

Compliance Master Plans

Are You Traveling Without One?

by Timothy Joy, Scott Rudge, and Joanne Izyk

Successful business leaders routinely expect intelligent, comprehensive, and accurate business plans with which to gauge the potential or bearing of an organization. Amazingly, in the pharmaceutical and biotechnology industries, a similar demand for concomitant compliance plans can be almost nonexistent. Operating without a compliance plan is risky for businesses that rely on obtaining and sustaining regulatory approval for their products — approval that is substantially based on demonstrated compliance with regulations and various ancillary current good practices and scientific expectations. Hence, failure to implement and execute a comprehensive compliance plan can be disastrous.

This is not to suggest that compliance considerations are alone in the category of critical business deliberations. Clearly monetary, technical, and other strategic issues all variably balance atop the organizational pyramid. Equally clear is that an ineffective or absent compliance plan can lead to serious and sometimes fatal damage to a well-designed and otherwise flawlessly executed business plan whether for a development-stage company experiencing delayed marketing approvals or a commercial company afflicted with recalls, warning letters, or consent decrees. On the positive side, acting to prevent such unwelcome scenarios

can be as easy as demanding or, depending on your specific organizational role, encouraging, developing, implementing, or executing a carefully crafted compliance plan. A comprehensive compliance master plan is not a simple compliance and quality manual, policy document, mission statement, or even your collection of SOPs (numerous as they may be). No, it is a detailed but user-friendly master plan that fully outlines all essential parameters that will guide the far-reaching and critical decisions affecting your organization's ongoing compliance status.

Those are decisions (big and small) that inevitably will be made many times every day by virtually every member of a pharmaceutical or biotechnology organization. To enhance this decision-making process, you should draft your compliance master plan as soon as possible, build it by soliciting feedback from all experienced parties, integrate it with your technology, and share it freely. Strive to create a compliance “neighborhood” where everyone in your organization wants to live.

This discussion focuses on enhancing cost-effective compliance with pharmaceutical regulations. However, progressive companies know that a similar organizational atlas can be beneficial in other compliance areas such as environmental, safety, employment, and business regulations. Those



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other areas may be somewhat easier to define, and the exercise to include them in a truly comprehensive plan can help draw an entire organization together on a common theme. The effort will essentially demonstrate that all parts of an organization share responsibility in consciously evaluating and effectively implementing compliance controls designed to keep people safe, provide life-enhancing products, and ensure that the business remains free of regulatory infractions.

So What Is a Compliance Plan?

Reasonable questions deserve practical answers. A compliance master plan is akin to the various prospective protocols regularly prepared and used in the

pharmaceutical and biotechnology industries to facilitate success through collaborative design. The “Compliance Plan” box provides a functional glimpse at an example table of contents (including individual section descriptive comments).

DEVELOPING YOUR COMPLIANCE PLAN

Understand the vision before you begin the process. In spite of our comment regarding business plans (which implies applicability to early-stage or reengineered organizations alone), compliance plans can be implemented at any stage. If you are fortunate, the implementation stimulus comes from a simple light-bulb event (maybe this article?) illuminating your organization’s attempt to navigate the intricate compliance landscape without a roadmap. In other cases, the illuminating event may be more serious and potentially damaging, such as a delayed product approval or a series of recalls — or worse. Regardless of the impetus, understand that assembling a compliance plan requires only four main steps: outlining the regulations, defining risk/benefit choices, integrating core technologies, and customizing the document’s framework.

Outlining the Regulations: Your compliance plan must first outline all regulations and expectations applicable to your core business and technology (see *Scope* in the “Compliance Plan” box). This step accounts for regulations from the agencies governing your target markets (domestic and worldwide) as well as globally harmonized expectations. The content must be robust enough to provide practical information to any member of the organization and truly interpret the requirements — not just reiterate regulations — all while remaining compact enough to keep the compliance plan from becoming an unworkably long document.

Defining Risk/Benefit Choices: The second step in developing the compliance plan is absolutely

vital. It entails considering and justifying risk and benefit choices that will ultimately determine where the leadership of your organization wants to position itself on the compliance continuum. Because some specific regulatory requirements are intentionally broad, and all regulations are inevitably subject to individual interpretation, simply proclaiming an expected adherence to regulations is insufficient.

To further clarify, the compliance continuum can be viewed as a bell curve representing compliance efforts by all the thousands of global pharmaceutical and biotechnology companies and their innumerable quality and compliance systems (Figure 1). This scale ranges from the inadequate systems at the far left that predictably yield undesirable compliance outcomes (e.g., warning letters and approval delays) all the way to the far right (and it is a long way) where ultraconservative compliance programs are touted and even accepted as the sole means of success.

As with most extremes, neither end of this scale should be your final compliance objective. Obviously, the outcomes associated with noncompliance are unacceptable business results. Alternatively, the cost of living in the ultraconservative district yields success at a price far greater than it may need to be, and that often includes technologically restrictive initiatives and policies — again, not preferred business results. To avoid being either grossly noncompliant or unnecessarily ultraconservative, pragmatic organizations use discerning approaches to fully assess the risk, benefit, and cost equations of their compliance plans. Through a combination of factors — not the least of which are diligent, contemplative, and cooperative oversight efforts of the various regulatory bodies — most compliance systems and their range of inputs, efforts, and outcomes ultimately fulfill the key expectations, achieve successful regulatory inspections, and win their

companies approval to market their products.

Determining exactly where and how you want your organization to fall on the compliance continuum must be the result of conscientious actions and decision making (1). Mark your compliance goals as data-defended organizational decisions, then weave the resulting philosophy throughout your compliance plan. Although your organization could choose to live at either extreme, be certain that whatever the choice may be, it is a corroborated decision and not simply the result of “creep” (toward either extreme) that inevitably happens when prospective communication, formal analysis, and justification are not required.

Integrating Core Technologies: The third step in building a compliance plan is thoughtful integration of core technologies with quality and compliance systems. That is accomplished through the feedback of experienced professionals in each area affected by compliance initiatives and expectations. It is vital to include input from research and development, operations and manufacturing, clinical, medical, and (obviously) regulatory affairs and quality assurance. Aggressively soliciting and then using such far-reaching input will provide the best opportunity to make both the routine and critical pieces of each area interlace as neatly as possible into a comprehensive and effective compliance plan.

Customizing the Framework: Finally, your compliance plan document itself must be constructed within a customized framework designed to provide a suitable foundation for the actual tools of compliance management. Overall, this framework should ensure that the plan sets and describes balanced compliance objectives for your organization obtained from a risk–benefit analysis specifically applied to your core business. It should provide an executable and fully dynamic road-map to achieving those goals on time and within budget. The plan ultimately serves as an information benchmark for the

COMPLIANCE PLAN

Purpose: Be sure to delineate your specific product and technology applications

Scope: Outline the intended marketing jurisdictions, the applicable regulations, and ancillary expectations

Approach:

- Create comprehensive and integrated regulatory/quality/compliance strategies, with an emphasis on maximizing harmonized tactics for multijurisdiction requirements
- Justify strategy implications and alternatives

Implementation:

- Address all specific considerations, including relevant milestone-related timelines
- Ensure universal participation, assign responsibilities, and summarize expectations
- Estimate and disclose the impact on resources

Tracking and Reporting:

- Define mechanisms for monitoring progress
- Include a long-term calendar for reporting deadlines

Periodic Review and Updates:

- Describe the periodic review process to ensure that dynamic strategies and initiatives remain current
- Describe plans and expectations to enhance regular and milestone-related compliance activities
- Commit to formal executive management updates

entire organization (top to bottom). As a benchmark, the compliance plan streamlines all compliance-related activities by providing each individual, team, and diverse group with the details and subsequent empowerment to practice the long-held tenet that quality and compliance are a part of everyone's job.

THE COMPLIANCE PLAN EXPERIENCE

There will be ancillary benefits and rewards. A compliance plan is fundamentally intended to add value to your organization by helping to put and keep your products in the marketplace. However, many additional benefits accompany the implementation and execution of a well-designed compliance plan. They include the following, in no particular order.

Management Participation: Your executive management team will have an opportunity for top-level input into, required concurrence with, and then a documented prospective summary view of the compliance objectives and rationale of the company. That summary should include resources needed, complete risk-benefit parameters, and how much compliance will cost.

Leadership Accountability: It is clearly appropriate to have a single executive overseeing quality and compliance, but that person must also lead in demonstrating accountability. A compliance plan begins and documents that accountability process. As the compliance benchmark, the plan allows for convenient periodic progress reporting to an executive management team or compliance oversight committee.

Reduced Subjectivity: Compliance decision making for new or evolving issues will become more predictable when you have a plan documenting your organizational compliance rationale. Predictable compliance decision making reduces organizational stress and confusion and leads to more effective project planning and execution.

Establishing a Benchmark: The ability to direct everyone to a single source for determining your company's compliance expectations will enhance your efforts to make quality and compliance a part of everyone's job. Providing a consolidated organizational interpretation of how the company intends to comply with global regulations, guidances, and requirements that apply to your technology and business will

eliminate the variability of having each person interpret those diverse requirements individually.

Promoting Uniformity: Any written procedure that includes specific compliance parameters or objectives (and virtually all do to some degree) will evolve from the common themes and expectations outlined in a compliance plan. This will improve compliance consistency within your written procedures. Such uniformity can eliminate redundant inquiries regarding compliance implications and thereby facilitate implementation.

Complete Participation: A compliance plan facilitates teamwork by elucidating common compliance goals and expectations for all departments within your organization.

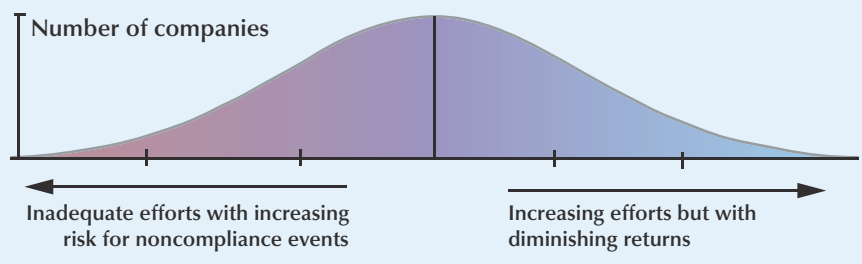
Functional Value: With proper design, a compliance plan (or portions thereof) can serve as a ready-made template for periodic compliance gap analyses. If yours is a development-stage company, that template can form the basis from which to derive your annual compliance enhancement plans. In both cases, the effort invested in developing a plan serves multiple purposes.

COMPLIANCE PLAN DOOMSAYERS

Developing and implementing a compliance plan is an attainable objective. Some compliance professionals will tell you that a comprehensive plan like the one described here is impractical, an enormous undertaking, a mistake, or simply unnecessary. Such pronouncements come with a variety of reasons, some as apparent earnest justifications and others as poorly conceived excuses. However, innovative compliance professionals immediately recognize that the systematic approach of a prospective compliance plan holds several keys to success.

Do not accept arguments that the arena of pharmaceutical and biotechnology compliance is too dynamic, complex, or subjective for a structured plan. Indeed, although that may be partially valid,

Figure 1: Bell curve of compliance



the reality actually reinforces the plea for the distinct attention that a compliance plan brings to the quality and compliance process. Strive to make your structured compliance plan itself dynamic and adaptable, your compliance perspectives more intelligent than a single person, and your organizational compliance goals forthright and coherent. Understand that a successful compliance program will not happen without guidance or without a decision that you will make a good-faith effort to comply.

Let that basic understanding and principled decision begin the evolution of your compliance plan, and watch as it helps propel you to product approvals and a successful conclusion to your business plan. Quality professionals can often be heard appropriately making requests like “Show me the data.” Now it’s time for everyone else to sincerely ask those same quality professionals, “Where’s our compliance plan?”

REFERENCE

1 Clemen, RT, *Making Hard Decisions: An Introduction to Decision Analysis*. Duxbury Press: Pacific Grove, CA, 1996. 🌐

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