
Regulatory and Innovation: It's Possible*

Can ad/promo regulatory professionals be innovative thinkers? Some have argued that these two terms are incongruous and that asking a regulator to bring innovation to promotional marketing is paradoxical. While the regulatory function is charged with risk management, this does not prevent these professionals from thinking outside of the proverbial box to help their marketing colleagues achieve business objectives. Indeed, regulatory professionals who ask questions, put their ego aside, are solution-oriented and don't let past experiences and beliefs taint current or future collaborations can propel their companies' brands to new heights.

Be Open to the Possibilities

"Your past experience with regulatory professionals will color your present perspective on their creative value," explains Stacy Joseph-Reese, Director of Regulatory Promotional Review for Teva Pharmaceuticals.

"Marketers that have seen the benefits of a collaborative partnership are more likely to be open to innovative ideas from members of the promotional review team. Marketers that expect to have tension will be more likely to experience tense relationships."

It's important to always assume good intent when working with new functional team members and respect the experience that regulatory colleagues bring to the table. With a united approach, teams can evaluate new concepts and brainstorm innovative approaches in the face of complex business challenges.

Do Your Homework

Even if regulatory professionals have collaborative personalities, experience does matter.

Joseph-Reese strongly believes that regulatory professionals must come to the table having done their research on the issues brought forward by commercial. "When regulatory professionals are fully knowledgeable about the key topics, they can effectively navigate the barriers and help formulate innovative solutions."

Supplement what you don't know by researching the topic. Background research can include analysis of FDA guidance documents, medical reviewer comments, violation letters and feedback from the Office of Prescription Drug Promotion (OPDP).

Explain Why

When marketers understand the 'why' behind regulatory boundaries, they can provide suggestions or recommendations for consideration to address the concerns. Then together Regulatory and Marketing can determine how to achieve these same goals with meaningful and compliant tactics which align with the strategy.

More often than not, explanations are needed for certain 'subjective' words that can't simply stand on their own – for example, *off-label*, *outside the regulations*, *violative*. Innovative regulators provide context and detailed examples so commercial understands the rationale behind questions and concerns.

Be Solution Oriented

A solution-focused approach helps commercial teams meet business objectives while saving time and resources.

“When launching a new product, getting the promotional materials into the market is a key priority. Teams must consider the need for seeking FDA advisory comments on core materials, the implications of potential feedback and impact on timelines,” says Joseph-Reese. Researching FDA enforcement letters, previous advisory feedback and guidance documents can help drive strategy or provide clear and supportable regulatory direction when this path is not taken. Specific examples and recommendations can help the team collaborate on thoughtful solutions. For example, I have proposed revised content for a draft sales aid by creating a visual mock-up to help the team understand the proposed regulatory solutions and quickly reach final agreement.”

Plant the Seed Early

Marketing and Regulatory can interact even earlier to engage in informational discussions about strategies and tactics. These conversations can set expectations and frame up the innovative idea before a formal review takes place.

Joseph-Reese explains that “Too often marketers have spent time and money on an idea before the concept review. With high level discussions, you can begin development with your eyes open because expectations have been set based on a real understanding. This prevents too much back and forth because you can collaboratively work out issues before money is invested.

Embrace Cognitive Flexibility

Cognitive flexibility has been broadly described as the ability to adjust one’s thinking from old to new situations and to overcome habitual thinking in order to adapt to new situations. Moreover, professionals that exhibit cognitive flexibility can simultaneously consider two aspects of an idea or situation at one point in time.

Cognitive flexibility techniques help regulatory, legal, compliance and medical functions think more creatively and strategically when working with Marketing. We can teach how to shift a previous belief in response to a change in rules. For example, if the belief is that, “It’s not possible to compliantly execute a digital tactic or campaign because FDA guidances are still gray,” we can help adjust the thinking to examine all the possibilities for how a digital tactic might be executed in compliance.

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