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COMPLIANCE

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Lean Compliance for Midsized Companies

Turf battles, redundancies, and inefficiencies in handling compliance efforts cost companies millions each year. The five themes of lean compliance – simplicity, rapid prototyping, agile risk, grow knowledge, and proof – are offered to stem the tide of wasted expenditures.

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INTRODUCTION

Compliance costs your company at least $5,400 for each person who works with you[1] - if you are doing everything right. Chances are, however, your company - like most of its peers - has redundant compliance and quality systems efforts that are costing you an additional 1.1% of your total revenue.[2]

To reduce costs, biopharmaceutical and medical device regulatory agencies around the world (including the U.S. Food and Drug Administration (FDA) and its European Union counterpart) insist that a risk-based methodology prioritizing compliance efforts can work. And yet, for small to mid-sized biopharmaceutical and medical device companies faced with poor international currency conversions, growing generic competition and legislatures increasingly concerned about soaring healthcare costs, risk management hardly seems to fit the bill.

So what does control compliance cost?

BOTTOM LINE LOSSES

Research by the Ponemon Institute found that while 86% of companies suffer from multiple, disjointed efforts at compliance, more than 61% of companies further exacerbate their own struggles with poor communication and turf battles between Quality Assurance, Regulatory Affairs, Quality Control, Finance, Records Management and Information Technology.[3]

And in Europe, where risk-based compliance management has long been a favorite push of regulators, only 42% of companies prioritize their efforts and resources based on risk.[4]

Lest one think that these costs completely cover compliance (including quality systems), the research firm IDC conducted a three-year study of regulatory-related projects at companies in the U.S., Canada, and the EU that revealed even more disturbing trends: mid-market companies (those with revenue of $250 million or less) spent over $2 million each during the first year of the study, and by the end of the three-year study, many had spent close to $7.3 million just on various regulatory-related projects.[5]

Clearly, controlling compliance costs needs to be a priority for any biopharmaceutical and medical device business executive focused on his or her organization operating efficiently and effectively.

LEAN COMPLIANCE

The author advocates an approach based on Toyota's Lean techniques for manufacturing and product development. By designing and implementing a strategy to reduce, if not eliminate, duplication and wasted effort, and shift compliance from a reactive, controlling mindset to a proactive, problem-solving outlook, this "lean" strategy strengthens compliance while streamlining and simplifying its real-world look and feel.

As an added by-product of going lean, the author's clients and colleagues have discovered that their business flexibility has improved. For those firms still in the process of getting to market, this has meant a significant increase in time-to-market speed.

In the author's fifteen years of experience working with cost-effective compliance and quality systems, a "Lean Compliance" approach with five core stratagems can be initiated, adapted, and expanded throughout any biopharmaceutical or medical device organization in less than six months.

FIVE THEMES OF LEAN COMPLIANCE

Central to Lean Compliance is recognition by the biopharmaceutical or medical device executive that his or her short-term, immediate goal, starting day one, is to make compliance easier. Within a few months, the integration points across his or her organization (including its quality system) that help achieve streamlined compliance will begin to pay off. And, over the long-term, a Lean Compliance strategy will help the executive drive profits by delivering speed and business flexibility.

Theme One: Simplicity

In the late 15th century, Leonardo Da Vinci noted, "Simplicity is the ultimate sophistication."

At its essence, this means creating a single compliance program under which quality, regulatory, safety, financial controls, electronic security, internal corporate policies, records management policies, and so on, are managed. In the author's experience, this is usually the hardest hurdle to overcome in implementing a Lean Compliance strategy.

The author, his colleagues, and his clients have had the most success beginning simply: focus on the most important item that will drive

all decisions; the one concept that if phrased as a question, every activity, suggestion, resource move, funding request, new project idea, etc., must meet. For instance, when one of the author's colleagues decided the most important aspect of compliance for her company was continual improvement, then the question became, "How will this _____(new project request / process suggestion / additional resource request / etc.) help us achieve and demonstrate continual improvement?"

Over the years, the author has found that there are really only two tactics to achieve this sophisticated simplicity:

- Invest a great deal of time, money, and effort upfront in order to achieve lower costs down the road. Spend time determining the one, most important compliance concept for the entire company, train everyone, then review all policies, projects, procedures, and so on for adherence to that one most important message. In over fifteen years of working with Lean Compliance, the author has found few companies with the leeway to take this road.
- More practical, in the author's experience, has been for biopharmaceutical or medical device executives to take a prioritized, staged approach, breaking the implementation of the overall strategy into a mix of "low hanging fruit" and multi-month projects so as to sustain momentum. However, this takes long-term vision and the willingness to live with the renovation clutter until the implementation is near completion. For instance, under a phased approach, the biopharmaceutical or medical device executive might ask each functional area in his or her company to decide upon its most important compliance item; the executive team then compiles, revises, and refines amongst the many to achieve the company's most important compliance concept.

There are other aspects of simplicity to keep in mind as well. Policies and procedures need to be written in clear, tangible language. The one core message needs to be consistently communicated across the organization. And the one most important compliance concept needs to be compact. Key to clear communication, constant application, and organizational buy-in is conciseness.

Years ago, during the author's first experience as a medical device executive being audited, the investigator explained his philosophy on the role of conciseness in compliance:

"If I see a simple, one or two sentence quality policy, then I know it's going to be a pretty good audit. If I see a quality policy that runs on and on…and I've seen more than a few…then I know the audit's not going to go well for anyone involved."

Put another way, if the biopharmaceutical or medical device company's one most important compliance concept is not simple and concise, it's not important.

Theme Two: Rapid Prototyping

During the author's career as an executive in research and development and new product commercialization organizations, the author gained a keen understanding and appreciation for a development principle called "rapid prototyping." Rapid prototyping is the use of models or tools to quickly develop prototype products (including software) that can be assessed, often through formal testing or consumer focus groups.

Similar to the philosophy of rapid prototyping is the FDA's Quality by Design initiative espoused by Dr. Janet Woodcock and others at recent FDA meetings[6] and publications.[7] Put simply, Quality by Design is determining, and then embedding, the required safety and efficacy minimums as early as possible in medicinal product development to then carry forward into final production.

By extending the interplay of these two philosophies to compliance and quality systems, the biopharmaceutical or medical device executive can steer an emphasis on determining and embedding the minimum regulatory controls as early as possible in any process, procedure, or system design (or revision). Thus, before writing a standard operating procedure (SOP) or policy, draft a flowchart that highlights critical decision points and potential controls. Implement this flowchart. Then use mock audits or test runs to assess the controls and the business flow. Refine and test again, this time in a different manner (e.g., if a mock audit was used beforehand, use a test run-through the second time). Finally, write and wordsmith the detail behind the flowchart.

In the author's experience, this also has a subtle benefit for any organization: the number of fingers in the pie, so to speak, will quickly be reduced. Process flowcharts leave little room for wordsmithing arguments and the incorporation of process suggestions from those not involved in the process. While this may sound critical, the author's own unfortunate experience bears this out. Years ago, one of the author's colleagues unintentionally sabotaged his own company's efforts at compliance - something he (and the author) only recognized years later - by consistently insisting on very detailed, standardized template language in every standard operating procedure (SOP), setting a tone akin to what might be in a legal contract. While on the surface this seemed like a good idea to everyone involved (including the author at the time), the real-world impact was simple: the line operators, lab technicians, and other personnel who actually had to follow the SOP found it too difficult to follow and understand (even when it was a process that they had originally designed), and promptly ignored it, setting the scene for noncompliance.

The one most important compliance concept accepts this organizational reality: the more people that have to follow a procedure or policy, the simpler the procedure or policy needs to be. Rapid prototyping for compliance is a means to apply your single most important compliance concept in the real world, without spending a lot of time or effort to rewrite policies and procedures until after you have it "right."

Theme Three: Agile Risk

To grow and sustain the value created by eliminating waste and redundant efforts, there are two aspects of agile risk critical to Lean Compliance: risk management and agility.

Risk management is fairly straightforward; more has been written about risk management in the past few years when it comes to compliance than the author need delve into. However, in order to streamline and simplify operations, quality, and compliance efforts, the biopharmaceutical or medical device executive needs to simplify and streamline risk management. The target is an understandable process used by everyone in the organization to make decisions, from the summer intern to the chief executive officer. In the author's experience, keeping with whatever current risk assessment and management tool being used today (such as Haz-

ards Analysis and Critical Control Points) is fine. Yet, in order to push it across the organization in a simple, concise, understandable way that encourages broad adoption, simplify it as much as possible. For example, reduce risk classifications to no more than three levels. (See the FDA Expert Briefing, Simplifying IT Change Control, from October 2007[8] for an example of how to tackle this at a global and local level if your organization is multi-site.) Simplified risk management does not strive for perfection, but rather aims at wide-scale adoption and usage to get everyone in the biopharmaceutical or medical device company singing from the same choir book when it comes to making and managing decisions and controls.

Risk management must be tempered with flexibility and agility. This allows the biopharmaceutical or medical device company, along with growing its knowledge (see below), to achieve continual improvement, something that investigators and auditors increasingly expect to see from company quality systems and compliance programs. Agility also keeps policies and procedures from becoming so rigid that they cannot adapt well to changing business climates.

One approach to achieve flexibility within policies combines the concept of "reasonable" risk, the rapid prototyping approach discussed above, and what executive management innovation expert, Bill Cope, in a March 2007 article on policy best practices, stated was the true nature of any policy or procedure: "policies and procedures are intended to deal only with the regular and routine."[9] In other words, write policies and procedures for 95% of the intended audience. An engineering SOP should be written largely with engineers in mind, not the document specialist, quality manager, or regulatory affairs person reviewing it.

When assessing controls for incorporation into policies and procedures, the author recommends looking to the FDA's definition of "reasonable" as approximately equivalent to a 2% or greater chance of occurrence[10]. This only adds further weight to the argument that an engineering SOP should be 95% written for engineers; the odds of a marketing manager or quality assurance analyst attempting the engineering job specified in the SOP are significantly less than the "reasonable" threshold of 2%.

Theme Four: Grow Knowledge

Knowledge management is an important topic for any value-driven strategy. Too frequently, however, the author has seen this is interpreted to be some sort of glorified document management system. The advice the author gives his clients and colleagues bears repeating here: if you buy it, it is not the solution - it is a tool. Rather than looking for silver bullet technology, biopharmaceutical and medical device executives should consider starting with a repository for all compliance and quality information and data.

Use this central repository to share metrics, trends, and current activities between sites and departments; this is especially crucial if the company has two or more sites that make the same biologic or medical device or follow-on products (such as a combination device assembled across a multi-site production chain).

Care should be taken that knowledge management does not turn into a data dump. This will render the knowledge repository useless and so is to be avoided. One of the author's clients continually asks her teammates, colleagues, and outside contractor's, the "so what" aspects of the data. For her, the raw data is far less helpful than the trending analysis; the detailed audit checklist and finding notations are important, but the one or two page audit summary document is most helpful to people across her organization to make sure they do not repeat similar mistakes (or are able to achieve similar successes).

The author recommends that each executive ask - for any proposed information to go into the repository - what is hoped will be able to be done, proven, or shown with the information. Consider further asking whether the information is important to the company's quality, compliance, and strategic business objectives? Does it support the company's one most important compliance concept?

By working through these questions before information is placed in a knowledge repository, the biopharmaceutical or medical device executive makes it easier for people to find answers to questions and avoid doing duplicate work. The auditor is also given a faster means to assess the company's compliance level. Taken together, these then translate into more productivity, less time away from business dealing with auditors, and lower costs.

To keep these benefits in mind, the author advocates thinking of knowledge management as knowledge growth, not just data capture. Information management, electronic backups, a document management system, and records retention rules are just skeletal components and tools. Real knowledge management allows a biopharmaceutical or medical device company the ability to act with wisdom to grow and succeed. When it comes to compliance and quality systems knowledge management, biopharmaceutical and medical device executives would do well to heed the Japanese proverb, "Knowledge without wisdom is like stacking books on the back of a donkey."

Theme Five: Proof

Eventually, every biopharmaceutical and medical device executive will face a regulatory investigator or third-party auditor who will question what was done, ask for the logic behind the decisions, and then push for proof of intent to comply. While record-keeping is essential, demonstrating intent to comply with regulations to an outside skeptic, like an auditor, can be difficult. Many companies have taken an approach using metrics and trending toolsets such as those in Six Sigma or other methodologies.

Just as the author suggested a simplified version of risk assessment methods to give everyone in the company the capability for better decision-making, the author advocates a simplified set of metrics available to everyone in the company at any level.

Create two sets of five measurements each: one set of five metrics to showcase progress in improving the safety and efficacy of the product (for instance, fewer side effects or less significant side effects); the other set of five metrics to demonstrate the scope, continual improvement, and effectiveness of the controls, checks and balances on company processes and personnel (for example, reducing the resolution time in nonconformances combined with a reduction in overall nonconformances and a corresponding rise in positive patient or customer feedback).

In the author's experience, biopharmaceutical and medical device companies should avoid more than five measurements in

each of these two broad areas. Executives need to be able to act upon what has been measured, and have what has been measured understandable by everyone in the company (as well as to the outside auditor or investigator). Ten actionable metrics can be more than enough to demonstrate significant progress corresponding to a strong intent to comply and the most important compliance concept. By limiting his or her company to no more than ten measurable intents to comply, the biopharmaceutical or medical device executive minimizes the risk - when it comes to audits and compliance troubles - of falling under the late 16th century proverb, "The road to perdition is paved with good intentions."

FINAL THOUGHTS

For biopharmaceutical and medical device executives who need to build an internal business case for going lean with compliance - and quality systems - programs, there are a number of publicly available (at the time of writing) industry reports on the world-wide web, including the Pharmaceutical Research and Manufacturers of America (PhRMA)'s *Pharmaceutical Industry Profile* (updated yearly) and *Value of Medicines* from 2006; the Ponemon Institute's *Audit & Compliance Professionals Survey* from 2007; a transcript of the 2007 audio-interview from *Knowledge at Wharton Business School* with Dr. Roy Vagelos, the retired CEO of Merck; the author's firm's own report from 2006, *Ten Ways to Control Compliance Costs*; the Advanced Medical Technology Association (AdvaMed)'s *Critical Path* presentation and regulatory comments from 2004 and 2005; and the Europe Economics Report, *Costs of Compliance*, from 2003.

Compliance and quality can add enormous business value, not just support core functions and meet regulatory requirements. A strategy that calls for going lean with compliance and quality programs will help biopharmaceutical and medical device executives tightly integrate their entire organization to achieve business objectives and bottom line growth for this year and the next.

Are you ready?

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ARTICLE ACRONYM LISTING

FDA	Food and Drug Administration
SOP	Standard Operating Procedure

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