Executive Summary

Bio-pharma companies face multiple challenges when it comes to optimizing their two critical commercial processes: brand planning and promotional material review/approval. The two processes need to be effectively integrated in terms of their structure, governance, processes and systems, and their respective outputs need to be aligned to ensure that the promotional material is “in-market” within the window of opportunity and ahead of the competition (see Figure 1).

As the bio-pharma industry seeks to optimize its entire go-to-market model, the promotional material and approval process (spanning the legal, medical and regulatory functions, or LMR) is transforming from a transactional requirement into a competitive advantage.

Before embarking on such a transformation, bio-pharma organizations should have a clear understanding of the LMR process. This position paper outlines 10 key points to understand when considering an LMR transformation. It also highlights our industry-leading approach to

Achieving Equilibrium, Alignment

![Figure 1](image-url)
developing and implementing LMR transformation roadmaps (read more about our capabilities on page 7).

**Ten Key Questions**

1. **How are promotional materials developed?**
   Within a bio-pharma company, the commercial team (marketing) traditionally has ownership for transforming scientific data and brand messaging into clinical relevancy, as well as creating programs that can sustain anticipated behavioral changes.

   The marketing team, or other functions involved with originating promotional materials, will engage with various internal and external agencies in assessing and prioritizing the opportunities, as well as developing the strategies and tactics to achieve projected revenue and market share goals:

   - **External stakeholders** include promotional agencies, healthcare providers, patients, consumers, caregivers, patient advocacy groups, government agencies and clinical trial clinicians.
   - **Internal sources** typically include three key functional areas beyond the traditional commercial functions: Legal, medical and regulatory.

   The output is typically a tactical grid that includes a listing of the recommended activities, timing and costs needed to attain and sustain the brand goals. It can take weeks or months to develop and obtain the necessary approvals prior to using the promotional materials in the intended marketplace.

2. **What are the usual types of promotional materials?**
   Promotional materials are categorized to ensure it is clear to internal reviewers what the materials' purpose and intended audience are. This allows for classification upstream, as each of these types of materials has slightly different requirements.

   - **Branded materials** pertain to or refer to a product, either directly or implicitly (statements, colors, graphics, etc.). Examples include:
     - Product sales aids.
     - Advertisements.
     - Product learning systems.
   - **Unbranded materials** are intended for use with healthcare professionals and/or patients/consumers and do not directly or implicitly contain any reference to a product. Examples include:
     - Disease state information.
     - Healthcare policy presentation for a business meeting.
   - **Training materials** are provided to employees or agents involved in the direct promotion of prescription products. Examples include:
     - Train the trainer decks.
     - Training documents on a sales aid with a new indication.
   - **Field communications** are messages targeted at internal employees that may contain company and/or product information. Examples include:
     - Announcements on new clinical trials and publication of scientific studies or articles.
     - Updates to formulary status, drug pricing and reimbursement.
     - Instructions on selling strategies and tactics.

3. **Why are promotional materials reviewed and approved prior to distribution?**
   Global bio-pharma companies have internal directives, policies, standard operating procedures and work instructions to demonstrate their commitment to preserving the integrity of the host country’s healthcare system through compliance with the governing body requirements.

   In addition, these internal company initiatives are intended to create and sustain a culture of compliance and ethical behavior across the organization, as well as to demonstrate to external regulatory agencies that this is a key priority for the company and for all of its employees.

   The ultimate goal is to ensure there are appropriate and effective procedures in place to ensure that the company is in compliance with all applicable country laws and regulations, and that their employees conduct company business with integrity.
How are promotional materials reviewed and approved prior to distribution, and are there any specific requirements or regulations?

There is an internal LMR review of promotional material, typically initiated by the brand team or the functional area that has created the material. The LMR process defines the various functional area activities, as well as the roles and responsibilities for the submission, review, approval, production and distribution of promotional materials (see Figure 2).

Within the U.S., this process dictates that the steps, timing and functional roles for adherence to FDA regulations and related guidance documents, PhRMA and company policies – including standards of business conduct ethics and compliance code of conduct – that are designed to ensure information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner. It also ensures compliance with pertinent federal laws and regulations.

What U.S. government agency is involved, and what is its role?

The FDA comprises numerous branch agencies and offices. For instance, the Center for Drug and Evaluation Research (CDER) provides oversight for human prescription drugs and select biologics. Within CDER, there is the Office of Prescription Drug Promotion (OPDP), formerly the Division of Drug Marketing Advertising and Communication (DDMAC).

The OPDP’s mission is to protect the public health by ensuring that prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.

In addition, the Office of Inspector General’s (OIG) mission is to protect the integrity of Department of Health & Human Services (HHS) programs, as well as the health and welfare of program beneficiaries. Its Compliance Program Guidance for Pharmaceutical Manu-
facturers (the “OIG Compliance Guidance”) focuses on establishing and maintaining an effective compliance program; the integrity of pricing information provided to the government to establish payment amounts; industry relationships with healthcare professionals, particularly related to practices that have the potential to corrupt physician judgment (e.g., kickbacks); and compliance with the laws regulating drug samples. The OIG Compliance Guidance provides the foundation for the U.S. pharmaceuticals compliance program.

**6** Is there a U.S. industry advocacy group that helps establish guidelines?
The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading biopharmaceutical researchers and biotechnology companies. PhRMA’s mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies.

**7** What are the global (non-U.S.) requirements for establishing guidelines?
Global health authorities also influence the manner in which life sciences organizations review, submit and distribute promotional material. Organizations in the UK adhere to a self-certification process. The Association of the British Pharmaceutical Industry amended its Code of Practice to increase the transparency of working practices between the industry and healthcare professionals.

Germany, the leading drug market in the EU, requires long audit trails and comment histories to be available indefinitely. France, considered a highly regulated system, requires all promotional materials to be filed and approved before dissemination. Italy has a 10-day waiting period before executing promotion “at risk,” and Russia seeks to ensure that by 2020, the majority of drugs sold within its market are made by local manufacturers. Brazil reformed the way it evaluates regulatory submissions, and China has created its own approach.

Meanwhile, the International Center for Harmonization (ICH) has a forum for a constructive dialogue between regulatory authorities and the pharmaceuticals industry on the real and perceived differences in the technical requirements for product registration in the EU, U.S. and Japan in order to ensure a more timely introduction of new medicinal products and their availability to patients.

Ultimately, the same pharmaceuticals company operating in different countries will have unique requirements for promotional material review and approval, which will impact the process, timing, content, context and target audience.

**8** What are the pain points regarding existing LMR review and approval processes?
Although country regulatory bodies provide guidance on the overall promotional material review, approval and distribution process, each bio-pharma company takes its own approach to implementing directives, policies, SOPs and work instructions; therefore, no two companies are alike. In addition, there may also be significant variations in how individual companies operate and interact within and across each functional area.

Typically, the brand ownership function will release approved content to be tailored by each brand and/or market. If material is sent via e-mail or FTP, or there is a lack of system auditing, organizations will lose visibility into where or how that promotional piece has been used. This approach is inherently risky from a regulatory perspective, resulting in a proliferation of uncontrolled content copies and loss of version control.

Examples of pain points include:

- **The absence of a strong LMR operations governance model**, with the authority to establish priorities, approve resources and budgets, and ensure organizational alignment of behavioral changes, continuous improvement and quality metrics.

- **Effective development and deployment of directives, policies, SOPs and work instructions**, as they may not reflect the dynamic nature of the business’s need for timely action. They also may lack clarity on roles/responsibilities, foster utilization of complex escalation requirements and impose significant variations in functional reviewer risk management interpretations.

- **The transformation of the operating procedures into constractive technical specifications**, which can lead to signifi-
cant over-burdening of unnecessary “process-creep” and create an unfriendly and cumbersome technology barrier.

- **A lack of pre-LMR submission “gating filters”** to ensure material is submitted in a ready format for review and approval. Gating filters include upstream activities to accelerate the review/approval process, such as digital content and functional development (see Figure 3).

- **Inefficient utilization of a digital asset management (DAM) system and other factors, including the absence of promotional material utilization metrics, implementation of a corporate integrity agreement, acquisition of brands or other company legacy systems, changes in country regulatory requirements, regulatory body corrective actions, external creative agency actions and internal audit findings.**

What opportunities exist to optimize the LMR review and approval process?

Regardless of any given company’s situation, there is a clear, concise and effective methodology for assessing the current situation, identifying areas for improvement, prioritizing pain points, aligning the various stakeholders to participate in the solution, and establishing tangible metrics to achieve an efficient promotional material review and approval process.

Traditionally, organizations should focus on three main areas: people, process and technology. In addition, consideration should be given to the company’s LMR maturity level; that is, how does your organization compare with other peer companies relative to the number of brands, types and volume of materials, organizational structure and spend?

Figure 4 (next page) depicts a partial list of relevant questions to incorporate into a well-designed assessment plan.

What are the suggested first steps toward accelerating the transformation?

First off, no organization should feel the need to compromise on its ability to have material “market-ready” in a timely manner. The first step is asking a few fundamental questions to ensure that the key foundational commercial processes are balanced and aligned, including timing, resources and ownership.

Second, organizations should assess the current people, process and technology directives, policies, SOPs and work instructions, which will provide a significant source of forensic data to create a high-level LMR optimization roadmap.

Third, key stakeholders need to be aligned with the goals of the optimization initiative, incorporating the various user/administrator frustrations, the organizational culture and agreement on prioritization.
## Assessment Checklist

### People: How are they structured to ensure success?

<table>
<thead>
<tr>
<th>Highly Mature</th>
<th>Less Mature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global governance</td>
<td>Decentralized oversight</td>
</tr>
<tr>
<td>Country business lead sponsors</td>
<td>Single functional leadership</td>
</tr>
<tr>
<td>Commercial operations</td>
<td>Regulatory process ownership</td>
</tr>
<tr>
<td>Continuous improvement team</td>
<td>Ad hoc</td>
</tr>
<tr>
<td>Dedicated coordinators/facilitators</td>
<td>Functional leads</td>
</tr>
<tr>
<td>Dedicated librarians</td>
<td>Agency support</td>
</tr>
<tr>
<td>Routine communications</td>
<td>Technical communications</td>
</tr>
<tr>
<td>Comprehensive training</td>
<td>Process/technology training</td>
</tr>
<tr>
<td>Industry benchmarking</td>
<td>No assessments</td>
</tr>
</tbody>
</table>

### Process: Do we have a single voice on our approach?

<table>
<thead>
<tr>
<th>Highly Mature</th>
<th>Less Mature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk tolerance-based</td>
<td>Risk avoidance</td>
</tr>
<tr>
<td>Pre-review gating filters</td>
<td>Any material submitted</td>
</tr>
<tr>
<td>Designated reviewers</td>
<td>Mainly live meetings</td>
</tr>
<tr>
<td>Material classification</td>
<td>Full reviews</td>
</tr>
<tr>
<td>Digital material standards</td>
<td>All material equal</td>
</tr>
<tr>
<td>Digital beta reviews only on complex functionality</td>
<td>Digital beta reviews for all digital material</td>
</tr>
<tr>
<td>De-escalation procedures</td>
<td>Multiple review sessions</td>
</tr>
<tr>
<td>Effective champion/reviewer training</td>
<td>Process training</td>
</tr>
<tr>
<td>Material reviewer team charter training</td>
<td>Functional team training</td>
</tr>
</tbody>
</table>

### Technology: Do we have the right technology deployed the right way?

<table>
<thead>
<tr>
<th>Highly Mature</th>
<th>Less Mature</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-level process roadmap</td>
<td>Technical specifications</td>
</tr>
<tr>
<td>Global platform</td>
<td>Country-specific</td>
</tr>
<tr>
<td>Cloud-based</td>
<td>Local system operations</td>
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<tr>
<td>Global content sharing</td>
<td>Individual country development</td>
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<tr>
<td>Content audit/tracking</td>
<td>Post-compliance violation report review</td>
</tr>
<tr>
<td>Material development flow</td>
<td>Process-centric flow</td>
</tr>
<tr>
<td>FDA Form 2253 integration</td>
<td>Offline</td>
</tr>
<tr>
<td>Digital asset management system</td>
<td>Separate repositories</td>
</tr>
<tr>
<td>Integrated reference library</td>
<td>Separate attachments</td>
</tr>
<tr>
<td>Promotional asset management integration</td>
<td>Stand-alone</td>
</tr>
<tr>
<td>Creative agency interface</td>
<td>Separate creative repositories</td>
</tr>
<tr>
<td>Reviewer time management</td>
<td>Not measured</td>
</tr>
<tr>
<td>On-site support teams</td>
<td>On/off-site support</td>
</tr>
<tr>
<td>Automated metrics</td>
<td>Ad hoc reporting</td>
</tr>
</tbody>
</table>

Figure 4
**Our Experience and Lessons Learned**

When choosing a partner, organizations need to look for a foundational understanding of the four key LMR process pillars (see Figure 5), coupled with deep expertise and proven methodologies for accelerating the assessment, recommendations and implementation of change across the entire promotional materials development and approval value chain.

Our LMR workstream methodologies focus on measurable optimization achievements to address existing pain points and behavioral changes, upstream pre-LMR gating filters and volume constraints, and structure and sustainability resource modeling (see Figure 6, next page).

Without a comprehensive methodology for an LMR transformation, many companies wind up exerting a significant amount of time and resources, only to have such efforts wasted, as improvement pain-points, behaviors and volume return to their prior levels. This avoidable cycle then leads to additional frustrations and delays in getting material in-market. With the right partner, sustainability can be successfully structured, measured and pursued as a collaborative effort.

We partner with 27 of the top 30 global pharmaceutical companies, supporting the assessment and optimization of every aspect of their commercial, research and development, clinical and medical operations processes, including global promotional material review and approval processes and technologies.

Several examples of how we have supported the assessment, prioritization, value realization and implementation of transformative activities include:

- **SOP optimization, resulting in significant efficiencies:** We have initiated significant changes in the LMR process within weeks that would normally take months or years to implement the “old way.” The end result was a decline in help desk inquiries by over 80% and a throughput increase of over 30%.

- **Process compliance audits that identified and eliminated gaps:** We have partnered with LMR and compliance teams to assess and conduct internal audits to uncover gaps in existing review processes that ultimately eliminated the offending concerns that required proactive communications with regulatory bodies.

- **Governance, process and technology assessments, resulting in validated investments:** We have partnered with LMR and operations teams to justify radical changes in organizational structure and technology investments. The financial justification was easily recouped in the man-hours spent reviewing material and reworking creative material.

- **Agency, analytics and digital content production optimization, resulting in added value:** We have led large cross-functional teams, including procurement, analytics, digital hubs, brand management, business process, LMR, IT and information management, to decouple

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**LMR Process Pillars**

- **Structure/Resourcing:** Centralized operations team to manage the LMR review process.
  - Centralized team most often resides in commercial/marketing operations with both process and system responsibilities.

- **Governance:** A formal, cross-functional governance team to make strategic decisions.
  - Formal vision/mission for the LMR function, with clear mutual and/or individual objectives, reflecting a more strategic view/direction for the function.

- **Process:** Marketing operations typically “owns” the SOP, facilitates updates and enforces compliance; governance team reviews and endorses all changes.
  - Final review decision through the consensus of the LMR review team.

- **System/Metrics:** Best practice is the movement toward a common technical platform that is configurable based on local country needs.
  - Most organizations need a more robust metrics/reporting capability.

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Figure 5
non-added value services from their creative agencies to allow for a flexible and streamlined approach to content creation, digital development, campaign analytics-effectiveness, and on/off-site LMR operations support.

Contact us at inquiries@cognizant.com to discuss how our expertise, insights and recommendations can accelerate your assessment, optimization and promotional material throughput.

About the Author

Andrew Isaacs is a Principal in Cognizant’s Marketing and Marketing Analytics Practice. He has over 25 years of life sciences experience, focusing on leading global commercial operations and technology optimization teams, marketing excellence, brand management teams, life cycle 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. Andrew can be reached at Andrew.Isaacs@cognizant.com.

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