Managing Regulatory Compliance in the Pharmaceutical Industry

Abstract
Changes in regulation, alongside the introduction of stringent anti-corruption legislation, are forcing pharmaceutical companies to renew their focus on compliance. Globally, pharma organizations have to embrace a holistic approach. This involves aligning complex and disparate risks and regulatory compliance activities to the overall corporate strategy. This paper examines some of the legislation and proposes an approach built around people, processes, and technology that can help companies manage compliance more effectively. The proposed approach links core elements of risk management, assurance structures, and governance with the foundation elements of organizational culture, change management, and data and knowledge management. It identifies the main risk influences – corporate strategy, organization values and business model, statutory changes, new laws, industry standards, new business risks – and how pharmaceutical organizations can mitigate the risks by creating a systematic approach and a culture conducive to compliance.

The Increased Risks in Regulatory Compliance
The pharmaceutical industry is coming under increased scrutiny across the value chain from drug discovery to post-marketing surveillance. Pharma organizations are understandably keen to avoid the negative publicity, fines, and possible court cases associated with bribery and corruption. They are also mindful of patient safety issues where failures can jeopardize the future of entire enterprises.

In 2012, GlaxoSmithKline was fined $3 billion for wrongly branding the antidepressant drugs Paxil and Wellbutrin and failing to report required safety data on Avandia, a diabetes drug.¹ Johnson & Johnson agreed to pay more than $2.2 billion to resolve allegations that it offered illegal kickbacks to increase sales of its antipsychotic medication, Risperdal.²

The cost of litigation is on the rise. Pharma companies have suffered serious reputational and financial damage due to legal and compliance failures. Estimates suggest that between 1991 and July 2012, pharma companies have paid more than $30 billion in fines for compliance and regulation issues and settled more than 230 cases.³

Enforcement agencies are increasing pressure, and there are more regulatory action letters to pharmaceutical and biotech companies regarding social media communication. The FDA issued an enforcement letter to Novartis for its use of a Facebook widget that promoted its drug Tasigna without communicating any relevant risk information.⁴ The Prescription Medicines Code of Practice Authority (PMCPA) reprimanded Bayer for promoting its prescription medication on Twitter.⁵

Regulation is becoming tighter day by day. With the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act by the United States, regulatory scrutiny and enforcement actions will continue to increase. A range of regulators (including the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, the European Agency for the Evaluation of Medicinal Products, and the Food and Drug Administration (FDA) in the US) state that Life Science, Biotech, and

Pharmaceutical companies must conform to industry guidelines such as Good Manufacturing Practice and Good Laboratory Practice. Added to these, there are laws related to patient privacy such as the Health Insurance Portability and Accountability Act (HIPAA) in the US. Funding sources are put under scrutiny by the Patient Protection and Affordable Care Act (PPACA) in the US. The Sarbanes-Oxley (SOX) Act considers financial accounting and reporting as well as internal controls. Companies can also fall foul of the Foreign Corrupt Practice Act (FCPA), False Claims Act (FCA), Occupational Health and Safety Act (OSHA), and Intellectual Patent Rights legislation.

Within this context, the pharma industry continues to focus on compliance without assessing enterprise-wide risk. There is seldom a coordinated effort to manage risk across the organization, and business units often operate in silos without each unit being aware of enterprise-wide initiatives. This fragmented approach, with its duplication of effort, has cost implications. All of this underlines the need for a holistic approach where governance will ensure compliance and contain risk.

Pharma organizations the world over can derive benefits from improved transparency, whether for internal compliance reasons or external disclosure.

Internal benefits include greater efficiency, as compliance, embedded in the DNA of operations, reduces the need to repeat or re-do tasks. Compliance leads to quality improvements and prevents errors or failures before they occur. It reduces repeat work such as R&D time devoted to post-marketing changes and effort spent for remediation after compliance breaches. Better data leads to informed decision making. Effective compliance programs, integrated with risk management, enable organizations to actively monitor their risk profiles. This allows them to look holistically at risks, within the organization as well as from partners, alliances, vendors, and suppliers, to ensure that all risks are properly mitigated.

Other external benefits accrue: An effective and clearly communicated compliance program leads to increased trust with patients and investors and other key stakeholders. It can also contribute to brand loyalty. Good compliance plays a key role in competitive differentiation.

An Approach to Managing Regulatory Risks and Achieving Compliance

The essence of an effective compliance program is summed up by the U.S. Federal Sentencing Guidelines § 8B2.1(a)(2) that states that an organization must establish and maintain a culture that ‘encourages ethical conduct and a commitment to compliance with the law.’

For effective compliance, organizations need to contain complex and disparate risks. They need to ensure that regulatory compliance activities align with the overall corporate strategies for people, processes, and technology.

Organizations need to contain disparate risks and ensure regulatory compliance activities align with the overall corporate strategy. Effective compliance management integrates risk management, controls and processes, and assurance and governance structures using tools and data.

This should be backed by a strong organizational culture, an enterprise-wide awareness program, and business discipline. This holistic approach to the management of compliance will lead to greater awareness of regulation and help with the implementation of a focused plan to mitigate non-compliance. Influences such as statutory changes, new laws, industry standards, and emerging risks can result in fundamental changes to the way organizations operate. Factors such as a company’s values, corporate strategy, and business model drive organizational policies. Embedding compliance policy in the strategy and business objectives can help create a ‘compliant organization.’

To be effective, organizations must adhere to all the elements shown in Figure 1. This is simple in concept but challenging in the reality of a large, complex, global enterprise. Central to the idea of the holistic approach to compliance management is the understanding that compliance is a continuous process and not a one-time project.

Table 1 cites specific interventions that pharma companies should undertake.

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<th>Elements</th>
<th>Key Parameters</th>
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| **Risk Management** | • Establish a risk-conscious culture at all levels of the organization  
• Create an enterprise risk management system not only within the organization but also in third-party relationships with Clinical Research Organizations (CROs), Academic Research Centers (ARCs), alliances, and suppliers. This will enable:  
  • Performing business risk assessments to identify new risks in: research collaborations to source innovation, acquisition and launch of compounds or products as part of M&A and alliances, use of social media, changes in the IT landscape (for example, the adoption of cloud computing), business in competitive landscapes such as emerging markets  
  • Prioritizing risks and preparing plans to mitigate them  
  • Actively monitoring changes in the risk profile  
  • Reporting incidents |
| **Controls and Processes** | • Identify relevant business, employment, anti-corruption, and environmental laws and regulations from local, national, and international authorities and assess their implications  
• Design processes and standards to support the compliance policy, such as data handling, data archival for both pre-clinical and clinical research, product registration for market entry, and monitoring product safety and effectiveness post entry. A social media strategy with respect to medicine promotion and information should also adhere to this policy  
• Document key processes; create standard operating procedures including shipment inspection procedures, proper storage and distribution checklists, and guidelines to ensure processes are implemented  
• Define a common set of internal controls across regulations and internal operational requirements that align with key risks and policy areas  
• Identify and define KPIs |
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| Quality Assurance Structures    | • Create a continuous improvement process that includes: determining the root cause of compliance gaps, identifying and addressing risks, evaluating trends, anticipating future risks based on emerging changes in regulations or business conditions, and determining timely solutions  
• Enhance internal and external reporting against established KPIs to improve internal decision-making and ensure full regulatory compliance. This will increase investor confidence and also improve external decision-making with regards to customers and suppliers  
• Audit and review the effectiveness of such a framework regularly                                                                 |
| Governance                       | • Appoint a compliance officer and form a compliance committee and risk council. The compliance framework should be owned by a senior employee, who should monitor policy breaches and conduct regular tests to ensure conformity with the latest regulations  
• Define timelines for compliance  
• Use the services of legal firms for updates to the framework based on changes to laws  
• Embed a culture of compliance within the organization by allowing employees to raise concerns confidentially and anonymously. Ensure compliance issues are investigated and resolved fairly and consistently. Develop and enhance existing whistleblowing and incident management processes |

Table 1: Key Elements of Regulatory Compliance

Table 2 shows how the organizational influences drive compliance.

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<th>Organizational Influences</th>
<th>Effect on Compliance</th>
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| Corporate Strategy        | • Establish corporate compliance policies so that compliance sustainability is an integral part of organizational strategy  
• Link the organization’s vision and strategy to a set of KPIs with clear, measurable goals                                                                                                                   |
| Organizational Values     | • Promote integrity and ethical values in decision-making across the organization and increase accountability                                                                                                    |
| Business Model            | • Abide by corporate governance standards and regulations  
• Make the decision-making process as ethical as possible                                                                                                                                                       |

Table 2: Organizational Influences on Compliance

Table 3 lists the foundation elements and how they can build compliance into the way pharma organizations do business.

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<th>Foundation Elements</th>
<th>Role in Compliance Management</th>
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| Organizational Culture     | • Provide employees meaningful incentives and rewards for ethical behavior  
• Encourage compliance by taking a zero-tolerance stance on the issue                                                                                                                                                     |
| Organizational Awareness   | • Build awareness of the relevant compliance laws by organizing training and education programs for employees  
• Inform employees about standards and disciplinary guidelines through mailers and bulletins                                                                                                                                 |
| Business Discipline        | • Make compliance an integral part of the working plan in all business divisions  
• Ensure that the internal audit team periodically checks the level of compliance to prevent misreporting by process owners                                                                                           |
| Tools and Data Management  | • Use metrics and benchmarking to review effectiveness  
• Use technology to inform decision-making. The CEO, CFO, or Compliance Officer should be able to view the status of all instances of compliance and non-compliance, complete with drill-down details such as location, process owner, and the law in question  
• Establish a repository for reuse of information assets, checklists, templates, best practices, and compliance related training materials. This will make it possible to share best practices across units |

Table 3: Foundational Elements in Compliance Management
Embarking on the Compliance Journey

Building better compliance begins with an understanding of the maturity of existing programs. This can be assessed using the capability maturity model developed by the Software Engineering Institute (SEI). There is no one-size-fits-all approach to compliance, as every enterprise follows a framework specific to its own internal operating environment. However, as depicted in Figure 2, organizations planning to improve compliance must follow industry best practices based on these principles: identify, access, and prioritize; design; implement; and monitor and review.

The success of implementation will depend on various factors, including a focus on individual country regulations, documentation of standard operating procedures, and risk assessment against patient safety and efficacy. Consideration should also be given to the requirements for a new drug to be approved for marketing in any particular country and close monitoring of drug promotions and advertising.

This approach should be structured carefully and incorporate a well-designed reporting and monitoring mechanism to provide a reasonable degree of assurance to management, boards, and audit committees. To monitor the implementation of the regulatory compliance framework, and the maturity attained, key performance indicators need to be defined for each of the elements shown in Figure 2. The frequency of monitoring and reporting on the KPIs will depend on whether they are event driven, such as when a new regulation has come into effect, or whether they provide insights into the way the organization is functioning. The latter could include the cost of failed projects due to unidentified risks.

Visual representation of performance metrics and scorecards makes it easier for decision makers to review the information and take appropriate action.
Conclusion

This compliance approach will help pharma companies contain risk, and improve profitability through the optimal use of resources, knowledge management, and best practices. It can also improve their brand value. Applying these principles will help achieve critical business objectives against the backdrop of a complex regulatory landscape. By turning regulatory obligations into strategic opportunities, companies can reduce performance cost and improve control effectiveness.

Organizations should understand that these benefits of integrated compliance management will be fully realized only when a systematic and coherent approach is applied. That includes proper training of staff, effective communication, and the visible support of senior management. Strict disciplinary actions for violations, regular review and revisions, as well as the use of KPIs and benchmarking will also contribute greatly to the chances of sustainable success.

About the Author

Dipanjana De has 14 years' experience in Consulting and IT. She has worked in Life Sciences, Healthcare, and the Public Sector across various functions including Program Delivery, Pre-Sales, Solution Consulting, and Domain Consulting. She is currently Lead – Pre-Sales and Solutions – for the Life Sciences group in the Global Consulting Practice of Tata Consultancy Services (TCS). Prior to joining TCS, she advised the Government of Andhra Pradesh with Atos Origin in its governance reforms programs. In that capacity, she focused on the provision of transparent governance through the introduction of change management initiatives such as e-Governance. She has also led consulting assignments funded by the World Bank, the UK’s Department for International Development (DFID), and the US Agency for International Development (USAID).

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