# 2020 COVID-19 Pandemic Regulatory Impact Pulse Survey

*Study Fast Facts and Entry Support Guide*

**September 14th, 2020**

GENS & ASSOCIATES

## Survey Background and Introduction

Gens & Associates Life Science research projects are renowned for their quality, insight and precision by providing a unique perspective on industry status, challenges and opportunities, investment priorities, key trends, and the solution/service provider landscape.

The 2020 pulse survey will be our 36th study since its inception in 2007. The current health crisis caused by COVID-19 marks 2020 as a significant year where this global pandemic has shifted how businesses operate. The survey purpose is to examine how the pandemic is impacting regulatory organizations today and how they are responding. We believe tracking the responses over the next year will provide significant insight as to what processes and priorities are being accelerated to adapt to the shifting environment.

During this summer, we interviewed representative samples from both industry and provider networks to explore learning priorities and obtain feedback on the initial survey design. We held several design session focus groups to review and provide feedback on the final survey design.

The survey opens September 14th and closes on Monday October 19th (5 weeks). The survey has 19 questions in the sections below and should take you between 10 - 15 minutes to complete.

1) Demographics
2) Business Operations
3) Ways of Working
4) Regulatory Activities

By participating in our study (no fee), you and your company will gain the latest regulatory research from the pandemic response including:

- ✓ *Track temporary and permanent changes coming due to the COVID-19 pandemic and what those changes mean for your RIM and regulatory organization.*
- ✓ *Understand where processes and priorities are being accelerated for performance improvement in post-pandemic environment.*
- ✓ *Understand how shifts in work environment and initiatives affect operations and business outcomes.*
- ✓ *Incorporate practices contained in the survey to improve operational performance.*

## Number and Type of Participants

- Individual responses are required as many of the questions are structured to gain insight about personal views and experiences.
- Participating individuals from each company will represent a variety of regulatory roles including affairs/strategy, operations, regional/local affiliate, regulatory CMC and Regulatory intelligence/policy.
- We are expecting between 30 and 50 companies to participate each having around 10 individual responses. They represent pharmaceutical, biologics, generic, consumer health, agricultural, diagnostic, and medical device organizations.

## Survey Link & Study Results

The survey PDF provided in the enrollment package is for reference only. It is not the survey entry method. Please use this link and email (see contact below) if you have any questions

https://www.surveymonkey.com/r/covid19regimpact

Once the study analysis is complete (estimated by mid-November 2020), you will be notified by email to the location on our website for the full study results under "Knowledge to Share". We will also be conducting a community debrief session (2 hours) virtually so all participants gain insights and key learnings directly from the core research team and have the ability to ask questions and explore the results.

## Survey Policy

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

1) Your company and individual information are held in strict confidence and is never released to any organization (this is one of our core tenants). All participants and participant companies are blinded in the study results. There is no way for another participating company to understand how each individual company or individual responded to the survey. Individual responses within companies adhere to the same policy. Companies will not know and cannot find out how individuals within their company responded to the survey.

2) All participants receive the detailed results (PPT) containing the analysis summary and question by question results.
3) A virtual community debrief session will be scheduled in mid to late November, open to the public, to review and discuss the results. There is no limit to the number of participants in a debrief session.
4) There is no fee to participate in this survey.

## COMPLETING THE SURVEY

We utilize a web-based product (Survey Monkey) and ask that you enter your responses directly into Survey Monkey. The hard copy of the PDF version can be used to review the questions and prepare your response. Once you are ready, simply click on the Survey Monkey link and take the survey (estimated 10 - 15 minutes). Note the PDF is not a "fillable" form.

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 | Time zone | Email |
|---|---|---|
| **Steve Gens (Managing Partner)** | EST | sgens@gens-associates.com |
| **Katherine Yang-Iott (Study Lead)** | EST | kyang-iott@gens-associates.com |
| **G&A Corporate Email** | | corporate@gens-associates.com |

**Survey Authors Bio:**

**Steve Gens** is the survey co-founder and leader with the first industry survey conducted in 2007. He has over 30 years of business experience with the majority in the biopharmaceutical and healthcare industries. His early career was spent at Johnson and Johnson and transitioned to consulting where he managed several healthcare consulting practices for Booz Allen Hamilton and First Consulting Group.

Steve has deep experience in strategy formulation and implementation, organization development, industry benchmarking, information management strategy, and facilitating strategic change. He consults for many global biopharmaceutical companies and with small high growth organizations. He has a Master of Science in Organization Development from American University with distinction for his field work and a BS in Business Computer Science. Steve is a frequent speaker and was named as one of the 2017 PharmaVoice 100 for his contributions to industry. **267-614-0935** or sgens@gens-associates.com

**Katherine Yang-Iott** is a core member of the Gens and Associates team with over 15 years of experience in the healthcare and pharmaceutical industry leading and managing complex interdisciplinary projects. She worked as a research scientist at Regeneron Pharmaceuticals and The Children's Hospital of Philadelphia before transitioning to consulting work, where she focused on strategy development and continuous improvement projects to support research operations. Katherine has a Masters of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelors of Science in Biochemistry. Katherine can be reached at kyang-iott@gens-associates.com.

**Greg Brolund (supporting survey process since 2009)** is a management and technology consultant with experience with global Pharmaceutical companies in product labeling, submission publishing, Health Authority interactions, pharmaceutical safety and pharmacovigilance programs and ICH eCTD, E2B and HL7 ICSR electronic submissions.

He has over 25 years of experience in all aspects of information technology including the Food and Drug Administration's drug review process and supporting systems and as Chief Technology Officer for the US Department of Health and Human Services. He holds a Masters of Chemistry degree from the American University in Washington DC.

## About Gens and Associates

We are a boutique Life Science management and organizational consultancy specializing in strategic planning and roadmap development, industry benchmarking, regulatory information management, organizational transition management, and working with leadership and project teams to accelerate change and value realization.

Our mission is to help all stakeholders in the regulatory 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.

We have both a consulting and research arm to support the regulatory eco-system with the following expertise:


More at [www.gens-associates.com](http://www.gens-associates.com)

## GENS AND ASSOCIATES INC. BENCHMARK HISTORY

1) **2007 eCTD/Electronic Document Management Survey (with ILSS)***
2) 2007 Promotional Material Process Metric
3) 2007 Labeling Pulse Survey
4) 2008 eCTD and Organizational Implications
5) 2008 Labeling Best Practices Survey
6) 2008 Regulatory Core Dossier Submission Strategy
7) **2009 Electronic Document Management/Collaboration (with ILSS)**
8) 2009 Industry Engagement
9) 2009 Regulatory Submission Management and Production Planning
10) 2010 Global Pharmaceutical Regulatory Affiliate Strategy
11) 2010 Regulatory Information Management & Health Authority Trends
12) 2010 Vendor Market Share Update
13) **2011 Collaboration and Content Management Trends (with ILSS)**
14) 2011 Regulatory Futures
15) 2011 Publishing and Dossier Management (organization and outsourcing)
16) 2011 Labeling and Promotional Material Organization Strategy
17) 2012 Regulatory Information Management Trends
18) 2012 Vendor Market Share Update
19) **2013 Managing Regulatory Information as a Corporate Asset (n = 37)**
20) 2013 Regulatory Operations Pulse
21) 2013 CTA Pulse
22) 2013 EDMS and Digital Archive: One and the Same?
23) 2014 Regulatory IT Resource Pulse
24) **2014 RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)**
25) 2014 Top 15: Cross-Divisional RIM Status Pulse
26) 2015 Next Generation Content Management Pulse (21 companies, 9 vendors)
27) 2015 RIM Addressable Market Analysis Update& IDMP Predicted Spend (top 500)
28) 2015 Content Management Vendor Landscape Analysis (market share and satisfaction-level trending, market dynamics, market share shift projections)
29) 2015 Mature Product Outsourcing Attitudes Pulse Survey
30) **2016 Pursuing World Class RIM: Strategies, Measures and Priorities (n = 54)**
31) 2017 Safety Systems Trends: Innovation, Operating Model and Growing TCO (n = 17)
32) 2017 Regulatory Services and Software Addressable Market Analysis Update (top 500)
33) **2018 Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)**
34) 2018 Submission Content Management Capability: Change Investment Pulse (n = 10) – Top 30
35) **2020 World Class RIM: Is Industry at a Performance Tipping Point (n = 66 phase 1, phase 2 open)**

***Boldface title** indicates a large industry study.