Expert Advice:
Designing Systems for Global Content Processes

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Historically, as companies grew organically or through mergers and acquisitions, the desire for greater quality, speed and efficiency drove major process harmonization initiatives, which in turn drove system consolidation. In other situations, the reverse was true, and technology advances sparked process harmonization.

This is the case with the emergence of cloud. Cloud-based solutions are driving harmonization efforts in many life science companies today. Cloud solutions bring far-flung organizations together, unifying regional teams with each other and their partners. But harmonization efforts frequently displace people's familiar workflows and applications, which complicates implementation.

Effective content harmonization requires a global system that can balance the needs of the corporate office, satellite entities and partners. For corporate, the emphasis tends towards greater control and standardization, which enable process automation, streamlining and cost savings. Yet affiliates and regional offices have requirements and procedures that must also be accommodated to retire local, outmoded systems.

For companies considering content harmonization initiatives, this paper discusses best practices and the efficiency benefits they can expect from deploying a global system.

Why harmonize?
There are countless reasons for harmonization, but fundamentally, it comes down to improving efficiency and disseminating best practices across the organization. Anything that helps employees produce higher-quality work faster and with less duplication of effort is a good thing. Whether it's standardizing on a content platform for different corporate divisions or for one division that spans many continents, consolidation is an attractive goal for pharmaceutical companies. Yet transitioning to such a system isn't trivial, and corporate managers must work against

opposing forces such as corporate inertia, and the cost of system implementation and validation.

Large organizations commonly employ multiple systems for the same function. Companies and their affiliates are using on average three or more tools (e.g. Microsoft Excel, global system, regional system) to complete such tasks as managing labels and product registration information, preparing submissions or communicating with health authorities, according to several 2013 industry surveys by Gens and Associates. That's three or four ways to support the same regulatory activity, a duplication of effort that introduces both inefficiency and risk.

Breakdown of affiliates' time spent managing regulatory information

6% **4%**
15%
75%

RIM Tool Usage
HQ Info Requests
Duplicate Data Entry
Finding Info
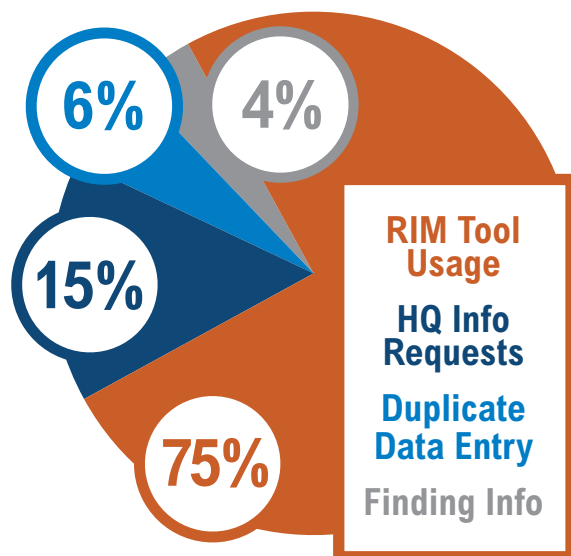
Source: 2013 Gens and Associates Industry Surveys

According to the survey of 43 affiliate offices representing 72 countries, 40% of time spent by local regulatory affairs professionals involves managing regulatory information, of which 25% is spent on "non-value added" activities such as reentering basic information and taking inquiries from other offices, because confidence in the quality of the information stored in global systems is low.

By enabling easy and secure access, centralized cloud solutions can circumvent the hurdles and risks introduced by operating separate systems. Instead of exchanging documents via email, sponsors make documents directly available to authorized parties both internally and throughout their partner ecosystem, thereby establishing an authoritative source for content.

Greater harmonization leads to increased productivity. By standardizing document names, locations and properties, people can access, reuse and report on information more rapidly. Duplicate effort is minimized, as are queries from headquarters. Instead of asking others to find information for them, people can find the documents and answers they need on their own. That also makes it easier for new employees to get up to speed, and accelerates transitions as employees move within the company.

Another benefit is automation, which can pay dividends when working with regulated documents within trial master files or regulatory submissions. These collections may comprise tens of thousands of different documents, many of which are contributed by individuals who are not familiar with the classification structure required by clinical or regulatory teams.

Best practices

So, how can you get started? No single approach will work for everyone, but some practices are universally beneficial.

• First, determine precisely why you want to harmonize and what benefits you hope to achieve. You will need to motivate users — the people actually using the system — based on the benefits they will derive.

• Next, assess the necessary scope and detail of standardization. Ask yourself these questions about each document type: what data do you need to easily find the right document? What information do you plan to reuse? What information is critical from a reporting perspective, both to ensure compliance and to monitor operating efficiencies?

• Whenever possible, standardize what you call things. Adopting industry-standard nomenclature makes it easier to collaborate with external partners successfully. If everyone else calls a document one thing, and your organization calls it another, your partners will need more training and make more errors when working with you, than they do with others.

- When designing your object model, define it with enough granularity that the system has the information it needs to automate processes and offload work from employees. For example, when managing clinical documents, one must include study, country and site, in order to auto-file an investigator's CV into the correct eTMF.

- Resist the temptation to require too many fields. Define sufficient metadata fields so users can find the information they want, but not so many that they become bogged down. The harder it is to input a file, the less likely people are to use the system.

- Let the application handle such tasks as file naming and numbering, version control and archiving. Users will then no longer need to remember if a file should be called "Financial Disclosure - Study 123 - Site 1234" or something else — the system does that work for them.

- Define the most fundamental base processes, and enable end-users to augment the process when appropriate. If one hardcodes a workflow with three levels of approval to reflect the process at headquarters, that workflow breaks down in satellite offices which have fewer layers of management. It is far better to have standard workflows that are inherently flexible, than to create multiple location-specific workflows for the same document type.

- Prioritize ease-of-use over accommodating every "what-if" scenario. Nothing impedes adoption of a new global framework more than making a system complicated to learn. Both navigation and training should be intuitive so that participants are motivated to forgo their local tools.

- Configure the application to automatically classify documents matching specified criteria into industry-standard taxonomies. Such solutions can ease the workload of employees who otherwise would do the work manually and increase the likelihood for error.

- Determine whether to serve related parties on the same application or to employ separate instances of the application. This decision is based on how much local autonomy is desired, and the level of integration available between instances of the application (note "local" can

Advice for the Executive Office

According to Tom Oblak, managing director for accelerated R&D services at Accenture, standardization enables companies to return to their scientific roots. By providing a consistent way of working, harmonization allows drug developers to concentrate on innovation, product development and science.

Oblack offers these tips for a smooth harmonization process:

First, understand why you want to harmonize. Standardization for standardization's sake isn't a compelling reason. Is the goal to achieve a particular quality objective or increase efficiency? Or, do you have another motivation? A predefined goal is required to guide system design decisions and make the best choices during implementation. Plus, without a clear and concrete advantage it will be difficult to get employees on board to change how they work.

Second, don't neglect the huge "change-management element" inherent in the success of harmonization projects. Identify a discrete business value that will encourage employee buy-in, but don't forget to engage workers to identify their needs and ease the transition between systems.

Increase Collaboration   **End-to-end Process Visibility**

Single Authoritative Source

Speed Time to Market   **Decrease Cost of Compliance**

refer to region, department or therapeutic area). You may want centralized user management and local control over business processes, or the reverse. Either way, you want a single authoritative source for your content.

Departments

Partners

Regions

HARMONIZATION

- Remember that successful change involves buy-in from those involved, so engage your employees to learn how these changes will affect their day-to-day work. Incorporating users' perspectives will help get them on board and minimize disruption to their jobs.

- Consider bringing in external support to facilitate the process. These projects are big but short-term, and benefit from a dedicated, singularly focused team that can deliver and move on.

Accommodating regional requirements

Naturally, friction may arise as companies begin to harmonize their systems and work processes. Users may wish to stick with what they know instead. Affiliates may prefer using locally-developed tools to capture their health authority-related correspondence and commitments. Simple differences in nomenclature can make it hard to find critical information, or for the system to automate tasks, like kicking off workflows to fulfill compliance-related obligations. Such work then must be done manually, which adds variability

and increases the likelihood of errors when preparing documents for health authorities.

Accommodating regional affiliates and partners adds another layer of difficulty. Local systems are typically easier for affiliates to use than a central system because they allow the affiliates to control data entry and define what information to capture.

> **"Affiliates want central systems in order to minimize the administrative overhead they face, but the systems must satisfy local requirements and be easy to use in order to decommission the local tools."**
>
> Steve Gens, managing partner at Gens and Associates

A central system must incorporate these local information requirements if regional affiliates are to decommission their local systems. Companies can standardize drug product, substance and manufacturing-relateding information, yet at the same time allow for flexibility with regional data such as local timelines for submissions, local filing fees, local shelf life and storage specifications. But pay attention to the user experience: the system must be designed so that it's easy to use and intuitive for all contributing parties.

Incorporating external partners

External or corporate partners are key stakeholders to keep in mind as you harmonize. R&D has become a highly networked business, with sponsors co-developing and deriving innovation from smaller research organizations. Outsourcing has become a routine aspect of drug development, and some 84% of the Gens and Associates survey respondents already outsource some part of their submission production efforts.

Harmonization enables companies to operate with external partners in a consistent way. Process, data and content become aligned, ensuring uniform quality output regardless of whether it is produced in-house, by a development partner or by a contract research organization.

Furthermore, having a global system in the cloud enables sponsors and partners to share documents and data directly. As a result, the boundaries between organizations become less relevant.

That's not only good for individual companies, it's good for everyone. "Cloud and harmonization move the industry toward a new way of working," says Tom Oblak, managing director for accelerated R&D services at Accenture. "In the future, there's an opportunity for utility-based solutions. You don't need a company-way when there's an industry-way of doing things that multiple companies adopt."

Conclusions

Without cloud applications, companies tend to place resources behind corporate firewalls. If external partners lack direct access, people transfer files by email, which is difficult to manage and introduces significant compliance risks. Furthermore, non-standard file naming and organization schemes make collaboration difficult even within a large organization.

Today companies can make their information systems broadly available in the cloud while maintaining control over content and security.

This combination of cloud flexibility, access and control allows content harmonization with business partners and regional affiliates in ways that were never previously possible. ■

About Veeva

Veeva Systems is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence and customer success, Veeva has more than 200 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Founded in 2007, Veeva is headquartered in the San Francisco Bay Area, with offices in Philadelphia, Columbus, Toronto, Barcelona, Budapest, London, Paris, Beijing, Shanghai, Osaka, Tokyo, Sydney, and Singapore. For more information, visit www.veeva.com