 1-week period "part time" should suffice for each Ambassador to review their sections with their teams to arrive at a consensus and complete their survey section.
- c. Facilitator will provide the following for each Domain Ambassador:
 - i. Section-Specific Survey PDFs (electronically fillable)
 - ii. Due date to return completed responses to Facilitator
 - iii. Copy of Study Guide with Terminology Guide
 - iv. Link to guidance video and instructions walk-through (section specific)

3. Submitting the full survey (all sections completed): Only 1 submission per company

- a. Once the Facilitator collects the completed sections from each Ambassador (PDF format), they will use this SurveyMonkey link to enter ALL responses:
<https://www.surveymonkey.com/r/GensQualitystudy2021>
- b. The completed survey will be submitted through SurveyMonkey. If circumstances do not allow for this option, the Facilitator can email the completed PDFs directly to Gens & Associates for us to create a manual entry. We will confirm answers with Facilitator prior to finalizing submission.

The survey will be open for 12 weeks, but we expect it will only take a couple of weeks, part time, for the Facilitator to gather and review responses with Ambassadors. We appreciate if all responses are in by Monday, September 20th, 2021.

Survey Structure and Number of Questions (53)

- **Demographics and Background (5 Questions)**
 1. Contact Info
 2. Survey Contributors
 3. Product portfolio type
 4. Number of medicinal / combo products
 5. Number of device / combo products
- **Organizational Baseline and Corporate Quality (8 Questions)**
 1. Corporate Quality Head or Chief Quality Officer
 2. Plans for Changes to reporting strategy
 3. Distribution of headcount across org (size of org)
 4. Priority Skills for future workforce
 5. Quality Council Membership
 6. Quality Council Purpose
 7. Knowledge Management
 8. Other Organizational strategies and practices
- **R&D Domain (12 Questions)**
 1. Org reporting structure
 2. Number of R&D Sites
 3. Governance structure at R&D sites
 4. Strategic initiative statuses
 5. Effectiveness of QMS Elements
 6. QMS Elements Investment plan
 7. R&D Quality Metrics characteristics
 8. Quality Risk Management
 9. Business Benefits
 10. Current use of technology
 11. Tech Primary automation use cases
- **Commercial Domain (13 Questions)**
 1. Org reporting structure
 2. Number of manufacturing sites
 3. Governance structure at manufacturing sites
 4. Strategic initiative statuses
 5. Effectiveness of QMS Elements
 6. QMS Elements Investment plan
 7. Commercial Quality Metrics characteristics
 8. Quality Risk Management
 9. Reporting time metrics
 10. Business Benefits
 11. Current use of technology
 12. Tech Primary automation use cases
- **Regulatory Compliance (6 Questions)**
 1. Functional Roles in Regulatory for Quality / Compliance
 2. Effectiveness of QMS Elements
 3. QMS Elements Investment plan
 4. Quality practices
 5. Strategic initiative statuses
- **Technology Strategy and Software Provider Landscape Status (9 Questions)**
 1. Tech Strategies
 2. Tech Investment Profile
 3. Tech provider Innovation Index
 4. Software Provider Landscape Status

SURVEY POLICY

Our operating principles remain the same as in our previous surveys:

- 1) **Your company information is held in strict confidence and is never released to any organization** (this is one of our core tenants). All participating companies are blinded in the study results. There is no way for another participating company to understand how each individual company responded to the survey. We do, however, acknowledge which companies participated in the survey (logo only in the appendix). If you **do not** wish to have your company logo appear in the appendix, please let us know.
- 2) **All participating companies receive the detailed results** (PDF) containing the analysis summary, peer comparison, and question by question results.
- 3) There are **optional community debrief sessions** to review and discuss the results. There will be a virtual session in the October-November timeframe. There is no limit to the number of participants in a debrief session.
- 4) **There is no fee to participate in this survey.**

- 5) **All participating companies may use the results freely within their internal organization with proper citation.** Permission can be granted to utilize benchmark information (with proper citation and credit) outside your organization upon written request (see contact information).
- 6) Typically, only one survey response is allowed per company unless you have distinctly different divisions (e.g., biopharmaceutical, medical device, or consumer products). Please let us know if you wish to submit multiple entries (one per division).

PRACTICE TIPS FOR USING SURVEYMONKEY

We utilize a web-based product (Survey Monkey) to collect survey responses. Only one submitted survey is allowed per company. **The hard copy of the PDF version or fillable PDF forms can be used to gather and agree on your company response which is then entered using [Survey Monkey](#) (estimated 10 - 15 minutes) by the facilitator (one individual).**

For those who are not familiar with Survey Monkey, here are a few considerations:

1. Survey Monkey associates each response to a specific computer. Please use only one computer to enter your response.
2. You may start and stop entry after completing any page. Survey Monkey “pages” are identified by the “Next” or “Done” buttons at the end of a series of questions. The responses are saved after you move to the next page. Note: you must have cookies enabled in your browser to resume where you left the survey. If cookies are not enabled, you will have to start from the beginning each time you open the survey. Please contact one of the survey team members listed below if you need assistance completing the survey.
3. If you stop entering your response before completing the survey, simply use the provided link to re-open your response using the same computer. You will be able to resume entry on the page you left the survey. Remember, SurveyMonkey pages are saved only after you click on the “Next” button or the “Done” button at the end of the survey.
4. If you need to change a response, you can also re-open the survey using the same computer and navigate to the appropriate question and update your response.
5. When you press “Next” at the end of each section, Survey Monkey will do error checking for the following:
 - a. Are all required questions completed?
 - b. Did you miss any rows for matrix questions where each row requires a response? Note, most questions have a “not applicable to our situation” for those areas that are not applicable to your organization.

- c. Is the format correct for those questions that require entry of numerical values?
Typically, we require numeric data to be positive integer values only.
6. Many questions also have an “Other, Please Specify” or “Comments if Needed” box in which you can further clarify your response.

FOR SUPPORT COMPLETING THE SURVEY, PLEASE CONTACT:

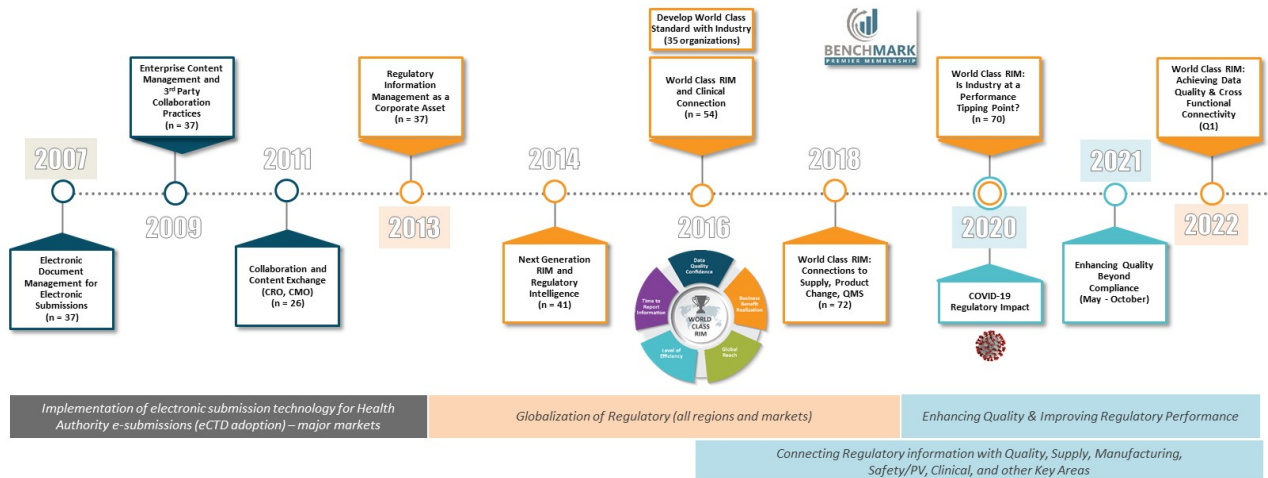
Name	Email
Steve Gens	sgens@gens-associates.com
Katherine Yang-Iott (Study Lead)	kyang-iott@gens-associates.com
Corporate Email	corporate@gens-associates.com

ABOUT GENS AND ASSOCIATES

A Life Science benchmarking and advisory firm specializing in performance improvement, strategy, industry analysis, and organizational transitions.

Our mission is to help all stakeholders in the regulatory and quality eco-system accelerate global transformation, increase efficiency and organizational agility to shorten approvals of effective new drugs and contribute to medicine affordability. We do this through strategic leadership, enhancing industry standards, collaboration and deep insights derived from our recognized research platform that bring precision to identify the most effective changes and outcomes.

Survey History Summary



More at www.gens-associates.com