2011 Life Sciences
Collaboration / Enterprise Content Management Survey

Executive Summary

To inquire about access to the detailed study results (67 slide presentation) please contact Steve Gens or Steve Scribner (see last page for contact information)

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Background

The Bio-Pharmaceutical Industry is undergoing fundamental change driven by globalization, emerging market criticality, scientific advancement, and cost cutting resulting in rapid organizational, process, and technology change. Our 2009 industry survey found collaboration to be the top priority in content management programs and an area of significant business investment as a change to a "collaborative-centric" operating environment was rapidly taking hold in industry.

Collaboration is at the center of many organizational, technological and process initiatives. We believe a fundamental shift in how companies operate has taken hold and our tracking of collaboration trends / methods has supported many companies with their strategic investments and direction. This involves changes to operating policies, information and content structures, technologies, team / organizational competencies, and business processes. The "new normal" is working in a global virtual workplace which requires global systems, 24x7 access to key information and content, seamless and secure content exchange, and the implementation of global information standards.

Our current survey focuses on the following topics or lines of inquiry:

- Collaboration trends (intra-company, business to business, sponsor to Health Authority)
- Enterprise Content Management (ECM) trends and strategies
- R&D Content Management and Regulatory Information Management trends
- Regulatory Operations outsourcing trends, methods, and satisfaction levels
- Software vendor market share and satisfaction levels
- Information Technology trends (platform strategy, cloud computing, etc.)

This survey focused on the Top 50 Bio-Pharmaceuticals as defined by Pharmaceutical Executive with a roughly equal participation rate distributed between European, Japanese, and United States headquartered companies (see Figure 1)

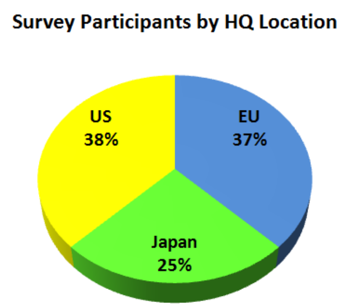

Figure 1 - Survey Demographics

Bottom Line: Industry Switching Gears, Processes and Solutions Struggle to Rapidly Evolve

Collaboration is a strategic business imperative with a high degree of focus and priority. A common challenge expressed by executives is the organization's ability to change solutions and processes to keep pace with the rate of business change. Our results find industry at a cross-road: there is significant ***incremental improvement*** in collaboration methods, information exchange, and vendor solutions along with increases in Health Authority collaboration effectiveness and content program effectiveness as compared to our 2007 and 2009 study data. While these improvements are important, the “collaborative-centric” business shift requires *rapid change* that goes directly against traditional approaches. Usual solutions are often “closed” and take too much time and are very costly to deploy. In our experience, the challenges include:

- Configuration complexity (those that are really customizations and are highly dependent on solution vendors)
- Gaining consensus on global solutions and process harmonization
- Lack of visibility into end to end information flows and processes
- Stringent validation requirements.

Many companies still operate in an “incremental change” mode when the situation calls for more rapid and transformational changes.

We believe the need for both internal and external collaboration will continue to be a top priority and many companies will need to “re-think” how their teams and solution providers work in order to dramatically reduce the time to deploy new capabilities and maintain existing ones.

Analysis Summary: Eight Salient Themes

Our analysis consisted of this year’s extensive survey data plus trending data from our other studies (see page 8). The combination of this benchmark data and our professional experience yielded eight primary study results:

1. Organization virtualization, globalization, and mobility are fundamentally changing patterns of work, giving a high priority to “rethink” the collaboration and content management environment
   - *Business model shift to a “collaborative- centric” environment is requiring a rapid change to processes, information flows, and global solutions*
   - *Requires innovation, not just “step-wise” investments or incremental solutions*
2. Business-to-business collaboration and content sharing remains a significant issue for many while Sponsor-to-Health Authority information exchange is effective and continues to improve
3. Clinical content (e.g. eTMF) is undergoing substantial investment and energy (80% of participants) to improve capabilities internally and with external partners
4. Regulatory Information Management is the clear trend as most view R&D content management, submission management, registration management, and labeling at a program level and are looking at individual vendors more strategically
5. Companies are slow to implement change to existing systems and are hesitant to adopt new technology and capabilities
   - *Fewer companies experimenting with “leading-edge” capabilities as most are taking a “wait and see” stance resulting in limited innovation*

6. The majority of vendors are focused on improving solutions for true global and mobile access while also creating new innovative solutions and services to support the shift to a collaborative-centric working environment
   - *ECM implementations are rapidly shifting from closed to open environments requiring reevaluation of security models to support external collaboration and workforce mobility*
7. SharePoint is the market leader in shared-space tools and is now gaining traction as a replacement for Documentum as a traditional ECM platform
   - *This viable alternative should fuel innovation (long overdue)*
8. Many are investigating Software as a Service (SaaS) and Cloud capabilities, but consider mature solutions and implementation for critical systems to be years away

Collaboration Section Summary

Collaboration methods, practices, and solutions continue to be a top priority for most participants with mixed results. Globalization and organization virtualization are 1) increasing the level and importance of collaboration solutions, 2) opening once closed content management systems and requiring mobile information access, and 3) requiring new leadership competencies to be effective in a global virtual workplace.

Our analysis found the following key points:

- Information exchange effectiveness continues to improve with Health Authorities due to the realization of ICH standards, adoption of HL7 and other standards and the use of electronic information exchange gateways
- Significant challenge for business to business (see Figure 2) information exchange continues since our 2009 benchmark. We believe a strong business case exists for improving this exchange (e.g. productivity, cost reduction, quality, and time savings)
- Affiliate collaboration levels have dramatically increased since 2009 due to emerging market support and the business goal of information transparency

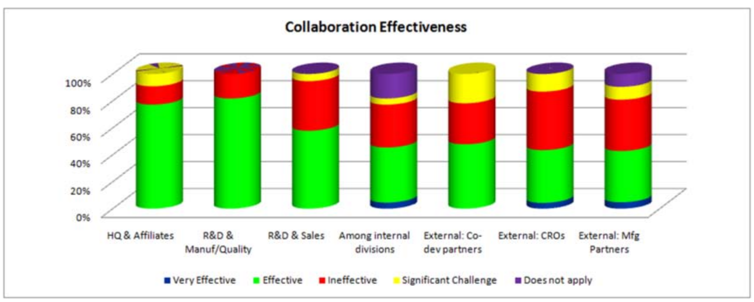

Figure 2 - Collaboration Effectiveness

- Global team effectiveness has strong positive ratings while mobile user access to internal ECM has low effectiveness ratings
- Adoption of social networking tools is slow compared to other industries
- 80% are using SharePoint for temporary collaboration practices

We believe significant investment will continue in this area for the next 2 – 4 years as companies adapt to the “collaborative centric” environment where global virtual teaming and instant “mobile” access to content is the norm.

General Content Management Trends

Overall, Content Management programs saw incremental improvement “across the board” compared to our 2009 survey and satisfaction levels increased for the first time since our initial tracking in 2007. Most participants continue to invest in ECM at a “program” level with several companies currently in a modernization cycle.

Our analysis found the following key points:

- Implementation of Clinical eTMF has grown significantly since 2009 with 80% changing or planning to change within 3 years
- Strong growth in ECM effectiveness for most content types
- Executives view ECM as mainly tactical (e.g. compliance) while several also view it strategically (e.g. processes that impact time to market).
- The industry made a significant move to provide more ECM access for external partners since our 2009 study; this continues to be a key priority (see Figure 3)
- Electronic signatures are gaining acceptance and demonstrating business results (e.g. improved efficiency)
- Minimal uptake of structured content authoring; industry still in “learn mode” with tool vendor solutions maturing

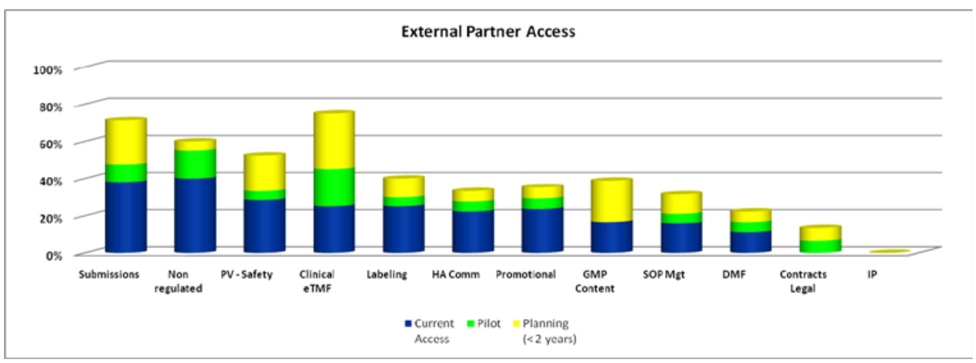

Figure 3: External Access to Content Type

We believe that companies will make incremental investments to improve their content management capabilities (usability, workflows, e-signatures etc.) and some will make significant investments to improve access by external partners because their business model requires it.

Research and Development (R&D) Initiatives / Content Management Trends

We have tracked many R&D initiatives and specific R&D content management capabilities since 2005 and found the industry as a whole is slow to adopt new standards unless they are mandated by Health Authorities (e.g. eCTD). We are finding this to be true for the DIA Reference Model and likely for the RPS submission format as well. The cancelation of the labeling PIM program earlier this year may result in a more cautious approach to new standard initiatives by industry and solution partners, in our opinion.

We found many participants espouse to have tight information integration with their content management platforms, however when compared to 2007 and 2009 data (see Figure 4), minimal movement from planned to production integrations was realized with the exception of Trial Master File (TMF) and Trial Management systems.

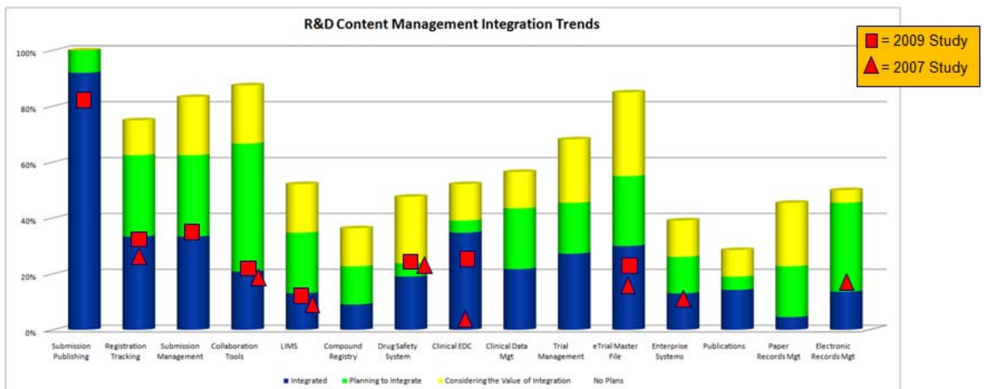

Figure 4: Integration Status

The top priorities for R&D content management programs changed slightly since 2009. Today collaboration tool integration, system performance, external partner access, and reduce total cost of ownership are the top 4 priorities respectively.

Other key points from our analysis include:

- The largest investment in R&D Content Management is SharePoint implementation
- The DIA Reference Model has significantly improved in terms of awareness and perceived value as it progresses towards a more widely used standard
  - Vendors are starting to adopt the model and provide actual implementation options
- The RPS standard is progressing toward adoption; however many participants cite implementation concerns /challenges
- The EMA announcement ending the PIM program has stopped all progress on PIM implementation and it is unknown if the EMA will “restart”, “rethink”, or “retire” PIM
- Regulatory Submission Outsourcing has high satisfaction levels with the most

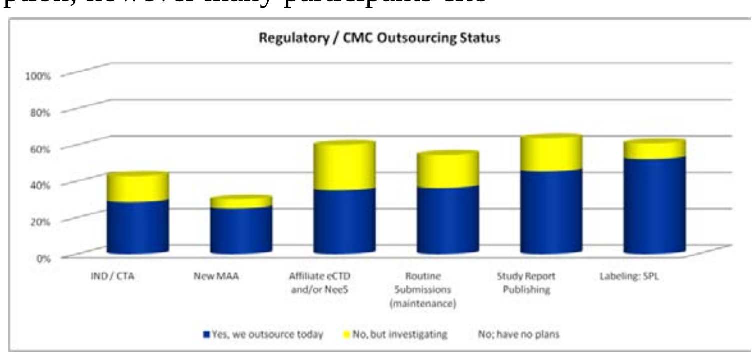

Figure 5: Dossier Outsourcing Status

focus (see Figure 5) on affiliate e-submission support and report level publishing (e.g. clinical study report). A variety of new methods have been piloted in industry with positive results (e.g. remote use of sponsor systems and processes by offshore labor).

Information Technology (IT) Management Trends

We introduced alternative IT solutions (SaaS and Cloud Computing), archiving program strategy, Enterprise Architecture status, and enterprise search capabilities for this year's analysis along with our continued tracking of off-the-shelf (OTS) versus customized solution trending.

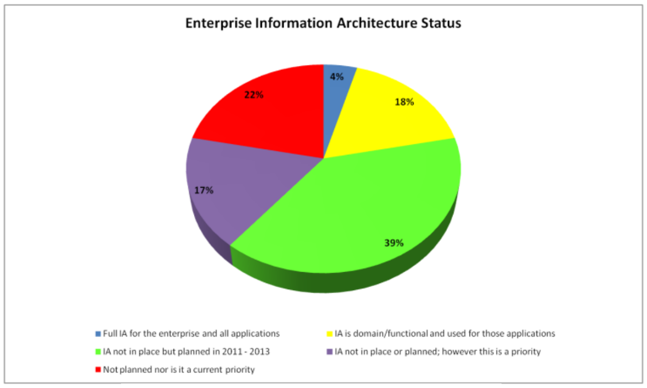

Figure 6: Enterprise Architecture Status

IT organizations are under tremendous pressure to improve capabilities, control cost, and manage an increasingly complex environment. Our results find more effort is being expended in managing capabilities from an enterprise standpoint with significant advances in enterprise search. There is also a growing priority around the development of Enterprise Architecture (see Figure 6) to guide information flows, integrations, and platform strategy. Most participants prefer off the shelf (OTS) solutions and value the ability to integrate different information solutions. However, our content management integration data is very clear that minimal progress is being made from a solution to solution integration standpoint.

Several vendors have adopted a Regulatory Information Management viewpoint that is gaining traction as a way to ensure that information integration is built into the solution as opposed to integrating multiple solutions in a "best of breed" approach.

Overall, vendor satisfaction has risen incrementally since 2009 with minor market-share change in the publishing and labeling areas. We clearly see a moderate change in the document management (movement to SharePoint), registration management (mature OTS solutions), and submission management (emerging solutions) areas.

Other key points from our analysis include:

- The trend to utilize OTS products continues as fewer participants have customized Documentum solutions although some still intend to upgrade their customized solutions – mainly in the top 15 companies in the industry
- SharePoint is being embraced as an alternative to Documentum with production examples in Clinical, TMF, and Quality Content Management systems
- Virtually all participants have or are developing an electronic record archiving program, however there is no clear leading provider of e-archiving solutions

- There is a high degree of interest in new capabilities such as Software as a Service or Cloud computing; however the number of production examples and pilots is still very low and are focused on clinical and promotional materials content
- There is a clear and growing interest and production use of enterprise search tools that support cross repository search and retrieval. We believe the use of these tools could support extending the life of existing systems by increasing access to and visibility of information in legacy systems
- Most companies continue to support a centralized approach to content distribution, often retaining a Citrix solution for global access
- 22% have Enterprise Information Architecture (EIA) programs in place and 56% are planning to have an EIA program within 2 years

We expect SaaS and Cloud to become viable options within 3 years as the technology matures and the adoption of industry data standards grow along with the realization of common industry practices for many content intensive processes. This combination will be very attractive for small and mid-tier companies who might prefer to "rent" a capability rather than incurring the cost of building and maintaining. We also expect progress on EIA that should help Information Managers become more strategic and solution portfolios easier to integrate across divisional lines.

Conclusion

The biopharmaceutical industry is maintaining quality and compliance through incremental changes to processes, technology and internal organizations. It is facing the challenge of supporting rapidly increasing collaboration among geographically dispersed virtual teams of internal colleagues and external partners. More than ever, Bio-pharmaceutical companies and will need to meet the challenge of maintaining quality and compliance while rapidly introducing new processes and capabilities to gain a competitive advantage in the global marketplace.

Other Industry Benchmarks

1. 2007 *Electronic Document Management/eCTD,* ILSS & Gens and Associates Inc.
2. 2008 *eCTD Pulse – Organizational Implications (Quantitative)*, Gens and Associates Inc.
3. 2009 *Electronic Document Management/Collaboration,* ILSS & Gens and Associates Inc.
4. 2009 *Industry Engagement*, Gens and Associates Inc.
5. 2010 *Regulatory Submission Management and Production Planning,* Gens and Associates Inc.
6. 2010 *Global Pharmaceutical Regulatory Affiliate Strategy,* Gens and Associates Inc.
7. 2010 *COTS Market Share Analysis*, Gens and Associates Inc.
8. 2010 *Regulatory Information Management Industry Benchmark*, Gens and Associates Inc
9. 2011 *Regulatory Trends*, Gens and Associates Inc.

Research Team

Steve Gens has 25 years of business experience with the majority in the biopharmaceutical and healthcare industries. His early career was spent at Johnson and Johnson and then moved into 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 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 and also with small high growth organizations that are planning for significant change. He has conducted 14 industry surveys that research areas such as collaboration practices, regulatory information management trends, enterprise content management, and virtual teaming effectiveness that are utilized extensively by industry and its key solution vendors. Steve has a Master of Science in Organization Development from American University and is certified in Change Management from the NTL Institute of Applied Behavior. **Contact:** **sgens@gens-associates.com** or **267-614-0935**

Steve Scribner is a seasoned consultant with over 40 years of experience in business solutions development. For the past 19 years, he has focused on enterprise document/content management consulting with 24 different engagements to build corporate vision and strategy in the Pharmaceutical or Life Sciences industries. He specializes in mergers and acquisitions, business value, strategy, user requirements, globalization, harmonization and business process redesign. He has a BSEE degree from Brigham Young University with an emphasis in Computer Architecture. **Contact:** **sscribner@ILSSconsulting.com** or **1-910-215-5539**

Greg Brolund is a Global Pharma management and technology consultant with extensive experience in business processes and supporting IT for product labeling, submission publishing, Health Authority interactions, pharmaceutical safety and pharmacovigilance programs. He served as the Rapporteur of the ICH M2 Working Group Rapporteur from 1998 through 2002 for the development of the initial production version of the eCTD and the implementation of the E2B ICSR electronic submission. He has 25 years experience with the FDA leading development of FDA's internal IT systems in support of the CDER and CBER submission review process. After leaving the FDA, he served as the US HHS CTO and was a pharmaceutical industry consultant with Booz Allen Hamilton. He holds a Masters of Chemistry degree from the American University in Washington DC. **Contact:** **gregbrolund@cfalls-llc.com**