Raising the Regulatory Voice

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To continue to advance in our careers, we regulatory professionals must develop a powerful regulatory voice, both inside and outside our companies. Regulatory expertise and technical skills are not enough, particularly in the face of increased regulatory requirements and scrutiny compounded by rising pressure on regulatory professionals to do more with less.

A powerful regulatory voice helps us achieve results across the multiple aspects of our professional lives. A powerful regulatory voice shapes a company's interaction with health authorities. It also contributes to successful working relationships with colleagues and partners across a range of disciplines, including our own regulatory colleagues. For example, the regulatory voice is often central in obtaining budget dollars, managing direct reports, leading cross-functional teams, persuading other departments to comply with regulations and guiding senior management. When the regulatory voice is not heard, an untenable product moves forward through development, companies endure fines and consent decrees, products are withdrawn, pipelines shrink and jobs are lost.

Within the ever-changing regulatory environment, regulatory professionals are, therefore, the key conduits to ensure that teams act in a consistent, compliant manner. Consequently, our regulatory voice is imperative to both individual and organizational success. It is one of the key facets of professional growth that continues to strengthen and evolve throughout the careers of regulatory executives.

Raising Your Regulatory Voice

Raising your regulatory voice is not about turning up the volume. Impact comes not from how loudly you speak, but from how clearly your audience understands what you say. To partner with colleagues and health authorities, you must attune your message to each audience; homing in on the critical issues affecting them and on what they need to do—not on what you think they should know.

Most communication problems arise from a failure to focus on the critical issues in a manner that is compelling to each audience member. Spending more time on understanding the issues from their perspectives makes communication more effective and your efforts more efficient. This becomes even more important when multiple people are addressing the same audience. Everyone on your team needs to be in alignment, not just in their understanding of the audience, but also in their unified focus on a well-defined outcome. Sometimes, what seems obvious to you is not at all apparent to someone else on your team, so it is essential to agree upon outcomes in advance.

Plan

Rather than raising the volume of the regulatory voice, strengthen its persuasive focus through a clear communication plan, a plan that ensures

We define "voice" as a characteristic of identity. For example, if we were to speak of Aristotle's voice, we would not be referring to a vocality but rather to those personal characteristics that make Aristotle's words identifiable as Aristotle's. Another more generic example would be to speak with a teacher's voice. In this case, we would be suggesting that the speaker is saying things in a way that associates the speaker with characteristics that one would associate with teachers *suis generis*. A regulatory voice would be one reflecting the professional identity of one clearly associated with regulatory discourse.

that the needs of the audience are met in a way that also drives your goals toward success.

- audience outcome
- audience analysis
- audience messages

These three elements, all focused on the audience, are the underpinnings of persuasion, whether you are communicating via a written document, slide presentation, interactive meeting or teleconference.

Audience Outcome

Defining the desired outcome in terms of what the audience will feel, think and do as a result of your persuasive effort is much more powerful than defining your content. For example, compare "I'll tell them about our budgetary requirements," to "They will agree to the unexpected increases in the budget." To move audience members to take action or make a decision, it is critical to affect not just their thinking, but also their emotions. The ideal audience outcome is, in fact, three outcomes:

- "Feel" outcome: As a result of this persuasion, the audience will feel ____ (e.g., reassured, trusting)
- "Think" outcome: As a result of this persuasion, the audience will think ____ (e.g., the increases in the budget are warranted)
- "Do" outcome: As a result of the persuasion, the audience will do ____ (e.g., approve the proposed budget in its entirety)

Audience Analysis

Persuading audience members to feel, think or do something begins with an understanding of their needs and concerns. Most audiences are not homogeneous so it becomes important to understand specific subgroups or even individual members. In the extreme example of a Food and Drug Administration (FDA) advisory committee meeting, it is important to develop a complete profile on each committee member, anticipating each one's concerns and likely questions. For less-critical interactions, it may be enough to gather key information on the aggregate audience or aggregate groups you can discern within the larger audience. If the audience is recurring—an operating committee or FDA review team, for example—it pays to keep an ongoing record of the kinds of questions each member asks, his or her issues of particular interest and/or preferences for scenarios over direct recommendations.

Audience Messages

Having defined the target audience outcomes and completed the audience analysis, you are now in a position to prepare the specific persuasive messages your regulatory voice will deliver. Strong logic should drive your communication. You should be able to distill the essence of your persuasive structure into just a few sentences that convey the desired outcome's benefits to the audience. If you can boil down your logic to just five sentences directly addressing the concerns you unearthed during your outcome planning and audience analysis, you can be certain of speaking with a tightly focused, persuasive voice.

The first sentence is your primary driving message. The next three sentences supply your main supporting points. The last sentence connects to the first and drives home the motivation for accepting your argument. This persuasive summary is an example of what many recognize as "the elevator presentation," and is particularly useful with impatient audiences.

Once the five sentences have been crafted, they can be expanded to provide proof, support and sub-points. This enables you to organize all your material around the focused messages and avoid being pulled off track. This approach also helps avoid including too much data by focusing on the main points first and allowing you to tailor the amount of support and proof of those points to the precise needs of the audience you are addressing. This will both literally and figuratively save your regulatory voice so that when you speak, you are heard, and helps avoid diluting your persuasive impact by saying too much.

Anticipate Issues

Nothing is simple, particularly in the complex and continually evolving world of regulatory affairs. Preparing your persuasive messages is not enough; you also need to anticipate likely issues these messages may evoke. By anticipating those issues, you can adjust the content of your messages and supporting points to address them directly, or save them to trigger questions for which you have prepared answers.

Developing the agenda for an End-of-Phase II meeting or preparing for an advisory committee meeting are examples of regulatory communication that demand anticipating issues and addressing them, both in the body of the sponsor presentation and during the question period that typically ensues. Through audience analysis, a regulatory professional with a strong voice can help a team determine each participant's key areas

of interest by looking at past performances in meetings, publications and other aspects of their professional interests that suggest likely concerns they would have about the product. A powerful regulatory voice can ensure that the team develops an issue-oriented focus for both the presentation and questions that may be asked.

This planning process demands a regulatory professional who understands the importance of fine-tuned regulatory communication and can help the team understand the rigor needed to succeed. This leader helps prepare colleagues through iterative rehearsals that allow teams to pursue lines of questioning in advance, anticipating entire sequences of questions and developing responses to each. This process can disclose flaws in the planned persuasive approach; the teams can then revise the approach to address these flaws so they are as well prepared as possible for any critical interaction, internal or external.

Speaking With One Voice

When your team members deliver the regulatory voice—either with you or independently—it is important that they offer a consistent and coherent representation to the various audiences. This is also true, although even more challenging, when a cross-functional team is involved in a regulatory interaction. One way to help ensure that a single regulatory voice is reaching your audience is by facilitating group agreement on the strategy and messages prior to developing the persuasive content.

Persuading your colleagues of the potential effectiveness of their approach requires the integration of the abilities discussed above. A strong regulatory voice can help a team avoid common mistakes relatively inexperienced teams make when interacting with FDA. For example, your team members need to feel compelled to listen when you tell them that company science does not trump FDA interpretation; reviewers rarely like to hear company lectures on science; not all FDA team reviewers are experts in a particular therapeutic specialty; ego is best left at the door; part of a good review is often good personal relationships between company and FDA representatives; a company's recent reputation plays a role in the review; they can ignore FDA advice only if they are prepared to offer a strongly supported rationale; and ignoring issues is dangerous. Teams that listen to the regulatory voice can spare themselves misery.

Recording and Disseminating the Regulatory Voice

Drug and device development knowledge is captured in its documents—in INDs, protocols, package inserts and, above all, registration documents. The milestones of development are largely regulatory; the best companies capture these experiences and grow from them.

This knowledge capture, an essential component of knowledge management, offers the opportunity to develop another facet of your voice. The milestone debrief is an essential tool for capturing and codifying development knowledge, most of which has a strong regulatory core.

For a regulatory professional, knowledge management is not a separate physical or mental activity, but a potential leadership responsibility. Every interaction with the agency, every previous advisory committee meeting in a therapeutic area, and every regulatory document forms a piece of the knowledge management mosaic. This knowledge management is integral to the daily activities of regulatory professionals. Over time, it helps cross-functional development teams identify, capture and manage institutional knowledge accumulated throughout a product's development. Teams and entire enterprises can build upon the persuasive and scientific content they develop, using knowledge management techniques as the foundation of their work. This approach can help teams develop core messages and then anticipate and effectively respond to issues that arise, reducing the time that each team spends on overlapping tasks. Knowledge management can transform completed tasks, actions and results into individual, team, function and corporate learning.

Developing a Powerful Regulatory Voice

Developing a more powerful regulatory voice for yourself and your team is an essential aspect of both regulatory effectiveness and career advancement. Making your regulatory voice powerful and persuasive benefits not just your department but the entire enterprise. With the help of a strong regulatory voice, development moves toward a unified goal, creates viable products for the pipeline, generates approvals of marketable products, ensures the organization's health and well-being, improves relationships with health authorities, and assures a future for you and your team.

Authors

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