MLR Review: Pitfalls to Avoid and Three Keys to Success

Insights from Baxter, Cardiovascular Systems, Inc. (CSI), and LivaNova

For any medtech organization, the medical, legal, regulatory (MLR) review and approval of promotional materials is crucial for establishing effective communication with HCPs, patients, regulatory agencies, shareholders, investors, and research partners. All too often, however, the process creates confusion and friction between departments, increasing the risk of noncompliant communications reaching the public.

The complexity of building or revamping the systems required for these reviews can be daunting. At its recent Summit, Veeva MedTech brought together a group of panelists, each in the midst of implementing or transforming the MLR review process in their organization, to discuss review pitfalls and how to avoid them. Participating were Kate Nichol, VP of Clinical and Medical Affairs at LivaNova; Larry Litle, Senior Director of Global Regulatory Affairs at Baxter Healthcare; and Jim Wilson, Senior Director of Digital Marketing Transformation and Customer Communications at CSI

Preventing Confusion and Avoiding Pitfalls

Confusion can build, panelists agreed, as stakeholders grapple with trying to understand exactly what the review committee does; as they invite and prepare attendees to participate in the review; and as they identify and assign responsibilities to those who will be leading the process. Although compliance requirements are clear, there is no standard way to handle reviews, and each company has developed its own approach to reviewing and approving promotional materials. At Baxter, for example, the legal department is not part of a typical MLR review cycle workflow, but is brought in on a consultative basis, Litle said. At CSI, legal and regulatory are involved in every review, and marketing participates in almost all reviews, but clinical, engineering, or medical affairs representatives may also be involved when needed, said Wilson. Even terminology and acronyms can differ from company to company. People who work with those acronyms every day may often forget what they stand for, Nichol joked.

Panelists explored their companies' experience with MLR and why they decided to change or replace existing review processes. The following emerged as common challenges:

- **Obsolete software and platforms.** Review can become frustrating, or impossible, when existing technology cannot work with the media or file formats that need to be approved, such as MP4 video files. In some cases, when old systems or technology are no longer available, reviewers are forced to dig through archives and prior records to find decisions about brands, phrasing, and current medical research, which is time-consuming and resource intensive.

- **Inconsistent review processes.** Review processes must be consistent, panelists emphasized. Preparing for MLR review is labor-intensive and exceptionally detailed, and marketers will be frustrated if they follow all the rules established by the company, yet their work is rejected and promotion schedules delayed. Delays in product communication reaching the market are not only costly to a company's bottom line but can have significant impact for the patients who rely on products for health and well-being.
- **Uneven, burnout-inducing workloads.** When review depends on only a few core individuals, work will be poorly managed, and concerns about software and rules will become glaringly apparent. One person should not be assigned to handle all reviews. "If you're reviewing hundreds of materials a month, you'll forget what you said on one specific date, and every claim will come back for review over and over and over again," Nichol said. Without a common system or audit trail, reviewers are forced to spend time locating historical documents or re-reviewing previously approved claims.
- **Risk with process workarounds.** Companies may try to deviate from their usual review procedures to speed the process with seemingly simple, nontechnical reviews. For example, a marketing department may take small snippets of text or soundbites out of a much larger piece so that they can be reviewed more quickly for use in blog posts or social media. This can result in noncompliance, because a snippet taken out of its original context may invalidate the entire review. Panelists suggested that review should only be expedited when the company's regulatory affairs department has agreed that the changes are minor enough to justify taking that approach.

Three Keys to Successful Reviews

The following approaches have allowed LivaNova, Baxter, and CSI to stay ahead of review issues and prevent problems from occurring.

- **Establish process ownership.** It is vitally important, all panelists agreed, to set the work of analyzing and improving the review process apart from reviewing marketing tactics. It's just as important to ensure cross-functional participation on process changes to ensure accuracy and alignment. "You can't have 200 marketers all at the table at the same time and expect to come to a decision on how to make the review process better and faster. But you can get perspectives from a cross-functional team made up of people from marketing, medical affairs, legal, and regulatory departments," said Litle.
- **Establish and train power users.** MLR review involves a number of infrequent users —people who don't use the system that often and may soon forget what they learned when they last interacted with it months ago. Setting up and training power users will ensure that even the most casual users have access to the information they need to interact successfully with the MLR process.

- **Focus on engagement, execution, and executive sponsorship.** Panelists stressed the need to use these "three Es" to drive successful implementation. Engaging people early is key, whether developing a new process, tool, or marketing strategy. Choose stakeholders who represent every job function and discuss changes in a way that emphasizes how the changes will make each person's job easier to perform more accurately and consistently.

Only once all stakeholders understand the plan to improve process decisions and how it will affect them can you move to execution. Trust must be established by ensuring that rules are established and complied with, but also continuously examined, refined, and updated. In addition, they must be kept current, made workable, and equitably distributed, panelists noted.

Executive support for any new process is key to its success. Panelists found that being able to call on the Marketing, Clinical, and Regulatory Leadership to reinforce the value of the MLR process and the rules maintaining it, helped lead to top-down acceptance of new approaches.

Watch this video for more insights from this discussion.