

# The Seven Highly Effective Habits of Closed-Loop Compliance

by Patricia Santos-Serrão

As regulations in the life sciences continue to multiply, so do the compliance challenges that life-science companies face. Staying on top of new legislation, reinterpreting existing laws, and dealing with a maddening rise in lawsuits requires the constant attention of chief compliance officers.

For example, the ICH ([www.ich.org](http://www.ich.org)) is collecting final comments on new guidelines to complement the existing good manufacturing practices (GMPs), set to go in effect in November 2007 (1). These guidelines are intended to provide guidance on the contents of section 3.2.P.2

(pharmaceutical development) for drug products as defined in the scope of module 3 of the common technical document (2). And they will provide a model for a pharmaceutical quality management system (QMS) that can be implemented throughout the different stages of a product life cycle. The guidelines do not apply to contents of submissions for drug products during the clinical research stages of drug development. Based on this alone, it's clear that life-science companies must consistently and scrupulously maintain, update, and revisit their compliance processes and procedures.

But simply revisiting and revising old policies isn't enough. Companies increasingly look for ways to document that each potential compliance issue is an isolated, one-off incident that can be attributed to one individual or one incident — rather than a systemic problem indicative of a lax corporate



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culture. Although the compliance needs of life-science companies vary by niche, maturity, and market clout, all such companies share a universal need to prove to regulatory bodies and the public at large that they have done everything possible to comply not only with the letter of the law, but also with its spirit. Just ticking off checkboxes on a list of compliance requirements does not truly demonstrate full understanding of the benefits and consequences of compliance. You need to be able to convey that you have understood all issues and done everything reasonable to address them. Regulatory compliance is not complicated, but it is essential. For high-performing companies, failure is not an option.

As anyone who has been the target of a regulatory probe knows,

telling investigators that you have policies and procedures in place does not suffice alone. Inspectors and reviewers want to see that policies have been communicated to the affected staff members and that those employees have not only seen the latest policies and procedures, but also understood them and promised to follow them. You then have to repeat the training process as often as necessary, documenting every step along the way. This forms a foundation for closed-loop compliance. By using such a compliance model, you can minimize the risk of disruptive investigations, reduce risk to your company's reputation, and increase the probability of negotiated dispensations. The closed-loop compliance model highlights interdependencies across an enterprise and provides a proactive way to capture, identify, and remediate regulatory violations and compliance risk.

Recognizing that regulatory compliance and governance require constant vigilance and maintenance, top compliance and risk officers implement seven habits that form the closed-loop model. These habits provide a strategic way of looking at compliance that ensures a closed loop.

## SEVEN HABITS IN DETAIL

The seven habits of closed-loop compliance form a chain that can help you ensure that your company will make intelligent and informed

risk-based decisions. The seven links in this chain are

- 1 Tracking and interpreting regulations
- 2 Documenting policies and procedures
- 3 Implementing effective training programs
- 4 Capturing exceptions and deviations
- 5 Aggressively auditing and investigating anomalies
- 6 Managing exceptions and deviations
- 7 Implementing and measuring change.

#### **Tracking and Interpreting**

**Regulations:** The first step a company must take is to develop a clear ownership policy for tracking and identifying regulations that affect it. Once that's been done, you can create a list detailing who is responsible for interpreting these obligations and set up processes in which business and process owners agree on those interpretations. Completing the loop, an interpretation committee provides feedback to regulators on proposed or draft rules and their final interpretations. At this stage, you should evaluate the impact those interpretations will have on risks and training across your organization. With constant vigilance in mind, a committee must periodically review interpretations for each regulation.

#### **Documenting Policies and**

**Procedures:** The next step for your company is to make sure that all decisions are documented and traceable. Documentation must be supported electronically and maintained in a central repository dedicated to policies and procedures. By setting up such a central repository, you can automatically issue policies and procedures across your organization both consistently and cohesively. After identifying "owners" for these business procedures and using approved templates for capturing processes, your organization must follow a defined workflow — create, review, approve, distribute, consume, and retire and/or supersede — to manage

new content and any subsequent regulatory changes. Part of the documentation process requires implementing procedures that ensure the integrity of materials, including version control, security, acceptance, and audit trails.

#### **Implementing an Effective**

**Training Program:** Once you've taken on the first two highly successful habits above, if you're really taking compliance seriously, then you need to implement a formal and documented training program. Develop training materials that are recorded and mapped against your company's core values. Establish programs to introduce new employees to the company and disseminate information to employees who have been promoted. Take the time to create a standardized, clear, and recorded feedback loop to ensure that employees are aware of updates to policies and procedures. In marking these documents as read and understood, staff members attest to their commitment to following the policies and procedures as laid out by their organization. Many high-performing companies also link external training records to internal procedures.

#### **Capturing Exceptions and**

**Deviations:** In practice the best policies, procedures, and plans are "toothless" without monitoring, follow-up, and continued oversight. You need to proactively test your processes and automate them whenever possible to ensure that they are performed as required. You also need to ensure that your system is capturing all exceptions and deviations. At the very least, you can automate the scheduling and assigning of tasks to reduce the possibility of human error or fraud. Ultimately, effective compliance means being able to identify and view the results of a testing program as applied to any business unit, jurisdiction, topic, and/or regulation.

#### **Aggressively Auditing and**

**Investigating Anomalies:** Once you have a clear process in place to log exceptions and issues, you next

categorize and investigate those issues according to their severity and potential impact on your company. A well-designed automated system alerts all relevant people to incidents, exceptions, and material weaknesses, then lets them investigate such issues. An automated system also reduces the possibility of human error.

#### **Managing Exceptions and**

**Deviations:** Successful investigations take advantage of electronic data and audit trails maintained on a company's information systems. Proactively following a remediation or corrective action plan guarantees that problematic issues will not fall through the cracks. A company can then communicate with regulators about what it is doing to satisfy compliance directives and assure them that noted issues are competently resolved. Effective governance means proactively resolving all anomalies and documenting the actions taken. By addressing issues and resolving them, you are continually minimizing risk and improving your organization's business practices.

#### **Implementing and Measuring**

**Change:** Closed-loop compliance ensures that all identified problems are resolved. All issues or weaknesses that may have a material effect are prioritized to proper levels and then resolved by the person or people charged with their oversight. For effective risk management, you must be able to implement and manage change simultaneously across all your organization's geographic location. Create change-management plans for every alteration, and implement an automated system to route changes to the necessary parties.

#### **CLOSING THE LOOP ON RISK**

The key to the seven habits of effective compliance is that you must recognize that problems will occur regardless of how well you build your policies and procedures. Your goal must be to remediate problems and use them to further improve your business processes.

Following these seven habits enables you to

Figure 1: Closed-loop compliance



- Conduct risk assessment
- Make risk-based decisions
- Use the information and data from each of the habitual steps to operate in compliance with your regulatory landscape
- Demonstrate to regulating bodies that you are addressing risk head-on
- Show regulators that you are

mitigating risk accordingly.


In highly regulated industries, compliance is an ongoing concern and is too important to monitor and administer in an ad hoc, one-off way. Companies merge, laws are written, and agencies reinterpret the rules. So compliance officers must be proactive in managing risk by identifying laws

and regulations, agreeing upon their interpretations, dispensing information, monitoring procedures, addressing issues as they arise, and feeding the results into the process improvement element of regulatory interpretations.

Compliance officers need to close the loop by continually repeating these processes. A closed-loop model promotes a sustainable and cost-effective risk program, which is the only way to accurately capture and manage compliance risk while remediating regulatory violations across an enterprise. Compliance professionals who ignore the seven habits of closed-loop compliance may as well walk a tightrope, blindfolded, over a snake pit. It *can* be done, but not without incredible risk, so only the foolhardy need apply.

## REFERENCE

1 ICH Q8: *Pharmaceutical Development*. Section 3.2.P.2. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use: 10 November 2005; [www.ich.org/LOB/media/MEDIA1707.pdf](http://www.ich.org/LOB/media/MEDIA1707.pdf).

2 ICH M4: *The Common Technical Document*. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use: November 2000; [www.ich.org/cache/compo/276-254-1.html](http://www.ich.org/cache/compo/276-254-1.html). 

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