2016 Industry Survey
Pursuing World Class RIM: Strategy, Measures and Priorities

Study Fast Facts

December 18th 2015
SURVEY BACKGROUND

Gens & Associates Life Science research projects are renowned for their quality and insight by providing a unique perspective on industry status, priorities, trends, and the solution and service provider landscape. We have conducted over 30 industry surveys since 2007 which includes a large scale empirical study every 18 months. These large studies contain both new research and follow-ups to previous topics for trending purposes. By participating, your company will gain the latest research and understand your company’s position versus your peers in industry. The majority of study participants utilize this information for internal strategy, budgets, provider analysis, and performance goals and objectives.

2016 SURVEY TITLE

Pursuing World Class RIM: Strategy, Measures and Priorities


SURVEY TIMELINE

- Survey Enrollment: December 2015 – February 2016
- Research Analysis and Results: March 24, 2016 – April 15, 2016
- Participant Debrief Sessions: Begin late April 2016

NUMBER AND TYPE OF PARTICIPANTS

- Expecting between 50 and 60 companies
- Majority of Top 75 (by revenue) - Historically ~ 70% participation
- Significant expansion to smaller organizations beyond the Top 75
- We expect a blend of pharmaceutical, biologics, generic, consumer health, medical device, and vaccine companies to participate

RESEARCH INTRODUCTION

The purpose of this year’s survey is to follow-up on our empirical 2014 Next Generation Regulatory Information Management (RIM) and Intelligence Survey and to conduct more detailed research on strategies and metrics to achieve World Class RIM. The driver for this research is based on several trends including:
• Increasing the strategic value of RIM investments
• Gaining further efficiencies within Regulatory, its affiliates, and key touch points with product release, manufacturing change control, and safety/clinical trial tracking
• Increase operational efficiency and productivity
• Growing Health Authority complexity
• Required improvement in the usability of RIM systems for the infrequent, local affiliate, and mobile RIM information consumers
• Shifting provider landscape (Cloud, SaaS, and Mature Product Outsourcing etc.)
• Emerging Technologies being applied to the RIM space

**Survey Sections**

1) Demographics (5 questions)
2) Regulatory Information Management (RIM) Program (7 questions)
3) RIM Measures (6 questions)
4) Collaboration and Affiliate Network (2 questions)
5) Touch Points with Clinical (5 questions)
6) Authoritative Source and IDMP (4 questions)
7) Software as a Service / Cloud (3 questions)
8) Regulatory/Safety Outsourcing Trends (5 questions)
9) Vendor and Implementation Landscape and Satisfaction Levels (12 questions)

**Survey Policy**

Remains the same as our previous surveys:

• All participating companies are blinded (strict confidentiality is a core tenant)
• All participating companies receive the detailed results (PPT) containing the analysis summary, peer comparison, and question by question results
• There is an optional debrief session to review the results. This is by a web-based meeting or may be performed on site upon request (no limit to the number of participants)
• All company information is held in strict confidence and no company names will be provided in any survey results or in any discussions of the results
• There is no fee to participate in this survey
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 permission (see contact information).

Only one survey response is allowed per company. Please contact us if you would like to enter separate responses for company “divisions” (e.g. biopharmaceutical, medical device, or consumer products).

COMPLETING THE SURVEY

The survey contains multiple choice style questions and will require a small team representing Regulatory Affairs, Regulatory Operations, Trial Master File, and Informatics/Information Technology to complete the survey. We have found the small survey team approach is the most effective way to complete the survey and ensure the responses truly represent the viewpoint of your organization. The survey contains 50 questions. It may take time to gather and agree on the proper response. We have allowed 12 weeks to complete but we expect that it will only take a few days, part time, to gather and review your response. We hope that some companies can complete their responses by the end of February to allow us time to complete an interim analysis. All responses must be in by March 23th.

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 gather and agree on your company response, and then be entered into Survey Monkey (estimated 5 – 10 minutes) by one individual. 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. 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.
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
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.
CONTACTING US:

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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 (top 500)
28) 2015 IDMP Addressable Market and Predicted Spend for Top 250
29) 2015 Content Management Vendor Landscape Analysis (market share and satisfaction-level trending, market dynamics, market share shift projections)
30) 2015 Mature Brands Outsourcing Pulse
Definitions

Country Filing Requirements
Country Filing Requirements refers to a system or method of capturing individual country intelligence on information necessary for initial product filings, amendments /supplements /variations, renewals etc.

Data Governance
Data governance deals with coordinating the people, processes, standards, and technologies, in order to optimize outcomes related to enterprise data assets. This may include the broader cross-functional oversight of standards, architecture, business processes, business integration, and risk and compliance. In other words, it includes anything that can impact the integrity, quality, and security of company information.

Dossier Management
Dossier Management is related to creation and management of the dossier plan. The dossier plan is the specific assembly structure and associated content (planned and actual) needed to complete the production of a submission to be filed with a regulatory authority.

Change in RIM Capabilities
An investment in the capability (technology and/or process) beyond or in addition to, minor vendor software patches or routine maintenance.

Efficient / Efficiency
Efficient in the context of RIM capabilities and processes is defined as the effective utilization of resources, repeat-ability of process, and low error rates to achieve regulatory goals and outcomes.

Health Authority Commitment Management
A Health Authority Commitment Management system tracks ongoing and completed commitments made to regulatory authorities as part of the application review process or as a condition of approval. In many organizations, this capability will be included within the product registration management system.

Health Authority Correspondence Management
A Health Authority Correspondence Management system manages correspondence and associated responses to inquiries related to submission activities and/or audits. It is often used in conjunction with a submission EDMS or submission archive solution for traceability purposes.

Label Management
Label Management is a method of centrally managing the entire label life cycle—from initial design and review to production use and eventual obsolescence. In addition, it can provide traceability back to a particular version of a Company Core Data Sheets (CCDS) or Safety Sheet.
Master Data and Industry Standards
Master Data is the data that is common across business solutions and is required to be consistent in running an operation. Industry Standards are official data standards from official organization (ISO, Health Authority) such as the ISO IDMP and XEVMPD. Data warehouses and data marts support business decisions by collecting, consolidating, and organizing data for reporting and analysis with tools such as online analytical processing (OLAP) and data mining.

Product Registration Management
The purpose of a Product Registration Management System is to provide regulatory departments the ability to effectively manage the planning and tracking of global approved and pending changes affecting the registration status of a product. An effective solution facilitates global communication and collaboration while meeting local and regional regulatory needs.

Product Release Process
The Product Release Process comprises an assessment of the production process based on the relevant documents, records and relevant samples, to ensure that the requirements documented in the appropriate specifications have been met. The Product Release Process is part of the quality management process.

Publishing
The Publishing system provides a method of compiling necessary content for a defined submission activity, adding necessary elements such as hyperlinks (electronic submissions) or cross-references (paper submissions), and producing compliant output based on agency requirements.

Software as a Service (SaaS)
Software as a service is a software licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted. In this model, software vendors host and maintain the servers, databases and code that constitute an application. The majority of SaaS solutions are based on a multi-tenant architecture. With this model, a single version of the application, with a single configuration (hardware, network, operating system), is used for all customers (“tenants”). Increasingly SaaS applications support application customization / configuration by a customer to alter functionality and look-and-feel.

Regulatory Change Control
A Regulatory Change Control system enables transparency by managing the change control process across all relevant departments from initial request (e.g. impact assessment), through pre-approvals, change execution, follow-up approvals and implementation.

Regulatory Information Management (RIM)
The set of processes and tools used to manage content and data related to regulatory activities throughout the life cycle of a product.
Regulatory Soft Intelligence
Regulatory Soft Intelligence (experience based) involves documenting best practices learned through interactions with regulatory authorities and experiences with local registration procedures.

Submission Archive
The submission archive represents a DMS that is used to store official submissions, correspondence, or other regulatory authority interactions. In many organizations, this archiving is included within the submission EDMS.

Submission EDMS
The Submission EDMS is typically used to manage all submission related documentation (source and PDF). The repository will be used to manage the entire lifecycle of the documents in scope of system.

A Submission EDMS system will be used by authors, reviewers, approvers, and consumers of document content.

Submission Planning and Tracking
Submission Forecasting, Planning and Tracking involves capabilities related to creation and management of the submission plan and volume forecast. The submission plan is the outline of countries, target dates, and expected components and tasks that are needed to complete the production of a submission to be filed with a regulatory authority. The submission forecast collects the volume of expected submissions to support the annual product lifecycle (number of CMC or label changes, renewals, variations etc.) and is used for resource planning (internal and with service provider)

Survey Authors Bio:

Steve Gens has 30 years of business experience, with the majority of it in the biopharmaceutical and health-care industries. He is currently managing partner of Gens and Associates Inc. His early career was with Johnson & Johnson, after which he moved into consulting to manage several health-care consulting practices for Booz Allen Hamilton and First Consulting Group.

Steve has deep experience in strategy formulation and implementation, organizational development and performance, global virtual team effectiveness, industry benchmarking, information management strategy, and leading or facilitating strategic change. He consults for many of the largest global biopharmaceutical companies as well as with small, high-growth organizations.

Steve has a Master of Science in Organization Development with distinction for fieldwork from American University in Washington and a bachelor of science in Business Computer Science from Lock Haven University of Pennsylvania. He is certified in change management by the NTL Institute for Applied Behavioral Science.
**Greg Brolund** is a global pharma management and technology consultant with extensive experience in business processes and information technology (IT) support for product labeling, submission publishing, health authority interactions, and safety and pharmacovigilance programs.

He served as rapporteur of the Inter-national Conference on Harmonisation’s M2 Working Group, as rapporteur from 1998 to 2002 in the development of the initial production version of the electronic Common Technical Document (eCTD), and as rapporteur in the implementation of the 2B Individual Case Safety Report electronic submission. Greg has 25 years of experience with the US Food and Drug Administration in leading the development of the agency’s internal IT systems in support of the submission review processes of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. After that, he served as chief technology officer of the US Health & Human Services and was a pharmaceutical industry consultant with Booz Allen Hamilton. Greg has a Master of Science degree in Chemistry from American University in Washington, D.C.

**Sarah Powell** has 28 years of experience in pharmaceutical and related regulated industries (Clinical, Quality Control, Regulatory Affairs and Regulatory Operations). In the past 14 years as a consultant, she has assisted clients with projects related to regulatory process improvements, standards development, defining filing strategies and writing and review of submission content. She has extensive experience with projects related to design and implementation of regulatory solutions (requirements definition through validation) including document management, submission planning, publishing, and registration management. Sarah is a past executive at Chiron, First Consulting Group and Liquent (PAREXEL). She holds a Bachelor’s of Science degree in Nutrition Science from the University of California, Davis.

**ABOUT GENS AND ASSOCIATES**

We are a boutique management and organizational consultancy specializing in strategic planning and transition management, organizational effectiveness, industry benchmarking, regulatory information management strategy, and managing the complexity of the global virtual workplace.

Our primary focus is the global healthcare industry where we have worked with 85% of the top 60 bio-pharmaceutical companies worldwide. We help our clients increase their organizational performance and business results by leveraging and maximizing their people and core information assets.

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