Regulatory, Legal and Compliance are High Value Partners for Companies That Want to Achieve Marketing Excellence in a Compliant Culture

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Regulatory, Legal and Compliance can now make a business case to management that demonstrates their value to the commercial organization. Specifically, these functions help Marketing fuel *marketing excellence* – a key strategy for an industry that strives to excel within a compliant, transparent culture.

Marketing excellence occurs when promotional review committees (PRCs) are more efficient so corporations don't waste time and money during the review process. As a result, more effective, balanced promotion gets into the field more quickly to protect and enhance public health and patient care.

Benchmark data below diagnose three key drivers of inefficiency and spotlight why a partnership between Commercial and Compliance contributes to 'smarter' promotion.

According to Abbott's Divisional VP of Regulatory Affairs, Tracy Rockney, who serves on the DIA/HBA Leadership Project Steering Committee, "These findings make clear what many of us have known in Regulatory for years – partnership is essential for success. What these finding also bring to the surface is the role of educator within a company – what function(s) should be responsible for educating on critical regulatory requirements? And should companies consider minimal threshold requirements across all functions in order to make decisions for the approval of promotional materials."

THE DATA*

Knowledge Gaps - When asked to pass an exam developed by former FDA officials that covers regulatory fundamentals, marketing professionals often incorrectly answered basic test questions in numerous categories, including risk communication; pre-submission requirements; reminder and disease state awareness ads; and use of spokespeople. Promotional agency staffers tend to fail questions on websites, press releases and use of spokespeople.

Schism – Given these knowledge gaps, internal marketing professionals and promotional agencies don't often agree with Regulatory on how to implement the following tactics within regulatory guidelines: digital initiatives, public relations activities (e.g., media tours, press releases); promotional education (e.g., speaker's bureaus, and slide kits); and advisory board meetings. Disagreements about compliant claims can increase interdepartmental tension, which results in less streamlined decision-making.

Waste - Companies could lose 25% of their time rewriting noncompliant promotional materials submitted by agencies with regulatory compliance knowledge gaps. This can translate into $200K/year/company assuming three regulatory reviewers, according to calculations based on survey data and average salaries. Time lost by Legal, Medical or Marketing is not included in this total (another area of financial vulnerability). Further, when agencies submit noncompliant campaigns, the agencies themselves could spend an additional $100-150K/ brand/year on rewrites.

"Management expects me to help reduce company risk and support marketing efforts through review/approval of promotion that advance a brand's objectives and maintain a competitive edge," explains former FDA Regulatory Review Officer Michael Misocky. "When materials are so non-compliant that they create extra work, my first priority must be risk reduction. The focus would not have to be so one-sided if marketing and agency personnel came to the table with a better understanding of basic legal/regulatory principles."

Alan Bergstrom, Daiichi Sankyo's Senior Director of Commercial Regulatory Affairs, outlines why partnership between Commercial and Compliance enables a company to strike the right balance between compliant materials and those that creatively execute brand strategy.

"It's our responsibility to help Marketing understand the benefits of partnership so we can collaboratively implement solutions. These include 1) pinpointing knowledge gaps that disrupt and slow down the review process; 2) educating anyone involved in the promotional process to put everyone on the same baseline of knowledge before they are allowed to initiate promotional tactics and take part in promotional review; and 3) changing the current promotional review process by bringing Regulatory and Legal into the Brand planning process earlier."

THIS THREE-POINT PLAN DELIVERS:

Efficiency – by reducing the number of rewrites for heavily redlined materials submitted by marketing and agency professionals that are not versed in regulatory fundamentals. Fewer rewrites shorten review cycles and reduce the overall number of cycles. When time isn't wasted rewriting, associated savings could fund more marketing materials or support a new hire.

Effectiveness – by freeing up time for Regulatory to focus on improving quality of claims. Educated marketers are better equipped to present creative ideas in compliant terms, reducing 'non-starter' concepts so more big ideas are executed. Fewer disagreements about compliant claims mitigate tension, streamlining decision-making. Sales materials get into the market more quickly because rewrites don't delay the review process.

Impact – by accelerating the transfer of accurate and non-misleading information about drugs and devices; deepening healthcare professional knowledge/insight on appropriate interventions; and enhancing patient/consumer decision-making.

Alignment and knowledge sharing between Marketing, Regulatory and Compliance can also create powerful business benefits, asserts Kristin Rand, Executive Director of Compliance at Seattle Genetics. Rand, former Director of Compliance at Genentech, and a member of the DIA.HBA Project Steering Committee, describes how the compliance function can supply competitive intelligence to the marketing and regulatory members of PRC. "When assessing and managing risk, especially in grey areas, compliance functions often benchmark what other companies are doing. The insight gained from these environmental scans can provide additional value to review committee members, not only regarding compliance and regulatory matters, but also business strategy."

2013 requires a new business model where marketers embrace Regulatory, Legal, and Compliance as high-value partners instead of seeing them as policemen (or proverbial "sales prevention/suppression" departments).

"When everyone who develops and reviews promotional materials is on the same page, companies reduce enforcement risk and increase efficiencies," asserts ex-FDAer Wayne Pines, CCC Advisory Board Chair. The outcome: business meets commercial objectives and manages risk, while delivering on the industry's mission to put patients first. ●

**For survey data, analysis and sources, contact ilevins@CommunicationCompliance.com*