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## The Impact of Mindset on Regulatory Compliance Efficiency\*

Trust is key for innovation, competitive advantage, and efficiency when working across countries, departments, and functions. This article spotlights the role our mindset plays in building trust despite differences in language, culture, time zones, and professional responsibilities.

Adopting a trusting mindset is particularly challenging when teams must collaborate around medical, legal, regulatory (MLR) and compliance decisions for product launches or new creative campaigns, especially for brands that use never-tried digital concepts. Further complicating the matter: Our brain chemistry makes it even harder to trust in situations where time is tight, pressure is high, and expectations for success may be daunting.

Yet, if we recognize the role mindset plays in building trusting relationships around risk management decisions, the benefit is significant, according to executives on the panel I moderated at a Healthcare Businesswomen's Association (HBA) conference. These include the ability to more fully leverage internal resources, drive creative problem solving, optimize promotional claims, and shorten review cycle time.

"Rather than misinterpreting dissenting voices as a show down, trusting team members feel confident to ask questions about decisions, request additional resources to support the promotional review process, and map out a plan to accomplish agreed upon goals," says Nicola Heffron, Global Head – Internal Medicine Franchise, Shire, and HBA workshop panelist.

Brain studies show that humans are neuro-chemically wired to react to situations with automatic thoughts based on past experiences. Productive automatic thoughts help us make sound decisions and effectively lead teams. Unproductive automatic thoughts focus our mind on negative details, make us draw over-sweeping conclusions on the basis of a single incident, or drive us to black or white extremes. Consider these examples:

A senior marketer works at a company under a Corporate Integrity Agreement (CIA) where reviewers are perceived to be "policemen." This executive automatically assumes that there will be no give-and-take during promotional review discussions and shows up at review meetings ready for conflicts. A regulatory lawyer spends 25% of the month rewriting non-compliant materials submitted by content originators. The frustrated executive automatically assumes that all promotional agencies will waste her time and feels stressed before she begins her review. Professionals working in cross-functional roles must acknowledge that automatic, negative assumptions and judgments may occur and then proactively address them as a cohesive, collaborative team.

As a precursor to the HBA workshop, our company utilized its diagnostic tool to assess perceptions among marketing executives and those in MLR and compliance roles about one another's function. The findings point to existing judgements and potential misperceptions.

Global team members can consciously choose to lead with facts by remaining aware of automatic negative responses -- a solution- versus subjective-focused mindset, which is critical for novel, first-time digital initiatives that can raise potentially unfounded concerns even before ideas are fully fleshed out. "Global deployment of high-tech solutions can raise many questions among cross-functional team members," explains Jessica Pfennig, EMBA, MLS, Enterprise Digital Leader at AstraZeneca, and HBA's Global Digital Innovators Chair. "Innovation within compliance demands a fact-based approach to alleviate concerns

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among disparate stakeholders. This includes pointing to digital policies and standards, monitoring for adherence, and regulatory compliance know-how among all stakeholders involved in digital initiatives.”

### **Building Fundamental Trust**

Historically, functions protecting the company from risk, and those tasked with meeting business objectives, pull away from one another instead of operating as partners. Yet, with a trusting mindset, differing perspectives can push organizations to higher levels of performance.

“It’s a brave new world when it comes to understanding how best to review and approve digital external communications,” says Diana Morgenstern, Senior Medical Director, Global Medical Affairs at Pfizer.

“Historical rules and ways of seeing things in MLR review may not fit the new age materials. This presents a prime opportunity to collaborate with cross-functional colleagues and work together to figure out what’s right.”

“Greater demand for real-world evidence and the need for faster data communication will make Medical Affairs an even more indispensable partner to the commercial operation

We are under pressure to perform at all times. That’s why I asked Rick Peterson, a legendary baseball pitching coach and speaker at CCC collaboration events, to share his “reframing” tips from his newly released book, *Crunch Time: How to Be Your Best When It Matters Most*. “At its core, reframing describes the skill of consciously and intentionally thinking about a situation from a different perspective. When we’re under pressure, our reflexive, instinctual reaction is to perceive challenging situations as threats. By reframing, we can choose how we respond so we deal with the situation more effectively, instead of automatically.”

The ultimate reframing to build trust: Professionals in medical, legal, regulatory, legal, and compliance must believe that it’s their role to help advance business objectives. Commercial professionals must believe that it’s entirely possible to enjoy a competitive advantage while operating within a compliant culture. Concludes Shannon Resetich, Global Franchise Head of Hematology at Shire, and HBA workshop panelist and Board Member, “Trusted relationships among cross-functional teams are the foundation for success, particularly for global teams. Each of us must be vigilant in scrutinizing our mindset and ensuring a collaborative nature with the same rigor we apply to driving a brand’s growth.”