



Taking Control of the MLR Review Process

In today's increasingly automated, hyper-connected world, pharmaceuticals companies must ensure that medical, legal and regulatory reviews are accurate, efficient, and risk-averse.

EXECUTIVE SUMMARY

Pharmaceuticals and biotech companies routinely undergo medical, legal, and regulatory (MLR) review to ensure that their products' claims, promotions, and training programs are medically accurate and in compliance with Federal Drug Administration (FDA) standards and other regulations.

This typically requires enterprises to establish promotional review committees (PRC) made up of cross-functional teams comprising medical, legal and regulatory experts. Understandably, PRCs must be extremely knowledgeable and precise; otherwise, drug companies run the risk of receiving warning letters from the FDA. The MLR process requires project managers to work closely with reviewers and key stakeholders – from marketing and advertising agencies to corporate leadership – to ensure that everyone's voice is heard. Simultaneously, marketing managers must get their products to market in a timely manner and avoid delays that can negatively affect financial performance.

Promotional materials target either consumers or healthcare professionals, and are distributed across various types of media, including print (brochures, posters, banner ads, flashcards, etc.) and digital (websites, mobile apps, TV commercials, interactive e-mails/PDFs, etc.).

This white paper explores the different phases of the MLR process and how analytics can be applied to answer key questions project/brand managers face, such as:

- How much time does it take for promotional material to reach consumers?
- What percentage of these materials is used versus the volume produced?
- What are the process bottlenecks that hold up the distribution of these materials?
- What KPIs should be monitored to help project managers track the material throughout the process (e.g., at what stage is it stuck in the pipeline? What are the reasons behind the delay?).

PROMOTIONAL MATERIAL REVIEW

The review process for promotional material typically starts with strategic planning – progressing through multiple stages over time. Figure 1 depicts the three broad phases (upstream, midstream, and downstream) of promotional material development and dissemination.

Upstream Phase

This phase starts with strategic discussions between marketing and leadership teams to review the market, the brand, and the proposed product portfolio, then moves to brand positioning and tactical planning. Once this stage is completed, organizations usually engage external agencies to gather ideas and recommendations for the product portfolio.

Key marketing team members and external agencies work together to develop project requirements and timelines based on the tactical calendar and business goals. Agencies then create an initial concept, and submit it to the marketers for their review. Following that step, the project moves to the next stage for kick-off with key stakeholders.

Midstream Phase

This phase begins with a kick-off meeting to help project managers connect with various stakeholders; introduce the promotion/marketing initiative; and assess how team members can leverage their area of expertise. The team typically includes key personnel from marketing; project managers; reviewers (medical, legal, and regulatory); external vendors (print and technology); senior leadership, and consultants.

Dissecting the Review Process

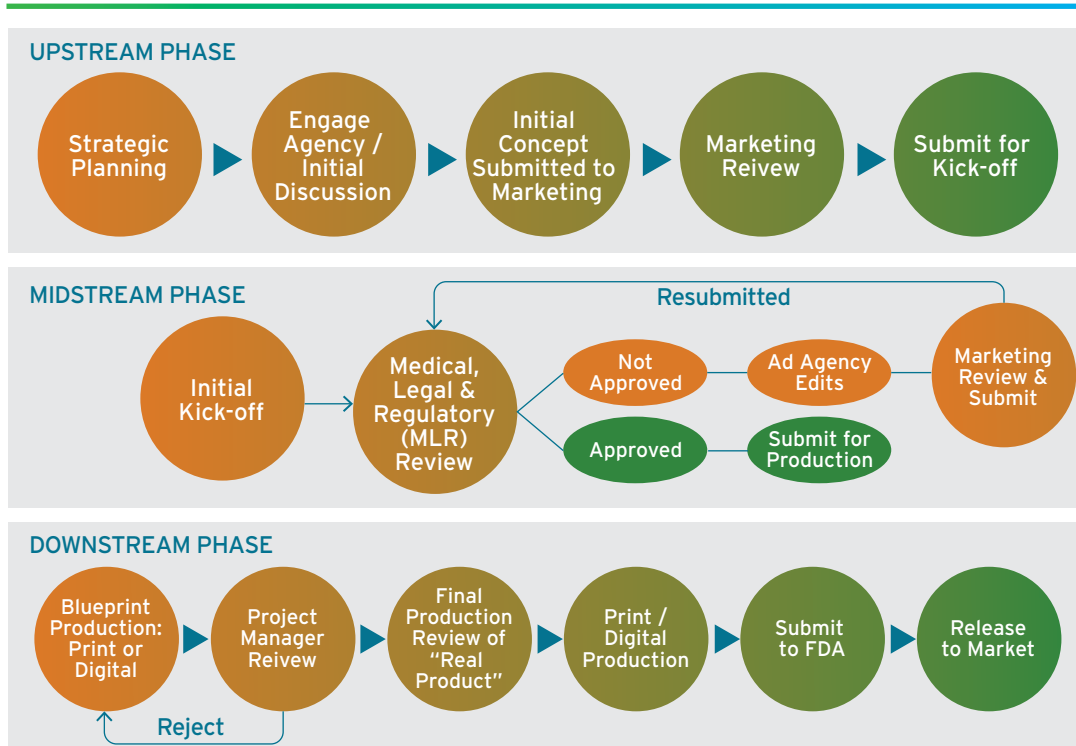


Figure 1

For pharmaceuticals companies, accelerating time to market requires a review process that is informed, cost-efficient and risk-averse.

The purpose is to share ideas, offer suggestions, and identify potential challenges/gaps that could stall or slow the initiative.

Following the kick-off meeting, marketing and external agency partners typically go through multiple iterations of the project concept before presenting it to reviewers for their respective approvals. Medical, legal, and regulatory reviewers scrutinize the content of the material to ensure that it is correct, consistent, and in line with the rules, regulations, and FDA guidelines within their area of expertise.

Downstream Phase

At this stage, the vendor submits the blueprint for print and/or digital for final review and signoff by the client organization to ensure that all requested changes have been incorporated. This usually entails multiple exchanges between the vendor and the client prior to signoff. Digital projects typically go through more iterations before they are submitted to the FDA prior to hitting the market.

PROBLEM STATEMENT

For pharmaceuticals companies, accelerating time to market requires a review process that is informed, cost-efficient and risk-averse.

Typical Challenges

Typically, marketing initiatives are based on an organization's requirements or developed in response to industry dynamics. Nonetheless, reviewers are often time-challenged due to industry resource reductions and competing initiatives that also demand their attention.

In the following pages, we will examine how to develop and optimize an MLR process that will have the desired impact and make the most of an organization's current resources. Most often, the number of projects evaluated or conceptualized at the strategic level declines before the next stage of project creation and review. Other projects are shelved before they reach the next stage of production due to factors such as budget cuts and market shifts. End users (e.g., sales representatives, healthcare professionals, pharmacies, and patients) end up ordering only a fraction of products produced and stored in warehouses. This funnel structure (see Figure 4, page 7) requires several tactical adjustments in order to deliver the expected outcome.

To determine the scope and goals of a project, companies must define key performance indicators (KPIs), which will help gauge the effectiveness of their efforts as they work through the process of preparing materials for MLR review.

APPLYING AN ANALYTICAL APPROACH

To address this situation, we recommend a systematic process for evaluating a project and plugging in the right parameters at the right time to achieve a common goal. All key stakeholders (marketing teams, reviewers, external agencies, leadership) must be aligned and in place from a project's beginning. A thorough analysis of key areas for improvement must be performed, and potential bottlenecks identified. To determine the scope and goals of a project, companies must define key performance indicators (KPIs), which will help gauge the effectiveness of their efforts as they work through the process of preparing materials for MLR review.

KPIs must be clearly defined and quantifiable, in line with stated business goals, and easy to

communicate to project teams within and outside the organization (see Figure 2).

While there are thousands of KPIs to choose from, many companies find it difficult to select those that fit the needs of their business and marketing requirements. Research tells us that less than 10% of all the metrics that are collected, analyzed, and reported in businesses are used to inform decision making. Even worse, 90% of the metrics produced end up overwhelming decision makers, who are thirsting for insights.¹

Analytics technologies enable companies to examine and decipher vast amounts of data that can be used to deepen knowledge, enlighten decisions, and develop KPIs that suit their precise requirements. KPIs are defined around the needs of MLR teams and regularly monitored to help spot gaps and target opportunities for improving accuracy and efficiency.

Developing Relevant KPIs

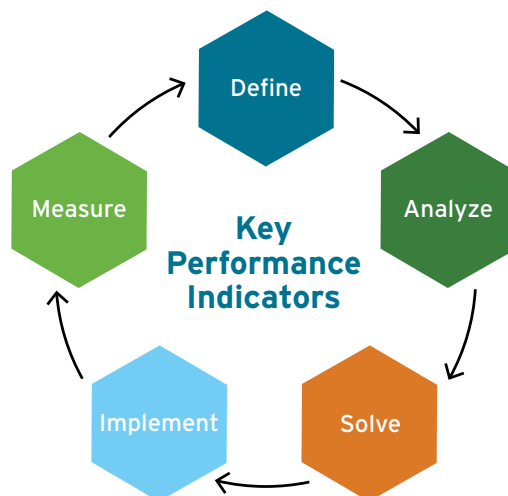


Figure 2

CREATING MEANINGFUL KPIS

There are numerous KPIs for tracking process efficiency. Figure 3 lists some of the most common ones.

These KPIs can help make the entire MLR process more efficient, and potentially generate more returns for the business (See Figure 4, page 7).

At the same time, KPIs must be monitored over a sufficient period, roughly three to six months, to properly assess their value. Having a comprehensive view of product KPIs helps marketers and reviewers streamline project planning, improve inputs, simplify the review process, and produce marketing material that is accurate, relevant and effective.

Prioritizing KPIs

S No.	Key Performance Indicators (KPIs)	Description	Value-Add
1	Entire Project Duration	Days to close a project, from initial kick-off to FDA submission.	Serves as top-level health metric to account for project duration.
2	Duration by Project Type	Classification of duration by project type (e.g., websites, e-mail, marketing collateral).	Predicts project completion based on type.
3	Duration of Each Stage of the Process	Classification of project duration at each step in the review process (e.g., medical, regulatory, legal review).	Uncovers bottlenecks throughout the process (high project volumes, changing priorities, product acquisitions, etc.).
4	Cycles/Churn at Each Stage	Number of rejections by medical/legal/regulatory/IT throughout the review process.	Helps assess the bottlenecks that might delay project completion.
5	Reasons for Additional Cycles	Number of projects rejected and the reasons cited by the reviewer.	Helps understand the cause of bottlenecks (unclear guidance from marketing, incorrect files, agency errors).
6	Stakeholder (Internal/External) Accountability	Assessment of the key stakeholders who are accountable for rejections at any stage.	Extends accountability to include not only the marketing team, but also internal/external parties.
7	Products Produced & Available in Inventory	Number and names of products produced and their availability in the inventory of internal/external vendors.	Enables the company to keep a close watch on products in inventory and their warehousing cost.
8	Products Ordered	Number of products ordered by end users (sales rep, HCP, patient, etc.).	Helps assess actual product utilization.

Figure 3

Aligning KPIs & Measurements: The Current Process

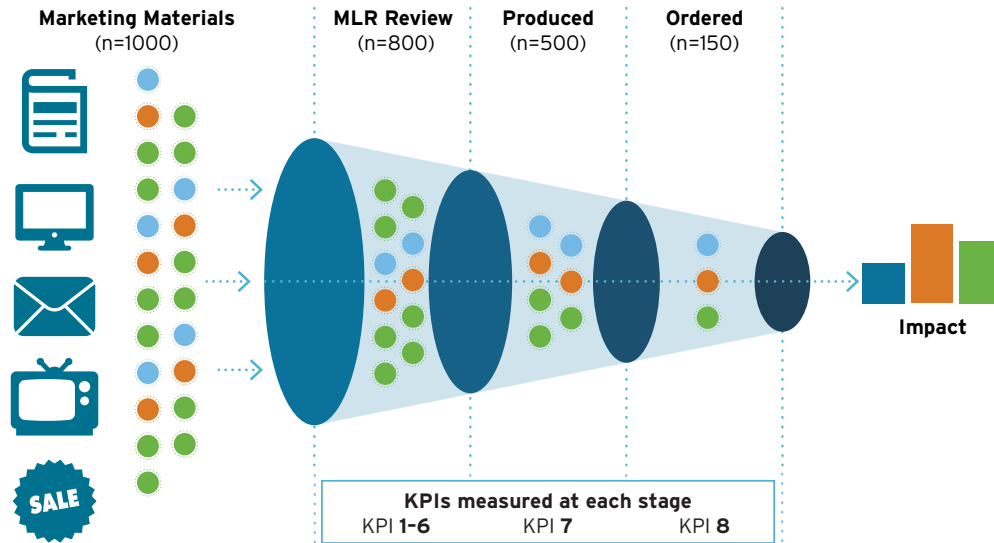


Figure 4

Aligning KPIs & Measurements: The Proposed Solution

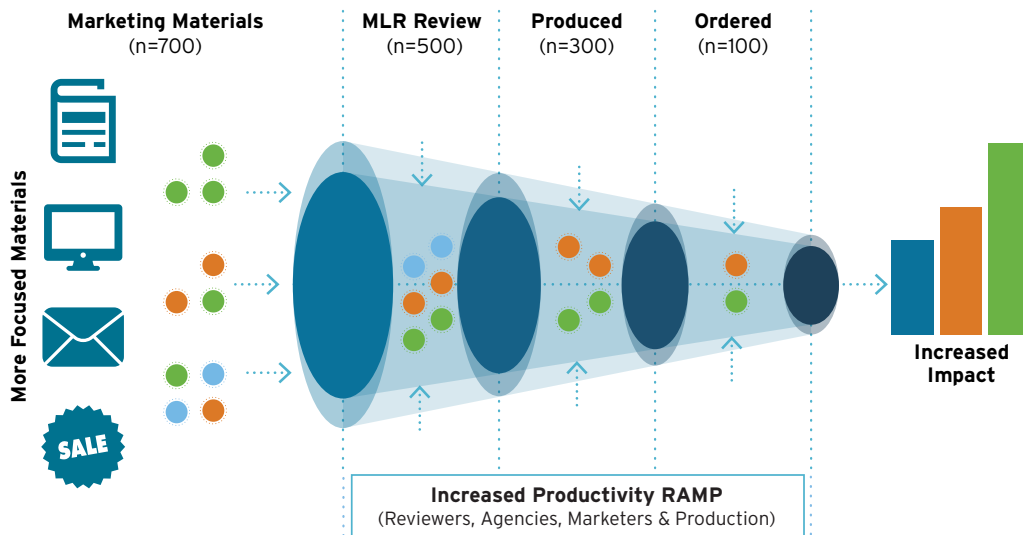


Figure 5

LOOKING FORWARD

The MLR process depends on balancing the collective efforts of reviewers, marketing teams, agencies, and production (print/digital). The goal is to produce promotional materials that are accurate, timely, focused, and adaptable for use in future promotions. In this way, companies can avoid flooding the market and overwhelming end users with too much information, and reduce the

workload for reviewers, agencies, sales channels, and production resources (see Figure 5). This approach (as detailed in the Quick Take on page 8) allows pharmaceuticals and biotech companies to leverage their investment in strategic promotions, assure the quality and integrity of their product portfolio, bring new products to market faster, and improve the MLR review process at every stage.

QUICK TAKE

Leading Pharma Company Takes Hold of the MLR Process

The client, a top pharmaceuticals company, utilized a robust promotional/educational material review process. All materials (brochures, ads, flashcards, rep-education assets, etc.) from the marketing team required multiple approvals by various groups (medical, regulatory, legal, compliance, IT) before going live. The client wanted to identify key bottlenecks and reduce turnaround time initially by one-third and eventually by one-half.

We collaborated with the company to:

- **Conduct a comprehensive data analysis**, tracking the average duration of the materials at each stage of the review process using historical data.
- **Identify relevant KPIs** that could ferret out bottlenecks in the review process.
 - » This analysis considered various factors – brand, media type (print vs. digital), material type (ad board, brochure, flashcards, etc.) – to understand the KPIs from different perspectives.
- **Create an executive-level, interactive dashboard** that marketing directors could use to assess the process month to month.

Because of this analysis, the client can now take advantage of:

- Interactive insights that enable the company's marketing team to gauge performance against KPIs and identify obstacles monthly.
- Information that enables the company's senior leadership to take immediate action and move projects faster through the review process.
- Reduced turnaround time (TAT) by ~40%.

FOOTNOTE

- ¹ www.ap-institute.com/what-is-a-key-performance-indicator.aspx.

REFERENCES

- <http://blog.themsls.org/2014/07/7-essential-considerations-about-promotional-material-review-and-approval/>.
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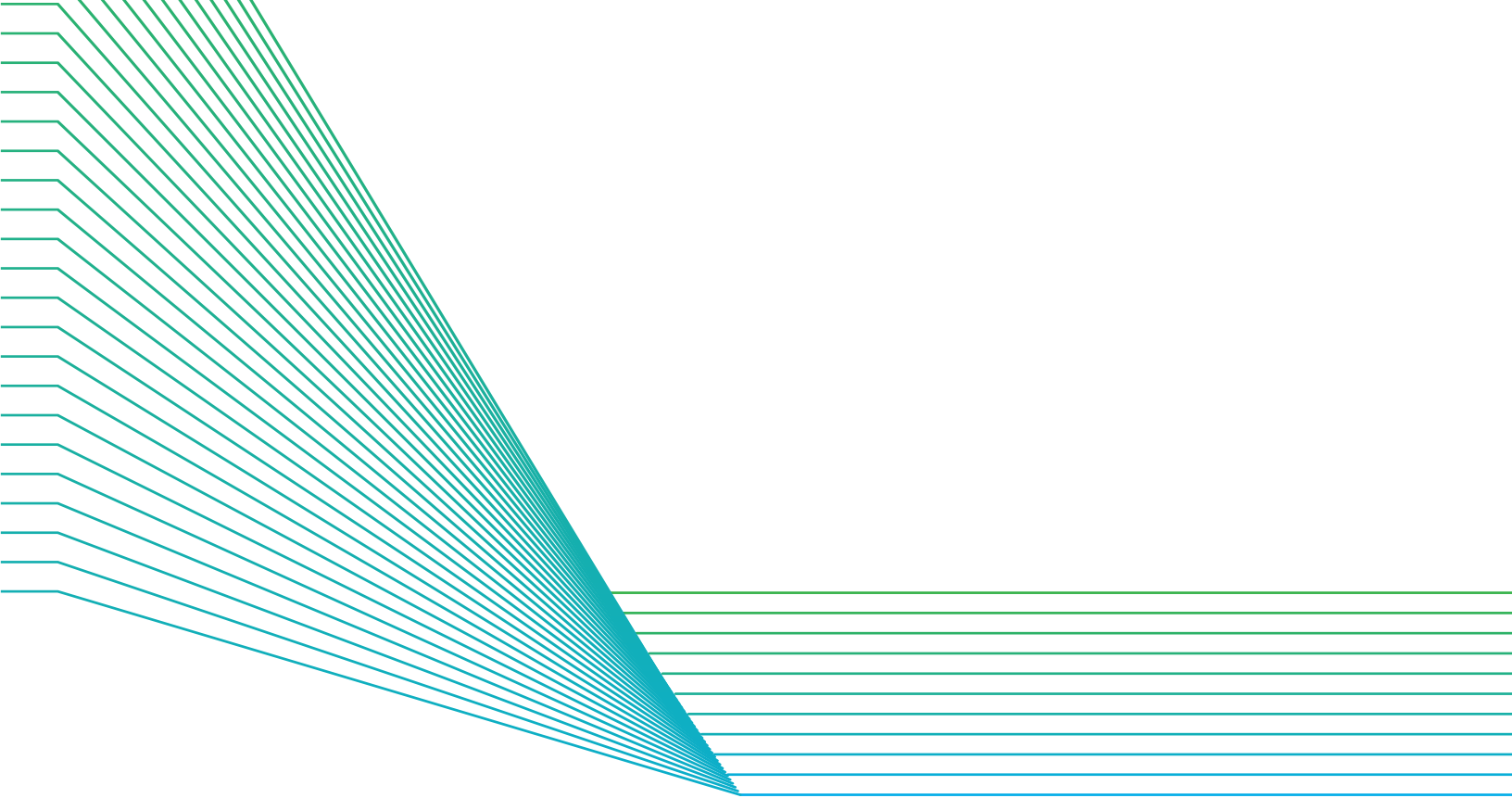
Ketki Gupta has more than nine years of experience in the field of analytics for the pharmaceuticals industry. Ketki has worked on a wide range of analytics projects, including promotion response modeling, sales force effectiveness, ROI for campaign management, and speaker program compliance and effectiveness. She also focuses on consulting and analytics around process efficiencies in various departments across the pharma industry. She holds a master's degree in Applied Operational Research and a bachelor's degree in statistics from Delhi University.

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ABOUT COGNIZANT ANALYTICS

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ABOUT COGNIZANT

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