Ten Ways to Control Compliance Costs

If you're struggling to contain compliance costs, you are not alone. Cost-effective compliance is a core component of global competitiveness.

Carry out these ten straightforward steps to get your costs under control today.

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develop your potential

ABOUT THE AUTHOR:

John Avellanet is a successful business executive and advisor, an internationally recognized regulatory compliance expert, a dynamic public speaker, and the author of more than 100 internationally syndicated articles, a contributing author to the book, Best Practices in Biotechnology Business Development (Logos Press), and the publisher of the monthly senior executive newsletter of regulatory intelligence and advice, *SMARTERCOMPLIANCE*™. A frequent guest on business radio shows such as *Tomorrow's Business* and *My Technology Lawyer*, he is a sought-after speaker at businesses, universities and industry trade associations.

Reprints and audio excerpts of many of John's published articles and interviews are on the Cerulean website (www.ceruleanllc.com).

In his workshops, John shares hard-hitting, practical information on:

- Cost-effective lean compliance
- Quality by design and improving product development
- Preventing trade secret theft
- Simplifying records management and IT compliance

If you're interested in having John hold a workshop for your company, or would like to gain private access to his expertise, please call, write or visit:

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OVERVIEW

This booklet is divided into two sections:

- **Ten ways to control compliance costs.** This section walks you through industry facts, experiences and ten best practices used in firms of all shapes and sizes, from ten man biotech startups to 10,000-person international pharmaceutical companies. Throughout, I reference my own experiences as an executive in both small startups and a *Fortune 50* conglomerate.

- **Making an informed decision on external expertise**. This section covers questions you should answer *before* you make a decision about bringing in consultants.

I have seen a lot of executives struggle with the concept of controlling compliance costs. Black and white proclamations of "right" and "wrong" leave little room for making balanced decisions. This report should help you avoid decisions that waste time, effort and money — assets that investors and shareholders alike are less and less willing to forgive.

Remember: there is one difference between a compliant, bankrupt firm and a compliant, profitable firm — you.

TEN WAYS TO CONTROL COMPLIANCE COSTS

The Steps in Brief

1. **Narrow Your Scope.** Define your "regulated records."
2. **Automate Common Controls.** Embed standard checkpoints and automate as much as possible.
3. **Prioritize Spending.** Where is your long-term information integrity and confidentiality at risk?
4. **Minimize Duplication.** Combine your controls, your documentation and your audits.
5. **Leverage Your Vendors.** Most companies start using their vendors' help, then drop off over time.
6. **Use Compliance Agreements.** Have your vendors and partners agree to support your compliance success.
7. **Inventory Business Systems.** Cross-reference with "regulated records" and focus on streamlining.
8. **Get IT Involved.** Without Information Technology (IT) help, compliance drops.
9. **Partner Proactively.** Bring together IT, Quality Assurance, Regulatory Affairs, Records Management & Internal Audit.
10. **Simplify Risk Management.** Get everyone involved.

INTRODUCTION

Across the globe, companies spend an average of $4.4 million to implement compliance, plus at least $0.23 million every year thereafter simply to maintain compliance at the previous year's level. And yet, according to a June 2006 Kennedy Information study, more than 73% of Chief Executive Officers are beginning to wonder whether these good intentions are paving a road to ruin.

"These ten steps have one goal: to keep your company out of the red by getting your money's worth from compliance."

Compliance monies that are misspent originate from failing to take a big-picture look at what you can afford over the long-term, what reasonable goals are appropriate for your organization, and what the steps are you can take to reach those goals without pulling money from your bottom line.

There are a few basic rules to avoid costly compliance pitfalls: think for the long-term, tackle multiple fronts in parallel, resist temptation for magic bullets, know the risk level you and your shareholders will tolerate, and do not throw good money after bad.

But basic rules cannot substitute for experience. The ten steps I detail here are from my years struggling myself with the interplay of compliance, information technology and organizational issues. These ten steps have one goal: to keep your company out of the red by getting your money's worth from compliance.

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NARROW YOUR SCOPE

"Expand your implied records to encompass other related processes and you instantly expand your scope, filling your budget and beyond."

Before going any further with your compliance efforts, sit down with your Legal and Records Management groups. Ask your counsel to compile a simple table or matrix that outlines the specific regulation and the record category (or categories) typically used satisfy compliance. Ideally, this will incorporate both explicit and implicit records.

Example:

Under sections 21 C.F.R. 110.10 and 211.25 of the US Food & Drug Administration's Good Manufacturing Practices, companies are required to conduct personnel training. The training record is the explicit record. Implicit records are the standard operating procedure used to track this information and the training material itself.

Notice the direct line of sight between the training [*the action required*], the training records (such as attendance, date provided, etc.) and the material itself [*the results*], and the procedure to maintain the integrity of that proof; there are zero degrees of separation. Expand your implied records to encompass other related processes (such as how you sign up for training, and so on) and you instantly expand your scope, filling your budget and beyond.

Then, ask your Records Management group to take the legal matrix and compare it with the internal company records that fall into the category, noting how and where they are stored (electronic, paper, both), and the intended length of their retention / archival.

This matrix serves as an objective set of boundaries for your compliance efforts.

AUTOMATE COMMON CONTROLS

Concurrently, have your Information Technology (IT/ICT) group map or flowchart your business processes, taking careful note of each decision or checkpoint or other approval juncture.

IT is ideally positioned to handle this task for two main reasons: one, technology underlies just about every business process in the 21st century; and two, IT personnel are quite used to mapping the flow of systems and programs, something that carries over nicely into business process mapping.

Identify similar points of decision-making or approval stages. Have IT determine if these processes and their approval points are automated, manual or a hybrid. The goal is to determine which points can be automated in similar fashion, if not in similar ways.

Example:

Just as authority to enter Company A's network is determined by a user ID and a password, so is access to the database containing

clinical trial records. The database can be structured so that it either utilizes its own user ID and password structure, or to simply reference the main user ID and password for the network. Choosing the former will provide you short-term, quick isolated compliance; selecting the latter option will reduce your overhead immediately, reduce the tracking of user ID's and passwords by your employees and will provide you long-term compliance.

"Prioritizing spending is quickly done with two passes. First prioritize resolving your greatest risk areas of long-term information integrity. Then prioritize for long-term information compliance and security."

Be aware, however, that many vendors with stand-alone "compliant" systems will not be in favor of the latter approach as it can quickly make their pat solution less a "solution" and just another piece of the puzzle you're assembling.

PRIORITIZE SPENDING

Often easier said than done, I've found that the fundamental key is to make two passes at prioritization. (I have assumed that patient and personnel health and safety, as well as drug or device efficacy, have already been accomplished – if not, those are your priorities.)

The first prioritization pass focuses on determining where your long-term risk of information integrity is greatest. Why? Because every day you delay, the risk goes up and so does the cost.

For instance, if your greatest risk is the data integrity of patient safety data from a clinical trial that you need to retain for 20 years, then validating the data's stability and integrity as it exists now, is a priority over of the process for either entering new data or archiving it. Then, simply work backwards.

The next prioritization pass is for data confidentiality and security. This is for both regulations and for corporate profitability. If your intellectual property leaks out, your long-term company prospects diminish rapidly. Worrying more about the validation status of your analytical laboratory spreadsheets rather than the security of the new product information that analytical is testing puts the cart before the horse.

*"The more you hear '*that's not my area of responsibility*' spoken by those accountable for auditing – whether in Safety, Quality, Finance, IT, etc. – the more likely your costs are out of control."*

Minimize Duplication

The ideal situation is simply to have one overall "regulatory package" that incorporates financial audit controls, health and safety controls, system validation, equipment qualification and other components of comprehensive compliance. So work toward this.

First, insist that all of your internal audits are not exercises in "willful ignorance." The chemical safety officer should know and understand enough about basic company policies on financial controls, risk management, patient safety and privacy, and validation

that he or she can at least alert someone more skilled in those arenas if a chemical safety inspection also turns up patient identification information laying out unsecured.

The more you hear "that's not my area of responsibility" uttered by those accountable for auditing – whether in Safety, Quality, Finance, IT, etc. – the more likely your costs are out of control.

Second, take the business process map completed by your IT department, and review it with each of the business process owners (e.g., Purchasing, Shipping & Receiving, and so on). Inevitably multiple, redundant decisions are made. Ask "why" and "why can't" or "why not" questions to determine where processes, but especially decision points or authorizations, can be simplified.

"Always keep foremost in mind your need to balance profitability and compliance. Having one without the other is a sure road to ruin."

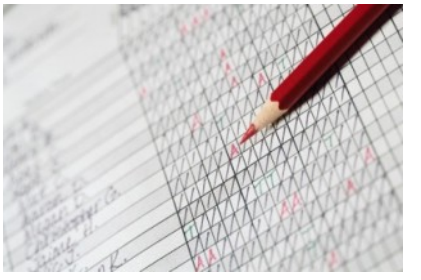
Example

In reviewing the process for ordering and then receiving chemicals, Company B discovers that under two different processes, one to verify the contents of the shipment and one to match the receipt to the purchase order, two people are involved, both looking at the same exact information and container. In one process, the purchaser is present, in the other, the receiving clerk. While this may, at one point have been due to an error along the lines, the company determines that the cost of having two people doing essentially the same task is higher than the risk of having to send a shipment back to get the originally ordered item.

LEVERAGE VENDORS

Each of your vendors should be able to provide you at least 30% of the compliance work you need completed. This works for copier and printer vendors, lab equipment vendors and IT suppliers alike.

First, ask for any Factory Acceptance Testing results or summaries to be forwarded to your Quality Control group. Ideally, this will include the tests performed, but if you can get that list orally from your vendor, that will work as well so long as you then document it.



Second, have the vendor install the equipment in a qualified manner. From a cost perspective, it is generally less expensive to have your vendor perform this work than for your employees to handle it. A good rule of thumb is to expect between a 10-20% cost increase over the purchase price without qualification.

Third, as part of any maintenance agreement with a vendor, insist upon at least a yearly preventative maintenance check, calibration and cleaning. If you recall the days of the copier repair technician coming to disassemble the copier to clean all the parts and ask how it's working, you know precisely how to structure this "health check."

Many software and hardware computer vendors also offer a similar assessment and "health check." IT groups can use the results

to show independent review of their settings and performance.

Be sure to maintain results from these yearly check-ups as proof of calibration and maintenance.

Lastly, nearly all vendors offer some level of training on their products, even if it's simply the installer showing you how to operate the device and when to call for help. If they do not have this documented, or have a user's manual, then simply document it and have the installer initial and date on a line reading "installed by and date."

"Craft a Compliance or Quality Agreement with any supplier of services (such as outsourced IT and Accounting services) that will impact your ability to comply with regulations; do not forget your partners as well."

If the installer does not wish to sign your document, then ask for a copy of the signed and completed work order from their company. Make a note on it of the instructions that you received, and if it came with a user's manual or other training guide.

COMPLIANCE AGREEMENTS

You can incorporate much of this vendor leverage, including a provision allowing your vendor's personnel to sign and date your internal company documents, by crafting a Compliance (or Quality) Agreement with your vendor. I recommend utilizing these agreements with any supplier of services (such as outsourced IT and Accounting services) that can pose a direct risk to your ability to comply with regulations; do not forget your partners as well.

You can have this either as a separate agreement or, more preferably, since it's often easier, as an addendum to your main contract.

There are three critical points to cover in any Compliance Agreement:

1. The vendor / supplier is accountable for adhering to the rules and regulations you are accountable for when supplying services, parts, etc. to your company. In other words, spell out that the IT outsourced provider is accountable for maintaining your data to be compliant with 21 CFR Part 11 and in ISO 17799 fashion if those are the two rules to which you adhere.
2. Clarify the ability to audit, both in person and on paper, how often audits will be conducted (I always recommend clients incorporate, as well, the ability to conduct audits randomly with 24 hours notice), expectations (i.e., if you expect to be able to have access to archived documents within 48 hours of a request, then say so), and, most importantly, the financial penalties for non-compliance at certain levels.
3. Require a summary document from each vendor on a yearly basis covering their compliance status, steps they've taken to continually improve their program, and what they foresee the current risks are (and how they are addressing).

Recognize that some of your minor vendors will likely not be able to handle all of this on their own and you may need to offer a probationary period. This, incidentally, can be an excellent compromise if you are just starting to qualify your vendors but can't afford to stop working with them until qualification is successful.

Inventory Business Systems

Pull together members of your IT department, with your Records Management group and the business owners of various business systems (Purchasing, Accounts Payable, and so on). Have Records Management review the explicit/implicit record-regulation matrix.

Have the business owners and the IT personnel identify the electronic systems involved in each regulated process.

Next, have IT cross-reference the map of the business processes and their decision points with each electronic system.

There are two main tangible outcomes of this work session: identification of gaps or redundancies, and the clarification of systems needing some level of compliance work done (such as validation).

There are also two main intangibles: compliance is now increasingly part of the day-to-day background of everyone's job, and then IT is more closely focused on business processes. Both of these are critical for long-term financial success.

Get IT Involved

In 2005, Proctor & Gamble discovered a very interesting correlation: when IT is less involved in the business processes, compliance goes down; when IT is involved (as an example, helping scientists with Material Safety Data Sheets (MSDS) on new formulations), compliance goes up.

They also noted something utterly unexpected: when IT helps get the business processes done rather than just focusing on technology and automation, costs actually decline while compliance improves.

"When IT helps get the business processes done rather than just focusing on technology and automation, costs actually decline while compliance improves."

Why? According to one of P&G's global project managers, the answer came from the users themselves: they felt more productive because compliance was less of a hassle; someone was always there to help. As one scientist noted, "I didn't have to worry about all the items necessary for a full MSDS. The IT guy and I did it together. He helped me fill in the gaps."

Have your IT department assign knowledgeable system specialists to each business owner area to answer questions and to provide business process (not just technical) support and help.

PARTNER PROACTIVELY

Bringing together your Records Management, IT, Regulatory Affairs and Quality Assurance and Quality Control groups together to partner and piece out specialized compliance tasks is a typical best practice. Unfortunately, it leaves out the most important group: Internal Audit.

The simple reality is that all audits are a push-pull of preliminary findings, discussions and pushback's before the finalized findings

are agreed upon. Getting your Internal Audit group into the room to at least discuss the findings that did not make it onto the final audit report is absolutely critical to driving down costs while achieving compliance.

Your Internal Audit group can also stage preventative audits or "check-ups" as part of your compliance program. Incorporate these into your final regulatory packages. Remember, the goal of compliance may be perfection, but the reality is proof of control and continual improvement. Your own internal audits done by your Internal Audit group (even if they are nominally just for financials) are solid proof of intent that shouldn't be left out.

Simplify Risk Management

Over the years, I have noticed a simple reality: the more complicated and comprehensive the risk management framework, the more it becomes an exercise in yearly three-ring binder collection.

If you want to drive down costs associated with compliance, then you need to simplify your risk management methodology such that it can be understood by everyone, from your shop floor steward to your outside shareholder.

"The more complicated and comprehensive the risk management framework, the more it becomes an exercise in yearly three-ring binder collection."

One of the techniques we use in our consulting practice is a streamlined risk management approach based on the US Food & Drug Administration's own internal risk-based methodology taught to their investigators.

You can create your own by simply taking your existing risk methodology and stripping it down to no more than ten categories, preferably seven or less.

Example

Last year, I worked with a company that had 40 pages of risk factors to measure and incorporate for each business area. In this case, the company had two entire pages just dedicated to the types of risks and severity possibilities to the patient / end user of the product. And this had to be reviewed for every proposed change in that product's march through production. Indeed, things had gotten so bad, that for every new product in the research or preclinical phase, out came the 40 pages of risk factors.

Of course, what happened was a process that had become an annual risk assessment marathon with colorful executive dashboards, and then was otherwise skipped over so that business could continue. Costs went up and compliance went down.

The simple reality is that people just need to be able to quickly surmise if there is a reasonable chance of harming someone. Even the so-called "man on the street", once they suspect the existence of a reasonable risk to another person, will expect appropriate safeguards to be taken. Use this to your advantage.

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For my work at this company, I suggested we use a definition of "reasonable" that was intuitively based: what would your typical shareholder think the chances of harm to themselves were? Or, alternatively, would you give this product to your child if this change went forward?

"Teach a simplified risk approach to all of your employees and have them use it daily for all the decisions they are faced with; compliance will go up and costs will go down."

We were then able to distill the 40 pages down to one page, including the overall process, with ten risk categories on a "yes – no – maybe – not applicable" scale. For 94% of the changes, this simplified approach was more than adequate. Any item that struck a "maybe" or "I don't know" chord, went on to the more comprehensive 40 page risk assessment.

The key here is to use this simplified assessment as your first-line risk management process, then tackle the more questionable items with the more detailed analysis. In this way, you avoid bogging down the vast majority of business activities.

Teach a simplified risk approach to all of your employees and have them use it daily for all the decisions they are faced with; compliance will go up and costs will go down.

Concluding Thoughts

Fundamentally, your employees and colleagues want to do "the right thing." Give them straightforward tools and techniques; avoid silver bullet solutions – they don't exist.

Bring your departments together and show them how each inter-relates and depends on the other; don't allow them to shrug off their accountabilities across the organization. Then provide them guidance, objective frameworks and advice above the fray.

"Chances are, you may already have all you need to correct course and improve your bottom line."

Asking your people, your vendors and your colleagues to help, will only speed this process and lower your costs if you recognize the need to think for the long-term.

If you have made compliance decisions out of a desire to "make it go away," acknowledge this. Take a look at the big picture and evaluate your options. Chances are, you may already have all you need to correct course and improve your bottom line.

Keep foremost in mind your need to balance profitability and compliance. Having one without the other is a sure road to ruin.

If you'd like a partner to help you achieve profitability *and* compliance, please call or e-mail me today.

Are you ready to develop your potential and turn compliance into a competitive advantage?

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CHOOSING OUTSIDE EXPERTISE TO HELP

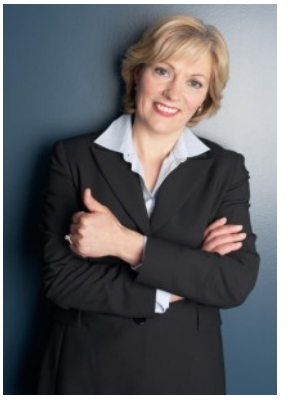
You should know the answers to these questions before you make a final decision about bringing in a consultant or outside advisor to help you plan and implement cost-effective compliance while reducing your executive exposure and risk.

THE COMPANY

- What is the size of their average client firm? Is that a good fit with your size?
- How long has the principal worked with R&D, product development, laboratories, manufacturing and compliance? Does it matter? Why?
- Will you be working with the principal or a junior team?
- Do you agree with the views and strategies espoused in the firm's published articles, speeches or interviews?
- How many complaints have been made on the company in your state and in any published compliant formats (such as the Better Business Bureau)?
- Is a significant part of the company dedicated to offering cost-effective, flexible compliance advice? Is that good or bad?
- Does the firm have strict limits on the number of clients it takes on or will the firm sign deals with as many companies as it can? How could this affect you?

THE PROPOSAL

Proposals tend to differ in the ways listed below:



- Did the firm give you a chance to review their assessment of the situation before giving you a proposal?
- How many times did the firm talk with you to clarify specifics before providing a proposal?
- Does the proposal provide clear expectations of objectives? Did you get a chance to review and revise them based on your understanding? If not, what might this indicate?
- Does the proposal provide phases or mini-projects to give you early results and reduced risk? Can you walk away after each phase with no further commitment or penalty?
- Does the proposal provide options for levels of engagement or is it dedicated staff augmentation? Note that the inclusion of resumes in a proposal is often a dead giveaway to the latter.
- Does the proposal draw a clear distinction between costs included and excluded (*i.e.*, travel, materials, subcontractors, administrative support, etc.)?
- Does the proposal recognize and refer to any non-disclosure or confidentiality terms and conditions?

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- Does the proposal provide a written guarantee? Are there third-party standards of ethics referenced? Can you collect more than your investment if the work is utterly unsatisfactory?

- Does the proposal disclose an available payment discount (for instance, 5% upon payment in full, discounts for referrals, etc.)?

- How often will you have regularly scheduled check-ins for both progress and to improve your working relationship and return on investment? Is this important to you?

- What post-project support will you have from the consultant? Will you receive help preparing for an audit after the project's over?

THE PLAN

- How much do you expect your company to change over the next five years? What are the trigger points in the plan to adjust strategy and tactics?

- Will you need to bring in another consultant later to account for changes or is knowledge transfer built into the plan?

- What guarantee do you have that the consultant isn't looking to supplement staff long-term?

- What is the average length of time your colleagues and competitors have hired a consultant for? Is this plan different? Why?
- Based on the average, how long will it take you to realize a return on your investment? Does the plan highlight realistic areas to target for improvement?

THE PRICE

- Can you pay the consultant without affecting your growth plans or depleting your resources even if the project was delayed by as much as 20% at some point in the future?
- Does the investment required match the long-term value of the engagement? (Generally, the more value, the higher the cost.)
- Can you expect at least a 5-to-1 rate of return?
- Has there ever been a situation where the consulting firm has had to raise fees on existing clients in mid-project?
- Does the company charge an initial, non-refundable fee?
- Is there a qualified referral discount or payment in full discount?
- Is the firm able to offer high service and quality in exchange for less on-site and travel costs?

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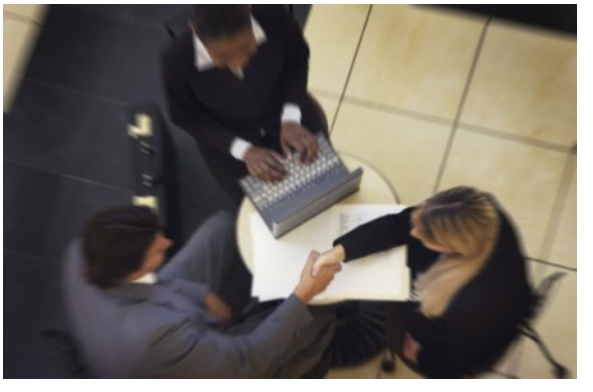
- Does the company focus its senior people on its clients at hand or only on the ones who bring in more than $450,000? How could this affect you?

Be very careful if the costs you are considering are dramatically different from the prices of another company for a similar proposal. Smaller, boutique firms tend to have less overhead which translates into lower fees than larger firms. However, keep an eye out for companies that offer a steeply lower fee; they may intend to raise their rates later on to make up for a low rate to get your business.

It's better to know the answers to these questions now than to wait until midway through the project or the proposal phase. Unfortunately, many consulting companies sell with their seniors and then perform a bait-and-switch, servicing their non-million dollar accounts with junior consultants. You need to feel comfortable knowing that your company is a top focus of the consulting firm.



The answers to most of these questions can be answered by an experienced consultant. Call the independent expert who gave you this book.

This booklet, prepared for executives searching for a solution to control—and ideally lower—the costs of compliance, is designed to provide you reliable, facts and insights so you can make informed decisions for you and your organization.

John Avellanet, the author of *Ten Ways to Control Compliance Costs*, is internationally known for his expertise in cost-effective compliance. Prior to starting his consulting practice, John was the CIO of a *Fortune 50* medical device subsidiary and was accountable for compliance with the FDA's 21 CFR Part 11, EU Annex 11 plus ISO-17799 and ISO-15489. He is available as a speaker and facilitator for on-site seminars.

For reprints of John's other publications, see the resource library of his company, Cerulean Associates LLC, at: *www.ceruleanllc.com*

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