Building Blocks for Greater Promotional Review Agility

How to Accelerate Promotional Content Development and Review

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These are the opinions of the contributors and not necessarily the organizations where they work.

This White Paper shines a spotlight on four fundamental building blocks* for greater promotional review agility as the need for faster review and approval of assets intensifies

Medical, legal, and regulatory (MLR) reviewers and commercial operations executives want to support their commercial organization by speeding up the approval of personalized, bite-sized and precise content required for customer centricity.

However, just because the industry is moving from paper to clicks does not mean that quality and compliance standards will be overlooked by MLR.

The key question: can agility and risk management co-exist?

Agility is the ability of an organization to effectively satisfy its target market by rapidly responding to change with a high degree of flexibility.

Is it possible to have a fast- moving promotional review process while ensuring regulatory compliance?

MLR professionals play an important role in advancing business objectives by making sure that materials get through review in a timely manner. That includes being flexible, for example, when there are extenuating circumstances, like the need to move material from print to digital to address the Covid-19 pandemic.

At the same time, commercial professionals have to be accountable for not engaging in activities that slow review down. For example, it is understandable that the commercial organization wants to update and refresh certain key promotional elements in branded campaigns.

Ideally, automation can support the commercial need for having a range of expressions to best align with the customer's role and communication style.

67%

are only moderately confident that derivative promotional assets can be reviewed more quickly because they always align with core messages

The COVID-19 pandemic places a huge pressure on a company's review team given the amount of digital content required.

Everyone wants approved content faster and completed yesterday.

*FUNDAMENTAL BUILDING BLOCKS TO BALANCE AGILITY WITH COMPLIANCE:

1 **Foster a collaborative mindset to achieve the need for speed**

2 **Ensure optimal knowledge sharing and protect historical knowledge**

3 **Automate critical steps in the process with AI to eliminate preventable errors**

**Building blocks are based on the Fierce Pharma Virtual Conference: a survey of attendees (N = 300), 10/13-16, 2020, and a panel presentation by contributors to this White Paper; interviews with executives on the AI journey; and testing of AI software during a proof of Concept (POC).*

1 Foster a collaborative mindset to achieve the need for speed

Everyone involved in the development, review and approval of content must commit to collaborative mindset. Flexibility is needed to keep content fresh throughout waves of a campaign, as there are many factors that can impact the campaign, such as content to support customer-driven digital engagement, changes in management direction, competitive intelligence to address, new market event, tailoring and adapting core materials for different HCP roles and addressing customer and field feedback.

However, content originators working on truly derivative pieces need to do their part by focusing on existing approved claims with required contextual information. It's best to avoid adding extra claims because it means that the piece is no longer a true derivative and can be rendered not approvable. It is possible to increase message frequency by repurposing already approved content.

All stakeholders can create a faster process by doing their own part, including putting the materials into the process that are close to approvable as possible. When the same claim is expressed eight different ways compared to the already established approved claims, reviews become longer. Sticking to approved messages shorten reviews. Developing dynamic claim libraries that are automated and updated by applying technology can facilitate this objective.

All team members from the start of the project must agree not to waste time and commit to preventing tos and fros.

When materials come in complete with the required context, the review process is smoother.

In addition to context, "complete" can be defined as overall being accurate, and consistent with approved claims, and no nuisance errors or typos in the ISI.

Promotional review teams would naturally expect the derivative pieces to sail through because they are built on already approved messages. Yet, over the years, derivative promotional materials continue to suffer from two kinds of scope creep:

1)) Project owners tweak the existing language in the materials

2) Reviewers change their mind

In both cases, the question needs to be asked: are these changes a must or a preference.

2 Ensure optimal knowledge sharing and protect historical knowledge

The need exists for a dynamic Claims Library for each brand that is accurate and always current. When you have an historical decision, and the only person who knows the answer to a specific question has left the company, time and resources are wasted. Claims and core message catalogs speed review by ensuring that all team members have access to approved messages on demand. They also offer a potential solution for achieving knowledge sharing and providing visibility to historical data.

75% of survey respondents do not have a centralized repository of approved messages.

It's inefficient to onboard new team members with no record of approved phrases, graphics, or environments. Content originators can easily submit materials that are violative, leading the commercial teams to spend money on assets that can't be approved.

Static claims libraries don't automatically update as new claims are approved and as previously approved claims are modified that are no longer approved for use. A dynamic claims library is updated in real-time with each approval or change in MRL or FDA guidance.

Interim steps to developing formal centralized database can include creating binders within your promotional review system that house the latest marketing materials. However, manual management of a claims database can be costly or time consuming to get it started. AI software can simplify the process so it's not a heavy-lift.

3 Automate basic steps in the process with AI to eliminate preventable errors

Use of AI has grown dramatically. Now AI solutions are available to improve content quality before MLR review. This is a significant advance since checking content for errors pre-MLR review has been manual for decades.

It is time consuming for reviewers to manually check content for accuracy and quality. A manual process also increases the likelihood of errors and redundancies, and creates variability in approved content. For example, errors in phone numbers for patient services are problematic. It's easy to miss errors when you are reviewing dozens of materials. AI can potentially give you another layer of accountability.

When asked to prioritize the number one barrier to a faster review process, the following errors were cited:

1. deviations from approved claims
2. incorrect or lack of context/qualifiers
3. general nuisance errors

Organizations no longer have to build a custom AI solution with high development costs and complex business rules. Software-as-a-service (SaaS) AI options are available for rapid deployment and minimal start up time, making AI easy to test with no disruption to an organization.

There are tools comparing AI use versus manual execution that can be employed to quantify the potential savings when new technology for pre- MLR review is utilized. An ROI Calculator can quantify the benefits of AI use pre-MLR review. For a company with an average of 1000 promotional pieces/ year, over $150,000 and nearly 3000 hours can be saved through automation. Targeted AI Proof of Concepts (POC) can provide robust metrics for comparison to historical data.

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Doreen V. Morgan, Pharm.D., M.S. has extensive drug development and global regulatory strategy expertise, including contributions leading to FDA approvals in multiple therapeutic fields. Currently, Dr. Morgan is Vice President Global Regulatory at Mesoblast Inc. having been VP Regulatory and QA at LEO Pharma Inc. Her career is defined by global leadership and key stakeholder engagement at mid to large pharmaceutical companies. Dr. Morgan has a B.S. in Pharmacy, M.S. in Clinical Therapeutics and Doctor of Pharmacy from St. John's University.

Joyce Pearl, Director of Commercial Communications at Mallinckrodt, previously the Director of Marketing Services. Joyce has over 20 years of Pharmaceutical experience. Starting out on the vendor side creating material to be reviewed and then managing the review process, training and editorial group at Novo Nordisk. At her time at Mallinckrodt, Joyce managed the Marketing Material process from Promotional Review through field distribution. Joyce worked to streamline the process, align the organization and strengthen communication and collaboration across multiple teams.

Ilyssa Levins founded SecureCHEK AI to help pharmaceutical and medical device companies save time and money, while managing risk. A 35+ year industry veteran, Ilyssa understands how to achieve both business and regulatory compliance objectives. An award-winning futurist, and published author, Ilyssa is on the cutting edge of applying artificial intelligence and natural language processing to increase the quality of content submitted for MLR review. Ilyssa was named one of the industry's 100 Inspiring People by PharmaVoice Magazine.