



The Regulatory Professional as Boundary Spanner

By Ira G. Asherman

Today's regulatory professionals find themselves in an ever more complicated and challenging environment. Their core responsibility is to ensure their firm's compounds move through the approval and labeling process as rapidly as possible.

The pressure to achieve this goal, among others, is constant and unrelenting, and the regulatory professional plays a central role in that process. He or she is the company's representative in dealing with the governing agency as well as the person who translates the agency's requirements and concerns back to his or her co-workers.

Everyone is concerned with how effectively the regulatory professional interacts with the agency. It is a process that everyone is watching and on which everyone has an opinion. Like it or not, the regulatory professional has a very critical and demanding audience.

Failure to appreciate the importance of the audience, and its impact on the negotiation process, can only lead to difficulty.

As a result, regulatory staff frequently find themselves caught between two masters. On one side are agency personnel, with their demands and concerns regarding what is required. On the other side are co-workers, who want to know when they will get an answer and why the process isn't moving along more quickly.

Frequently, these competing demands are incompatible. It is the co-worker side of the equation, however, that has the potential to get far more complicated. Not only does the regulatory staff feel pressure to hasten approval and provide firm timelines, but they are also pushed to call the agency to obtain information and move the process forward.

Regulatory professionals span the boundary between their companies and the agencies. To navigate that boundary effectively, they need to possess both strong technical and interpersonal skills.

The Boundary Role

Boundary role jobs are ones where employees, as part of their jobs, must come in direct contact with the public or employees of other firms or departments. James L. Perry and Harold L.

Angle, in their 1979 article, described the role in the following terms. He or she *"operates at the juncture of two systems: the parent organization and the organization in contact. As both the influencer and the target of influence from both insiders and outsiders, the negotiator is subjected to high levels of role conflict."*¹

It is this dichotomy that goes to the very heart of the boundary spanner's job. As Raymond Friedman and Joel Podolny pointed out in their 1992 article, *"One of the problems most frequently associated with boundary spanning is role conflict. As a boundary spanner interacts with members of different groups, he or she conveys to the boundary spanner the particular expectations that each group has about the boundary spanner's role, including how they should act, what values he should express and what interests she should represent. Given that each group's values and interests are different, the boundary spanner is likely to experience conflicting expectations of how to fulfill his or her role."*²

In the world of regulatory, this is a given. Everyone has an opinion as to how the regulatory professional should do his or her job, and the more important the compound, the greater the number of opinions as to how the job should be done.

How well regulatory personnel are able to manage this conflict goes to the very essence of their effectiveness. Their negotiation and conflict handling skills are constantly being tested, since in many situations there is no clear guidance, standard operating procedure or regulation that can be cited to answer the question.

It is a matter of opinion, and as such, the folks in clinical and marketing frequently feel that their points of view are just as valid, if not more so. Rare is the regulatory person who has not had others invoke their expertise and experience and tell him or her what he or she is doing wrong and should be doing differently.

Trust and its Importance

Trust is the essential ingredient in making this process work. It is the lubricant. High-trust relationships increase the possibility that company objectives will be achieved. Regulatory agency personnel know who can be trusted and who cannot.

As Jim Morrison, then the Center for Drug Evaluation and Research ombudsman, pointed out in a 1999 article, *"The most difficult aspect of any type of law enforcement or regulatory work is how to recognize who is trustworthy and who is not and to deal with each accordingly."*³

This relationship with agency personnel is essential to the regulatory professional. Regulatory personnel are always looking to build long-term, high-trust working relationships with agency staff.

Conversely, if they are to have the freedom they need to get the job done, regulatory professionals also need the trust and support of their co-workers, as any agency negotiation, by its very nature, is preceded by an earlier negotiation with the stakeholders. The regulatory professional and the stakeholders must be in agreement if the negotiation is to be successful.

As Dudley B. Turner points out: *"Research indicates that a negotiator who exhibits low goal congruence with his or her constituents has a weaker bargaining stance and more conflict with the opponent than does a negotiator with high goal congruence with constituents."*

*"In a high goal congruence condition, the negotiator would use his or her team member's information and ideas more readily than in a low goal congruence situation."*⁴

Trust allows for the sharing of information, and ultimately for work to get done. As Turner points out in a second article, *"Constituent trust in the negotiator is an important characteristic of the negotiator-constituent relationship."*

*"Research shows that as the negotiator feels more trusted by constituents, the negotiator feels less tension, feels he or she has more flexibility in the negotiations, and feels less of a need to defend his or her own actions to constituents."*⁵

Turner goes on to suggest that in low-trust situations, negotiators are likely to use a *"win-lose approach that may interfere with high joint gains. Research indicates that negotiators who perceive low trust from constituents try to build that trust by showing firmness or competitiveness in bargaining."*⁶


That approach with any regulatory agency can only lead negative outcomes. Trust brings additional benefits in that *"may actually allow conflict to surface without disruptive consequences... Relationships characterized by trust may be more likely to confront and resolve disagreements rather than smoothing them over."*⁷

The regulatory professional faces a dilemma, driven in part by the high trust that is so hard to develop. This is not easy to resolve and can have a significant impact on success.

At some point, the internal relationship will be tested when the regulatory professional disagrees with something stakeholders are asking him or her to do. Try as you may to negotiate with them, the stakeholders are clear and unmoving as to the steps you should take.

When you refuse, they are likely to question your motives and your commitment to the team and its objectives. In their eyes, you are not being a team player. This is a label you do not want.

This dilemma has come to be called The Adams Paradox, after J.S. Adams, the man who first described it.⁸ The following paragraphs outline the boundary role dilemma in greater detail.⁹



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General

- Boundary Role People (BRP) believe that their main objective is to strive for optimal, long-term agreements with external clients. They must develop collaborative, long-lasting relationships with the outside constituents in order to establish a climate conducive to negotiation.

Dilemma

- The dilemma begins when the internal constituents look at these outside relationships and question the boundary role person's loyalty to the company, which is usually expressed by a version of, "Who do you work for anyway, us or them?" This becomes a particular problem when the regulatory person is not willing to implement or take some action that the team wants. Why will you not make the call? Making the call seems so obvious to them, and is so wrong to the regulatory professional.

- In-house colleagues start to believe that the boundary role person's relationships with outside clients serve purposes other than the goals of the organization. They believe they are more concerned with the relationship than with the company's needs.
- Constituent distrust promotes increased monitoring of the boundary role person's actions. All of a sudden, people are offering help and assistance, not because they want to help but because they do not trust the regulatory person to adequately represent the company's interests.
- The boundary role person then attempts to gain back his or her constituents' trust, and in doing so, becomes more competitive with his/her external constituents.
- The competitive behavior causes problems in the relationship with the outside agent or, in this case, the regulatory agency, and as a result, problem solving and future negotiations suffer.
- As long as the BRP meets the expectations of internal clients, all is well. Failure to meet constituent expectations brings "disapproval and negative sanctions; conformity brings approval and positive rewards."

Robert Klimoski and Ronald A. Ash, in their article, "Accountability and Negotiator Behavior,"¹⁰ suggest one additional dimension to our understanding of the dilemma. They have found that people who were randomly appointed to their positions, rather than being selected by their internal constituents, have a more difficult time in reaching agreements and have reported greater feelings of pressure, frustration and difficulty during negotiations.

"Elected representatives, because of their mandate (stated group support through election), did not feel constrained by actual or expected reviews. They were freer to forsake their own group's feelings and adopt a new position."

The farther people are removed from the actual negotiation, the more aggressively they want the regulatory person to behave. They have little or no relationship with the agency and are more concerned with their individual product, while the regulatory person frequently invokes the big picture, namely the many other compounds the company has in development.

Further complicating the issue is the lack of knowledge co-workers may have about what regulatory professionals do for a living. In many organizations, the regulatory department is not seen in very positive terms. In addition, many people still do not see regulatory as a profession.

Until recently, very few, if any, people went to school to learn or get a degree in regulatory. People from across the academic spectrum

occupy regulatory jobs. This frees everyone else to tell the regulatory professional how to do his/her job. Although this is now changing, the residue still lingers.

What to Do

Being a regulatory professional has been described as walking a tight rope between two competing sets of demands. On the one hand are the agency and its demands and on the other are the demands and concerns of one's corporate constituents.

As was suggested in a recent workshop, "Our co-workers expect us to be far more aggressive than we are comfortable with being. When we resist or say no, they see us as poor team players. If we were good team players, we would make the call and do as they want. To make the situation even worse, when we make the call and things work out, it is the constituents that frequently take the credit."

If they had not pushed, the call would not have been made and we would still not have the answer. If things go poorly, it is because the regulatory person was not sufficiently assertive or did not follow directions. It is a no-win situation.

Addressing the Problem

The more fundamental question is whether or not it can be addressed. As indicated earlier, one probably cannot prevent the conflict, but what we must do is to find a way to address it.

First, what are the signs that the boundary role dilemma may be a problem for you or your department? Watch for the following:

- People volunteer to attend meetings with you.
- They ask for more frequent reports on your work.
- They check with others in your department about your work.
- Issues are frequently escalated to senior management.
- People talk about how things were done in the past or in their old companies. The people at their old companies are always remembered more fondly and clearly as more assertive.

Second, what can you do to limit the effects of the boundary role dilemma? Following is a set of steps that can alleviate the problem.

Action Steps

Any action steps that are taken must have as their driving forces the dual goals of building trust with one's co-workers and demonstrating that regulatory brings value to the team. Most regulatory professionals do not give sufficient time and attention to building these internal relationships.



- Keep people informed about your agency interactions. Use your company intranet to post what you are doing. Whenever possible, meet with stakeholders in person.
- Actively involve co-workers in the planning process. Solicit their opinions and be willing to share your own thoughts about what should be done. Be clear when you are not in agreement with them and make sure those disagreements are resolved prior to any agency meetings.
- Educate your colleagues. Take them with you to industry conferences and workshops. Pay particular attention to sessions where people from the agency you deal with are speaking. In addition, work with the team to analyze how the agency has treated similar drugs and how this may apply to your compound.
- Invite colleagues to come with you to agency meetings. The more they appreciate and understand what you are facing, the less likely they are to find fault. Initiate the process. Not everyone thinks this is such a great idea. As one individual pointed out, "Going to FDA is not a field trip and should not be treated as such."
- Conduct internal training. As one of our associates, currently a vice president of regulatory, pointed out, "Educate your company on the changing regulatory environment and pathways. Talk about the effect of new regulations, trends with regard to approvals, meetings, etc., and the external pressures facing the agencies that you deal with to help teams better understand where the agency is coming from, how the landscape is changing and make it less of a black box... Educate your team about your FDA or other HA reviewers, what have they reviewed previously, what were their positions on that? What are some of the things we can expect when meeting with this person?" Talk about the role of regulatory and its methods of operation. Tell people what you do and why you do it in a particular manner. Acknowledge that other firms may do it differently but demonstrate how your approach relates to your company's objectives.
- If you are conducting department-specific training, invite people from other departments to the program.
- Assess how people view regulatory and, when appropriate, take action to

correct misunderstandings. If you do not already do so, you should survey your internal clients on a regular basis to gain insight into their feelings about the department's performance.

- Demonstrate your interest in the work of your colleagues and how you can help them be successful. Attend their meetings and learn about what they find important. This serves to reinforce your interest and concern and allows them to see you as a co-worker, not some outsider.

Conclusion

The regulatory job is a demanding one. It is not possible to succeed as a regulatory professional without both strong technical and interpersonal skills.

The boundary role dilemma adds extra pressure to an already difficult job. However, one must learn how to deal effectively with the issues and conflicts that the job presents. Only by recognizing the issues and taking action can you be effective over the long term.

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Author's note

This article is the result of a series of interviews conducted with senior regulatory managers at several pharmaceutical firms. While I am not free to name them all, they know who they are and to them all I say thank you.