

# Positive Enforcement

By John Avellanet

Policies, presentations and procedures are just so much paper without the one critical component of good compliance: enforcement. For regulatory agency officials and the general public, today's enforcement lacks effectiveness. For business owners and C-level executives, today's enforcement inhibits innovation and stifles shareholder value. The sad truth is, both sides are right.

At February's US Food and Drug Administration (FDA) conference on regulatory enforcement trends, Michael Marcarelli, Director of the Center for Devices and Radiological Health, Division of Bioresearch Monitoring, identified "changing behaviors" as the first key to regulatory compliance. He noted that 60% of audit observations are traceable to poor attitudes within the inspected company.<sup>1</sup>

Given the extreme pressures on executives to drive home profits and bring new drugs and devices to market, all while navigating the competitive realities of the global economy, it is no wonder that compliance has taken a back seat.

Working to help companies develop cross-functional compliance strategies, the author frequently encounters executives who feel that regulatory rules are hurdles impeding progress. A study by the American Management Association backs this impression: 63% of C-level executives and business owners surveyed identified regulatory compliance as a major barrier to business success.<sup>2</sup>

Regulatory compliance, as it's so often enforced today, uses an authoritative approach that is not conducive to business success. Likewise, executive misbehavior and "it's not my fault" attitudes are poor adaptations to the complex realities of the world at large.

Compliance needs to be approached in a way that combines positive business outcomes and strong protection for the interests of the public at large. This burden lies squarely on the shoulders of regulatory affairs professionals.

## Positive Enforcement

Over the past few years, my firm has successfully coached clients and colleagues on a simple, highly effective strategy we call "Positive Enforcement."

Built upon cross-discipline expertise and experience, this method acknowledges that enforcement is at

the core of any robust compliance program. Without enforcement, trust declines, dependability falters and responsibility is isolated to individual character. Tackling enforcement in a positive, consistent manner seems to be the linchpin of good, long-term compliance.

Positive Enforcement provides fertile ground for trust to be cultivated and a culture of compliance to grow and thrive. And this is essential for good business and safe products.

Positive Enforcement has seven main principles:

- why, how & what training
- active translation
- focused choices
- good-faith constraints
- compliance agreements
- solution meetings
- relationship building

## Why, How & What Training

This is a three-tiered approach to compliance training.

First, every individual in the organization needs a high-level session that works backward from the applicable regulatory agency's mission (i.e., FDA's mission is to protect and promote public health) to the company's mission, their department's goals and finally to their individual job roles. Along the way, appropriate regulations that impact each link in this chain are touched upon in summary fashion. This lays the "why" foundation.

After this has been completed, the "how" layer is built. Individual applicable regulations are linked and discussed within the context of each department or work team and its business outputs (e.g., lab results, prototype designs, labeling layouts, etc.).

Finally, it's time to add the "what" layer: training on the individual on standard operating procedures (SOPs) and other protocols.

Addressing the why, how & what components of training is only as effective as your ability to master "active translation."

## Active Translation

This principle has two components: active listening and front-line translation. Translation is where compliance and enforcement start to crack.

Active listening is the ability to listen for the meaning behind complaints, frustrations and so forth. There are many good resources on the techniques,



from 33 books listed on Amazon.com to several good AMA seminars.

Much more difficult is mastering the translation component of the equation. Being able to translate compliance into the “languages” spoken by your IT department, scientists and researchers, engineers, senior executives, manufacturing floor operators, project managers, shop stewards, accountants, financial analysts, marketing directors, shipping and receiving personnel, etc., is critical to a common level of understanding relevant and helpful to each individual’s daily life of decisions and actions.

This is the fundamental difference between those organizations that “get it” (in terms of regulatory compliance) and those organizations that just cannot quite fit the pieces of the puzzle together. Peter Drucker once observed that the front line makes the bottom line. Translating compliance into the languages spoken by your front line makes all the difference.

## Focused Choices

Responsibility is fostered by choices with consequences. The natural tendency is to disguise punitive actions as consequences, but our strategy is to help individuals learn for the future rather than pay for the past. The goal is to encourage accountability.

The challenge for the compliance professional is to frame appropriate choices for your company: to shift the emphasis from finger pointing to problem solving.

The simplest method to encourage a focus on options and solutions is to ask “what” and “how” questions. Instead of arguing with a scientist who will not follow an SOP, try asking questions:

Scientist: The SOP’s wrong. We can do it my way and it’s still good science.

RAP: Can you tell me how that works?

Scientist: By reconstructing the molecules earlier, the end result is the same but it’s easier for us in the lab.

RAP: Okay, but since we can’t just change procedures on the fly, what could you do in the future to make it easier for all the labs but still protect the company and give the people who’ll use our new product proof that we made it in a safe, consistent manner?

Scientist: Well, what if we change the SOP to accommodate this new way?

RAP: Sounds good to me. When will you have the time to show me what to change?

The more you involve individuals in solving problems that might lead to noncompliance, the more you strengthen their understanding of compliance and

deepen their commitment to solutions in which they have played a positive role. You turn naysayers into vocal supporters.

## Good-Faith Constraints

We also need to be realistic with our choices. There is never enough time in any project or product development process to find a perfect process or reach a perfect decision.

We advocate making benefit-risk decisions based upon the information available and on objective standards of good faith actions and expectations. A recent court decision allowed the acceptability of a good faith defense if the good faith actions are based upon, and consistent with, objective, widely recognized standards.<sup>3</sup> The mission statement and guidelines of a regulatory agency provide part of this; broadly accepted industry standards (such as ISO, GAMP, etc.) fill in the gaps.

Compliance professionals can give their organizations the opportunity to make good benefit-risk decisions by pushing for data validity and protocol adherence. The additional benefit of this approach is the chance to meet two FDA standards of approval at the same time: the “substantial evidence” required of pharmaceuticals and the “reasonable assurance” of devices.

## Compliance Agreements

Companies should craft internal compliance agreements and have their employees and contracted staffing personnel review and sign them, preferably after the Why level of training has been completed.

Based loosely on the Corporate Integrity Agreements espoused by the US Office of the Inspector General ([www.oig.hhs.gov](http://www.oig.hhs.gov)), such an agreement covers codes of conduct, policies, audits, training, complaint reporting and handling, risk management principles, and the corporate protections afforded to internal whistleblowers. Consider creating a high-level summary report that is reviewed periodically by your company’s executive team and/or board of directors.

## Solution Meetings

Held at the company, departmental and/or team level, these scheduled meetings are dedicated to discussing and putting forth solutions for a single significant problem. These meetings are a mix of brainstorming, open discussion, decision making and scheduling.

Several considerations need to be kept in mind. First, expect some issues to be so thorny that resolution in a single meeting is unlikely; in this case,

schedule meetings weekly until tentative solutions are defined and accepted on a trial basis. Second, there is rarely a “right” solution; what served as a wonderful approach the first go-round may not work when a similar problem surfaces months later—let people, time, resources and context dictate viability. Finally, focus on trying solutions before rushing to judgment. Frequently, a “good enough” fix tried for a week opens the door to a much more beneficial long-term solution. Inherent within a culture of compliance is the ability to make mistakes, grow and learn.

### Relationship Building

The seventh component of Positive Enforcement is the long-term cultivation of relationships across your company, from top to bottom. You will be unable to effect behavior change and responsibility if you are unable to understand, appreciate and respect your colleagues’ points of view. The best way to encourage accountability and responsibility is to demonstrate respect for yourself and for others. This is the essence of leadership.

### Punitive Measures

When coaching clients on this strategy, some form of the following question always arises: “This is all well and good, but I’ve identified someone who is intentionally not following rules. Why shouldn’t I undertake a punitive measure?”

You can. Niccolo Machiavelli noted that the fear of punishment is always an effective means of enforcement. However (and this is the part typically forgotten), Machiavelli was unequivocal: fear-based enforcement is only effective when the punishment occurs suddenly, dramatically and publicly, leaving all “...at once satisfied and stupefied.”<sup>4</sup> Chances are, unless you are the CEO with an unfettered board mandate and the active backing of regulatory agency officials, you simply do not have the capability to carry this out effectively.

### Final Thoughts

Positive Enforcement is an approach to compliance designed to ensure a positive outcome for all the parties involved: you, your colleagues, your company, the shareholders and, most importantly, the public.

The seven principles foster a more flexible, solution-focused compliance culture of self-discipline, cooperation, good behavior and problem solving. The result is less stress, lower costs, more productivity, less time to market, stronger compliance and better business.

Are you ready?

### REFERENCES

1. February 6, 2007. From a presentation at the joint FDA and Food and Drug Law Institute’s Enforcement and Litigation Conference held in Washington, D.C.
2. AMA/HRI Strategy Execution Survey 2006.
3. US v. Hurwitz, 459 F.3d 463 (4th circuit 2006).
4. Machiavelli, Niccolo. *The Prince*, translated by Harvey Mansfield, Jr., University of Chicago Press, 1985, p. 30.

**John Avellanet** is the Managing Director of Cerulean Associates LLC, a Virginia, US-based consultancy focused on helping companies achieve profitability and compliance. He can be reached via email at [john@ceruleanllc.com](mailto:john@ceruleanllc.com).