Audit: When it Comes to Digital Promotional Content, Does the Life Sciences Industry Know What It's Missing?

With most brand promotional content now available online, it's time for life sciences companies to apply the same rigor and controls to digital content as they do for print.

Executive Summary

Less than a decade ago, promotional content for the brands sold by companies in the life sciences industry was overwhelmingly in print form. In today’s digital era, however, the tide has turned. Most brand promotional content is now digital and can be found on diverse channels, including any number of branded Web sites, technology platforms and medical communications forums, to name a few. Thanks to the relative ease of digital publishing, brand- and disease state-related content can easily be tweaked to target different audience segments, translated into multiple languages and disseminated to various parts of the world.

However, there’s a downside to the ease of publishing digital content: compliance risk. The proliferation of digital content creates a variety of tracking challenges, raising the risk of inconsistently updated information across channels, expired content, incorrect versions published, lack of access control (for patients vs. providers vs. insurers, for instance) and poor functionality of the Web site on various technology platforms. The chance for error only increases when multiple agencies are involved with developing and publishing content. In some cases, brand leads or those responsible for compliance may not even be aware of all the channels that contain their various brands’ promotional content.

The fact is, despite the life sciences industry’s efforts to establish and follow rigorous controls for internal review and approval of content, many life sciences companies have not been successful in adhering to their own standard operating procedures to ensure digital content compliance. Given the hefty fines that can be levied for noncompliance – as well as the reputation risks of inconsistent brand messaging – this can be a costly oversight.

Life sciences businesses, therefore, need to up their game when it comes to digital content auditing to ensure that published content and publishing processes remain in compliance with the organization’s medical, regulatory and legal (MLR) requirements. Such an audit needs to identify potential risks in published digital promotional content on existing brands, as well as content in development. The audit must also utilize process, governance and technology mechanisms to address and rectify the audit’s findings.

This white paper examines the risks of digital content today and how an audit is the first step toward discovering and mitigating risk.
The Risks of Digital Content

The volume of brand promotional content disseminated on digital channels is overwhelming. Our rough estimate is that for any given brand, its promotional content could appear on 10 to 20 different Web sites, targeting a variety of audiences, including medical professionals, healthcare providers, patients and insurance companies. Adding to the complexity, large life sciences companies may work with numerous agencies to generate and publish their promotional materials.

But while there’s no turning back from the inexorable move toward digital for life sciences brand promotion, the road so far has been bumpier than many realize. As careful as life sciences companies have been in the print world regarding compliance of promotional content with MLR regulations, few such controls are in place in the digital environment.

Typical risks include:

- Inconsistent warnings on brand Web sites.
- Incorrect references to prescribing information.
- Unapproved content accessible without passwords on sites containing content still in development.
- Out-of-date materials.
- Difficulty identifying current version of information.
- Minimal tracking of digital materials.
- Inconsistent customer experience across all sites.
- Poor site functionality.
- Inconsistent experience across technology platforms.

The Importance of Audit

The only way for a company in the life sciences industry to understand and minimize its risk exposure is to perform an audit of all its promotional digital sites and content, including what’s already been published and what is in development. Audits ensure that the content accessible to the public is compliant, accurate and consistent, and that all Web sites featuring brand promotional content are operating as intended.

Audits can also be a catalyst for validating that the right people have the right access to relevant content, that all obsolete and expired content is purged, and that a consistent customer experience is delivered across all sites.

In a broad sense, the role of auditing is to track “the five W’s”: who did what, to which asset, when, and where. The goal of the audit is threefold: Track access to digital content, report on findings and where. The goal of the audit is threefold: Track access to digital content, report on findings and where. The goal of the audit is threefold: Track access to digital content, report on findings and where.

A complete audit function will assess four categories of activity (see Figure 1).
Here is a closer look at these four categories, as well as what needs to be assessed in each of these areas, with the goal of bringing the organization in line with industry norms (see sidebar).

**Digital Functionality**
With the array of browsers and mobile devices in use today, it is important for the designed functionality of all Web sites to work as expected, regardless of how users are accessing it. Life sciences businesses need to plan around the structure, substance, workflow and governance of each platform and be mindful of its usefulness and usability to create a meaningful and interactive user experience across platforms. Validating the look and feel across platforms should also be an essential part of the audit.

**Materials Management**
Ensuring that content is accurate and consistent across channels is a fundamental piece of digital promotions and is not a place to compromise. Consistent and accurate content can be established by developing clear business rules around content development, guided by supporting mechanisms such as a digital asset management (DAM) platform. The DAM platform also ensures that standard operating procedures are followed that encompass all assets that need to be verified via the audit, and it can incorporate these findings into future process or technology recommendations. (To learn more, please read “The Rise of DAMification” and “A Blueprint for DAM, MAM Cost Avoidance.”)

The materials management portion of the audit also needs to ensure that essential elements are accurate across platforms, including important safety information (ISI), prescribing information, medication guides, patient instructions and approved uses.

The audit also needs to baseline the current process against guidance from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the U.S. Food & Drug Administration (FDA) and enable updates of important information. Any asset that a digital agency helped create that is non-compliant also needs to be communicated back to the agency, and a corrective action plan should be created to avoid errors in the future.

**IT Internal Controls**
In this part of the audit, organizations need to ensure that the people developing the content have proper access permissions. This can be accomplished by creating user groups, establishing user roles and assigning access rights. Doing so will also help maintain version control and track content history.

Effective and ongoing training is essential to clearly define and effectively manage roles and responsibilities. Regular lessons-learned sessions should be scheduled to capture what went right and what went wrong during the process.

---

**Quick Take**

**A Look at Industry Norms for Brand Promotional Content**

The following industry norms should be in place for digital content to be efficient, effective and compliant:

- Web sites operate as expected and offer a meaningful and consistent user experience across platforms.
- Internal controls and training must be in place to prevent access to in-development content.
- Information should be consistent across brand-owned digital assets.
- Web sites should be updated within 10 days for important changes.
- A robust content management strategy needs to be in place to track materials.

**Ensuring that content is accurate and consistent across channels is a fundamental piece of digital promotions and is not a place to compromise.**

The materials management portion of the audit also needs to ensure that essential elements are accurate across platforms, including important safety information (ISI), prescribing information, medication guides, patient instructions and approved uses.

The audit also needs to baseline the current process against guidance from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the U.S. Food & Drug Administration (FDA) and enable updates of important information. Any asset that a digital agency helped create that is non-compliant also needs to be communicated back to the agency, and a corrective action plan should be created to avoid errors in the future.

**IT Internal Controls**
In this part of the audit, organizations need to ensure that the people developing the content have proper access permissions. This can be accomplished by creating user groups, establishing user roles and assigning access rights. Doing so will also help maintain version control and track content history.

Effective and ongoing training is essential to clearly define and effectively manage roles and responsibilities. Regular lessons-learned sessions should be scheduled to capture what went right and what went wrong during the process.
**Process**

This part of the audit focuses on formalizing a sustainable and repeatable system. To accomplish this, it is essential to develop effective processes and establish the right process owners, as this helps to monitor and track assets being developed, assess risks and provide supportive guidance for a consistent approach.

**Expected Benefits**

When a bio-pharma asked us to assess its digital promotional content process, we found several areas of concern. The organization did not have an overall MRL process owner, and multiple stakeholders were involved with digital development. There were no digital content compliance SOPs, and its digital content audit practices were ineffective. The organization had no way to ensure tracking of expired content, its digital agencies were not updating content, and there was no centralized content repository.

We identified an array of benefits the bio-pharma could expect by implementing a four-phased audit in the areas of digital functionality, IT internal controls, materials management and process (see Figure 2). Additionally, the company would ensure compliance since the audit established robust and regulated adherence to SOPs and business rules. Transparency and accountability would also be ensured, from the time digital content is created, to when it is made accessible to the public. And lastly, auditing would make sure the brand's value proposition was highlighted, and that the key messages are clear and concise.

**Looking Ahead**

The digital era has transformed industries so quickly that many are still in catch-up mode. This is the situation for life sciences companies when it comes to digital brand promotions. Many gaps exist in these companies’ current processes, and many are simply not structured to develop and follow a reliable process that will result in consistent, accurate and compliant digital content.

An audit is the first step to filling these gaps. For organizations to adopt an audit capability for their digital promotional content, they should consider the following steps:

- **Preparation:** Establish a project governance team, define preferred communications channels, identify key stakeholders, refine roles/responsibilities.
- **Kick-off:** Identify a project sponsor, schedule stakeholder discussions, begin reviewing all published digital content, begin capture of all current documents, refine plan and timelines as needed.

**Benefits of Digital Content Audits**

**Weeks 1-6**

- **Phase 1a: Digital Functionality**
  - Ensure functionality as intended across platforms.
  - Highlight customer experience differences within brand.
  - Uncover and remedy incorrect consumer direction.
  - Input for digital agency corrective actions.

- **Phase 1b: Materials Management**
  - Ensure consistency and accuracy of in-market content.
  - Establish audit findings baseline for future activities.
  - Incorporate findings into future process/technology recommendations.

- **Phase 2a: IT Internal Controls**
  - Ensure proper permissions/URLs for digital developers.
  - Recommend IT owners and training responsibilities.
  - Incorporate findings into future process/technology recommendations.

- **Phase 2b: Process**
  - Provide supportive guidance for consistency in approach.
  - Recommend process owners and training responsibilities.
  - Incorporate findings into future process/technology recommendations.
• **Stakeholder interviews/content assessment/SOP review:** Review current digital content and compliance SOPs, meet and summarize stakeholder findings, define the scope of existing digital content production and publishing risks across all brands, sponsor status report on potential scope of risks.

• **Complete assessments/draft summary:** Complete a draft analysis of current as-is assessment, reconvene stakeholders for refinement, provide sponsor with summary of draft gap analysis and future needs, schedule feedback session from sponsor.

• **Finalize delivery and presentation:** Refine final deliverable based on sponsor feedback, in conjunction with sponsor, conduct internal finding meetings.

An effective audit will identify risk scope, clarify the severity of any issues, rectify errors found, assess underlying causes and recommend remedies. With more digital content being generated every day, the time is now for the life sciences industry to apply the same controls and rigor to this environment as the old world of print.

---

**About the Authors**

Andrew Isaacs is a Principal in Cognizant’s Analytics Life Sciences Business Unit. He has over 25 years of life sciences experience, focusing on leading global commercial operations and technology optimization teams, marketing excellence, brand management teams, lifecycle planning, stakeholder management and governance/change management. Previous to Cognizant, Andrew was the commercial processes and practices lead for a global pharmaceuticals company and chief strategy officer for a life sciences medical communications agency. He also introduced “marketing excellence” at a global life sciences company and launched multiple products and services and oversight for global new product development. He has an undergraduate degree in biomedical engineering, an M.B.A./M.S. graduate degree and post-graduate certificates in project management and new product development. He recently authored the point of view “Accelerating Bio-Pharma’s Marketing Transformation.” Andrew can be reached at Andrew.Isaacs@cognizant.com.

Lovelina Gupta is a Senior Associate in Cognizant’s Analytics Practice. She has over eight years of experience in both life sciences and healthcare, with a key focus on the U.S. market. She has worked on tools that facilitate sales force restructuring and sizing, sales direction and call planning, and vacancy management, and she has provided recommendations for optimal sales force strategies and deployment of tactical-level sales planning for a leading pharmaceutical company in the U.S. Lovelina has a bachelor’s in electronics and communications engineering. She can be reached at Lovelina.Gupta@cognizant.com.

---

**About Cognizant**

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world’s leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 75 development and delivery centers worldwide and approximately 211,500 employees as of December 31, 2014, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at [www.cognizant.com](http://www.cognizant.com) or follow us on Twitter: Cognizant.